CARDIOPULMONARY SUPPORT AND PHYSIOLOGY

TRANSFER OF PATIENTS RECEIVING ADVANCED MECHANICAL CIRCULATORY SUPPORT

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Objective: Improving results with ventricular assist devices have led to their wider clinical application. Centers can stabilize, support, and wean or transfer patients to regional transplant centers.

Methods: Prospectively collected data were reviewed to evaluate the clinical results of patients transferred to our institution while receiving advanced mechanical circulatory support.

Results: Since 1993, 16 patients were accepted while receiving support with either extracorporeal membrane oxygenation or a ventricular assist device. The 10 male and 6 female patients ranged in age from 9 to 60 years (mean, 42.1 years). Thirteen had had cardiac surgical procedures, two had acute myocardial infarctions, and one had myocarditis. The distance transported ranged from 0.2 to 309 miles (mean, 132 miles). Twelve patients were transferred by ground, and 4 were transported by air. Seven patients were originally supported with extracorporeal membrane oxygenation, 6 with centrifugal pumps, and 3 with ABIOMED ventricular assist devices (ABIOMED, Inc, Danvers, Mass). Two patients had clinical complications during transfer, and one had a cerebrovascular accident, recovered, was weaned, and survived. A second patient had hemodynamic deterioration. There were no technical complications associated with transport. Six patients were left on the original support device; 3 of the 6 were weaned and survived, and 3 died during support. The 10 remaining patients were switched to other ventricular assist devices: 9 patients to Thoratec devices (Thoratec Laboratories, Pleasanton, Calif) and 1 patient to a Novacor device (Baxter Healthcare Corp, Novacor Division, Oakland, Calif). Six of the 10 patients underwent transplantation and survived. Four patients died while being supported by the devices. Nine patients were discharged, with 1 late death at 29 months. Eight patients are alive 4 to 65 months after discharge.

Conclusions: These data suggest that patients receiving advanced support can be moved between clinical centers with acceptable risks. Because 33% of the survivors were weaned, transplantation is not required for survival. (J Thorac Cardiovasc Surg 2000;119:1015-20)

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Improvements in clinical results, technology, and clearances by the Food and Drug Administration of several ventricular assist device (VAD) systems have led to more widespread clinical applications, not only of sophisticated pulsatile devices but also centrifugal pumps and portable cardiopulmonary bypass systems or extracorporeal membrane oxygenation (ECMO). Most cardiac surgical centers in the United States now have the capability to provide short-term mechanical circulatory support with devices more advanced than the intra-aortic balloon pump (IABP). This availability

allows support to be initiated quickly at the community level. Patients can then be supported until myocardial recovery occurs or, if appropriate, referred to a regional transplant center. In most cases it is understood that the time necessary to locate a suitable donor heart necessitates that the temporary device implanted at the local center be switched to a longer term system that can provide intermediate interval support. Some community centers may transport a patient to the regional center for weaning when stabilized because larger institutions would have greater resources available and specific expertise in the field of mechanical circulatory support.

Patients and methods

Prospectively collected parameters from our mechanical circulatory support database were reviewed to identify patients transferred from outside institutions, while being primarily supported with mechanical circulatory support devices (VADs or ECMO) other than IABPs. Data were collected by cardiothoracic clinical nurses specifically trained and dedicating 100% of their efforts to mechanical circulatory support. All patients were in cardiogenic shock receiving multiple inotropic and antiarrhythmic drugs. They were intubated, paralyzed, and sedated. Some patients had an IABP, as well as VADs or ECMO.

Most patients were accepted from the referring center on the basis of information exchanged during several telephone conversations. Only 2 patients were seen by the receiving center before transfer from a neighboring pediatric hospital. Candidates were excluded for transfer if they were actively bleeding, severely hypoxic ($P_{O_2} < 50$ mm Hg on 100% oxygen), anuric, or receiving inadequate support as defined by an assist device flow index of less than 2 $L \cdot m^{-2} \cdot min^{-1}$, a mean arterial blood pressure of less than 50 mm Hg, or refractory systemic acidosis. Because patients were supported with either ECMO or VADs, hemodynamic parameters, such as cardiac output and cardiac chamber pressures, were not prime considerations in determining transfer acceptability. Neurologic status was difficult to assess; however, all patients were thought to be in neurologically intact condition before transfer. The logistics of patient transportation were jointly arranged by the referring and receiving centers. Air transport was accomplished by helicopter. No fixed-wing aircraft were used.

After transport and stabilization, each patient was evaluated on the basis of cardiac history, major organ function, transesophageal echocardiogram results, and device on-off data. By means of these parameters, patients were divided into 2 groups. The first group was made up of patients who would be left on the initial device. This included patients whose condition was deteriorating despite all efforts, as well as patients who were showing evidence of myocardial recovery. The second group was made up of patients whose deterioration had been halted and were thought to have irreversible cardiac damage that would require cardiac transplantation for survival. This latter group was switched to longer term devices (Thoratec; Thoratec Laboratories, Pleasanton, Calif; and Novacor; Baxter Healthcare Corp, Novacor Division, Oakland, Calif) that could support them until a donor heart could be located. Patients who were switched to longer term devices had their cardiac function evaluated serially after 2 to 3 weeks of stabilized support by means of echocardiograms, device on-off data, and cardiac catheterization with angiography in some cases.

The operative procedure for placement of the device was similar for all patients who were switched to Thoratec or Novacor devices. VAD implants were performed, using full cardiopulmonary bypass in beating hearts with normothermia and femoral-femoral or bicaval–ascending aortic cannulation. Preoperative and intraoperative echocardiographic examinations, intraoperative palpation of the intra-atrial septum, or both was used to determine whether there was a patent foramen ovale. Cannulation for a right VAD was from the right atrium or right ventricle to the pulmonary artery. For left VADs, cannula was routed from the left ventricular apex to the aorta. Technical descriptions and implantation procedures for devices used have been previously reported.[1-5]

For patients who were switched, once cardiopulmonary bypass was discontinued, heparin was fully reversed with protamine. As soon as postoperative bleeding had stopped and coagulation factors were normalizing, anticoagulation was initiated with heparin at 10 $U \cdot kg^{-1} \cdot h^{-1}$. This usually occurred approximately 24 hours postoperatively. Twenty-four hours later, heparin was increased to maintain the partial thromboplastin time at 1.5 times that of the control. As soon as possible, oral warfarin was started to maintain the prothrombin international normalization ratio at 3.0. Once the target level of warfarin (international normalization ratio of 2.5) was reached, heparin was discontinued. Aspirin, 325 mg/d, was started 7 days postoperatively if the platelet count was greater than 100,000 mm^3 and increasing. Patients left on the original devices received continuous heparin infusions to maintain the activated clotting times at 180 to 200 seconds. Prophylactic antibiotics were administered preoperatively and for a minimum of 3 days after VAD implantation.

Postoperative complications were defined as follows.

1. Bleeding. Chest tube drainage greater than 1500 mL/m^2 of body surface area during the first 24 hours after operation or the need to re-explore the previous sternotomy for bleeding.
2. Infection. Need for intravenous antibiotic therapy.
3. Pulmonary. Mechanical ventilatory support for more than 7 days after device implantation or the need to be reintubated.
4. Neurologic. Identification of a cerebrovascular accident by means of clinical findings, computed tomography, or postmortem examination.
5. Renal failure. Renal insufficiency necessitating dialysis.
6. Device malfunction. Mechanical malfunction of the control console necessitating a change to a backup console or malfunction of any other component of the device, such as the blood sac, valve, or electronics.

Survival was defined as being able to be discharged to home from the hospital.

Data were analyzed with the StatView for Windows statistical software package (version 4.53; Abacus Concepts, Inc, Berkeley, Calif). Values are reported as the mean ± 1 SD.

Results

Between October 1993 and June 1999, 68 patients were supported with VADs (n = 60) or ECMO (n = 8) at Saint Louis University Hospital. Sixteen additional patients were transferred to our institution while receiving advanced mechanical circulatory support. Age, sex, and diagnosis are shown in Table I. All patients were receiving inotropic drugs at the time of transfer, ranging from 1 to 3 (mean, 2.4 ± 0.6) drugs per patient. Fifteen of the 16 patients were receiving antiarrhythmic drugs, averaging 1.2 ± 0.4 drugs per patient. Only 4 patients were receiving vasodilators. The initial device inserted, time of transfer after initial device insertion, distance transported, whether the device was switched, and duration on the initial device are shown in Table II. The distances transported ranged from 0.2 miles (a neighboring pediatric hospital) to 309 miles (mean, 132 miles). Seven patients were originally supported with ECMO, 6 with centrifugal pumps, and 3 with ABIOMED VADs.

One patient (patient 5, 6%) had a cerebrovascular accident during transport, recovered, was weaned, and survived. The condition of an additional patient (patient 14) deteriorated during transfer with a decrease in ABIOMED flows (bleeding and right ventricular dysfunction) resulting in hypotension and severe systemic acidosis. No further clinical complications were associated with transport. There were no significant technical problems related to patient transfer.

Complications identified after transfer are listed in Table III. Six patients were not switched from the original device (Table II). Three of these 6 were weaned from their initial devices and survived. Three patients died while supported by the initial device (Table III). Ten patients were switched to other VADs, of whom 6 underwent transplantation and survived. Four patients did not ungergo transplantation and died while being supported by assist devices after being switched. Nine patients were discharged from the hospital. There was 1 late death attributed to cardiac arrhythmia at 29 months after transplantation. Length of hospitalization ranged from 1 to 175 days (mean, 51.1 ± 12.6 days). Hospitalization in nonsurvivors averaged 16.4 ± 20.8 days, with survivors averaging 78 ± 50.4 days of hospitalization. The 5-year actuarial survival was 45%.

The 10 patients who were switched to longer term devices were supported from 4.2 to 157 days. Four of these 10 patients did not have their cardiac function evaluated with the device off. The condition of 2 patients steadily deteriorated after placement of Thoratec assist devices and they died 4 and 15 days postoperatively. One was supported for 56 days while in continuous ventricular tachycardia, and 1 patient had a severe cerebrovascular accident early in her postoperative course. The 6 remaining patients had their ventricular function evaluated by means of the previously described techniques. After the assist devices had been off for 3 minutes, left ventricular ejection fractions ranged from 10% to 30% (mean, 19%) with rapidly increasing pulmonary artery wedge pressures and heart rates. The 2 patients who underwent coronary angiography both had patent bypass grafts that had been put in place at the original operation.

Table I. *Patient characteristics*

Age	9-60 y (mean, 42.1 y; median, 45 y)
Sex	10 male, 6 female
Diagnosis-procedure	CABG = 8
	MVR + CABG = 2
	MVR + AVR = 2
	AMI = 2
	Myocarditis = 1
	ROSS procedure = 1

CABG, Coronary artery bypass graft; *MVR*, mitral valve replacement; *AVR*, aortic valve replacement; *AMI*, acute myocardial infarction.

Discussion

For decades, clinicians have worked toward designing a simple and effective method of mechanically supporting the circulation during periods of transport. Initially, portable cardiopulmonary bypass units and then IABPs were thought to be reasonable options.[6-8] However, early cardiopulmonary bypass systems were cumbersome and difficult to manage. Portable IABP systems were efficient, but they had a limited effect in supporting patients with severe cardiogenic shock.

Over the past 20 years, mechanical circulatory support has made significant advances in several areas. Clinical results in both the recovery and bridge-to-transplant groups appear to be improving. The commercialization of several devices have helped to remove the investigational stigma from assist devices and made them more widely available. The Health Care Finance Administration and some private insurers have signaled support by providing reimbursement. Despite these advances, most centers recognize the significant resources required to initiate and maintain an active mechanical circulatory support program. The additional necessity to have a complementary cardiac transplant program tends to regionalize circulatory support centers.

Devices, such as the ABIOMED VAD, centrifugal pumps, and ECMO, allow local centers to support

Table II. *Device and transfer data*

Patient	*Initial device*	*Time of transfer (h after initial device)*	*Distance transported (miles)*	*Device switched*	*Duration on initial device (h)*
1	ECMO	24	22.0	No	48
2	ECMO	20	174.0	No	42
3	ECMO	12	22.0	No	24
4	ECMO	57	309.0	Novacor-LVAD	73
5	MED/BIO-BVAD	74	115.0	Thoratec-LVAD	90
6	MED/BIO-BVAD	77	20.0	Thoratec-LVAD	88
7	MED/BIO-BVAD	16	309.0	No	38
8	MED/BIO-BVAD	128	20.0	Thoratec-BVAD	142
9	MED/BIO-BVAD	62	115.0	Thoratec-LVAD	72
10	ECMO	20	309.0	Thoratec-BVAD	28
11	ECMO	1	0.2	Thoratec-LVAD	3
12	ABIOMED-LVAD	12	212.0	No	20
13	ABIOMED-LVAD	24	212.0	Thoratec-LVAD	36
14	ABIOMED-LVAD	72	265.0	No	164
15	ECMO	8	15.0	Thoratec-LVAD	12
16	MED/BIO-BVAD	13	0.2	Thoratec-BVAD	16

LVAD, Left ventricular assist device; *MED/BIO,* Medtronic/Bio-Medicus; *LVAD,* left ventricular assist device; *BVAD,* biventricular assist device.

Table III. *Complications and results*

Patient	*Complications*	*Outcome*	*Cause of death*
1	Renal and pulmonary	Died on device	Renal and pulmonary failure
2	Bleeding	Weaned-survived	
3	Renal and pulmonary	Died on device	Renal and pulmonary failure
4	Bleeding and infection	Transplanted-survived	
5	Bleeding and neurologic (CVA)	Transplanted-survived	Late death; arrhythmia
6	Bleeding	Transplanted-survived	
7	Infection	Weaned-survived	
8	Bleeding, infection, renal, and pulmonary	Died on device	MOF
9	Bleeding	Transplanted-survived	
10	Bleeding, pulmonary, and infection	Died on device	MOF
11	None	Transplanted-survived	
12	Pulmonary	Weaned-survived	
13	Neurologic	Died on device	CVA
14	Bleeding, pulmonary, and renal	Died on device	MOF
15	Bleeding and pulmonary	Transplanted-survived	
16	Bleeding, pulmonary, and neurologic	Died on device	Intracranial bleeding

CVA, Cerebrovascular accident; *MOF,* multiple organ failure.

patients who have refractory cardiogenic shock. Despite the fact that centrifugal pumps and ECMO have been available for some time, it is only recently that patients supported with these devices would be considered for transfer between institutions. It is sometimes the intent of the local center at the time of initial device implantation to stabilize and then transfer the patient to a larger regional center. This is especially true if the patient is less than 65 years of age and has no obvious contraindications to cardiac transplantation. Other times it may be decided to care for the patient locally, if there is hope that myocardial recovery will occur within a few days. If recovery does not occur within 3 to 4 days, then consideration may be given to transferring the patient for continued support, weaning, or transplantation.

For this initial experience, patient selection criteria were relatively loose. If the patient was less than 65 years of age and there were no obvious contraindications to survival, then the patient was accepted. To optimize the opportunity for survival, it was hoped that a majority of the transferred patients would also meet the criteria for cardiac transplantation. Our initial plan was to gain experience and establish referral patterns by accepting almost all candidates. Once experience was gained, we would then become more selective on the basis of criteria determined during our initial clinical experience. However, the number of referrals has been

relatively small, and it has been difficult to identify any accurate predictors of mortality. Several warning factors for transfer, however, have surfaced. These include parameters that would signal instability and jeopardize hemodynamics during the period of transport. This category includes active bleeding, inadequate device support ($<2\ L \cdot m^{-2} \cdot min^{-1}$), persistent hypotension (mean arterial pressure < 50 mm Hg), unresponsive ventricular arrhythmias, and refractory metabolic acidosis. Other factors that suggest irreversible organ dysfunction before transfer include severe hypoxia (Po_2 < 50 mm Hg with a fraction of inspired oxygen of 100%), anuria, and neurologic injury. All of the above-listed parameters can be accurately measured and evaluated, except neurologic injury. These patients were neurologically intact before their acute decompensation. From that point on, they were sedated and paralyzed. Our philosophy has been to give the patient the edge unless some clinical factor suggests a major neurologic insult.

The patients described in this report were transferred from a large geographic area where approximately 50 hospitals perform cardiac surgery and 5 centers perform cardiac transplantation. These 16 patients were sent from 10 institutions and undoubtedly represent a small percentage of the total number of patients receiving mechanical circulatory support in this area over this 6-year period. Three patients not included in this article were initially referred for transfer. In these cases it was decided that they would be better served at the referring center: 1 patient was bleeding, 1 had acute renal failure, and 1 patient was showing early myocardial recovery. One of these 3 patients with renal failure survived. Therefore these 19 patients represent the total number referred to our institution while being supported by either VADs or ECMO. Another 57 patients receiving inotropic drugs and IABP support were transferred to our facility during the same time period for heart transplant-VAD evaluation. Twelve of these 57 patients had VADs inserted (1 was weaned, 8 underwent transplantation, and 3 died). The number of referrals per year has remained fairly constant over this 6-year period, despite the proliferation of VAD systems into community hospitals.

We believe that the option of cardiac transplantation is what stimulates transfer in this patient population. Therefore a local center with an older patient (>65 years of age) or a patient with significant comorbidity that would exclude him or her from cardiac transplantation would probably not be referred. The oldest patient in this group was 60 years of age, and a preliminary evaluation of his medical history by telephone failed to reveal any obvious contraindication to transplantation. Patients older than 60 years of age would be considered for transfer with the hope that they could be weaned. Clinical experience, however, has identified age greater than 70 years as a predictor of mortality.[9] We have been hesitant to bridge patients on our transplant list older than 60 years.

Thirteen of the 16 patients were transferred within 24 hours of cardiac surgery. This postcardiotomy cohort was the largest subgroup for several reasons, including the acute nature of their deterioration, as well as immediate access to mechanical devices and personnel to implant and manage them. Postcardiotomy patients are especially unstable because of the frequency and severity of postoperative bleeding. Bleeding is a significant impediment to transport, and our recommendation was that all bleeding be controlled before initiating transfer.

In this small study the type of device implanted at the original center did not influence survival. Four of the 7 patients transferred while supported by ECMO, 4 of the 6 patients transferred while supported by centrifugal pumps, and 1 of the 3 patients transferred while supported by the ABIOMED VAD survived. Fortunately, 13 of the 16 patients were receiving biventricular support in the form of ECMO or biventricular assist devices at the time of transfer. The use of biventricular support during transfer reduces the problems associated with right ventricular failure and arrhythmias. At the same time, the need for continued biventricular support, including ECMO (6 patients were switched from biventricular support to left ventricular support after transfer), was associated with nonsurvival. Five of the 7 nonsurvivors were receiving biventricular support at the time of death, whereas only 2 of the 9 survivors required biventricular support.

All 16 patients had acute cardiac events. None had a history of congestive heart failure, and only 2 had previous myocardial infarctions. Therefore we considered myocardial recovery as a possibility in all these cases. Of the 6 patients left on the original devices, 3 showed no evidence of myocardial recovery and died, whereas 3 were weaned within 48 hours of device insertion. Four of the 10 patients who were switched to other VADs had complications that precluded weaning or transplantation and died while on support. The 6 remaining patients showed varying degrees of myocardial recovery; however, none met our minimum requirements for VAD removal. These include a left ventricular ejection fraction of 35% to 40%, a left atrial or pulmonary artery wedge pressure of less than 20 mm Hg, and a mean systemic blood pressure of greater than 65 mm Hg with the VAD off. Two of the postoperative patients undergoing coronary bypass showed some cardiac recovery and had coronary angiography

to evaluate the status of their bypass grafts. In both patients the grafts were patent. This was a surprising finding because these 2 patients had well-documented (enzymes, electrocardiography, and biopsy) intraoperative myocardial infarctions and very poor left ventricular function (left ventricular ejection fractions of 10% and 16%) during on-off studies.

The overall survival of 56% was better than we expected. Six of the 10 bridge-to-transplant patients underwent transplantation and survived—a survival similar to the overall survival of our bridge-to-transplant population (70%). At the same time, 3 of the 6 patients who were not switched to other devices were weaned and survived. This 50% survival was better than the 30% survival we have been able to maintain in our in-house myocardial recovery population. Of particular interest are the 3 postcardiotomy patients who were weaned from support and survived. This 23% survival (3/13 postcardiotomy) is similar to the survival results presented in a recent registry report.[9] The 6 remaining survivors underwent transplantation, which was an option that was unavailable at the original center.

Previous reports have described interhospital transport of patients receiving circulatory support with ECMO, centrifugal assist pumps, and paracorporeal VADs.[10-12] Survival in the largest series was 50%.[10] This survival is similar to ours and suggests that centers should anticipate near 50% survival in patients who are considered for transfer while receiving advanced mechanical circulatory support. This survival will vary on the basis of patient selection criteria, as well as the level of communication between the transferring centers.

Fortunately, only 1 patient was found to have irreversible multiple organ failure at the time of arrival at our institution. Her condition had deteriorated significantly during transfer, which took longer than 5 hours, and she eventually died while being supported by the original device. All transfers were accomplished by using conventional staff, which included physicians, critical care nurses, perfusionists, and emergency medical technicians. None of the personnel directly involved in the transfers were specifically trained in circulatory support or transport of such patients.

The transfer of a patient requiring ECMO or VAD support is not so much a problem of technical safety but rather whether the patient is hemodynamically stable to survive several hours outside an intensive care unit environment. For this reason, the total transfer time should be kept as short as possible, probably less than 5 to 6 hours. There were no mechanical or device-related complications associated with these transfers. Most patients had severe ventricular arrhythmias and moderate bleeding and were receiving multiple intravenous medications. Proper cannulation techniques and anticipation of complications should reduce technical risks significantly. A significant amount of blood-product volume should be available during transport, as well as emergency contingencies for the device being used. Space considerations during transport may limit the capability to carry backup battery power packs, hand cranks, and control consoles.

This article suggests that by using current technology and clinical techniques, patients can be effectively and safely transferred between institutions while receiving advanced mechanical circulatory support. These transfers can be accomplished by using available staff and transport.

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