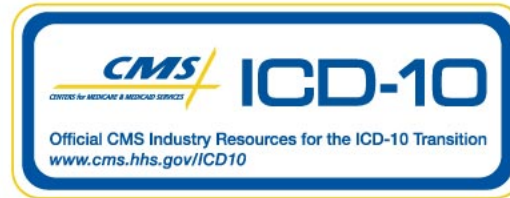


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Improved Survival Rates Support Left Ventricular Assist Device Implantation Early After Myocardial Infarction

Jonathan M. Chen, MD, Joseph J. DeRose, MD, James P. Slater, MD, Talia B. Spanier, MD,
Todd M. Dewey, MD, Katherine A. Catanese, MSN, Margaret A. Flannery, RN,
Mehmet C. Oz, MD, FACC

New York, New York

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- OBJECTIVES** Implantation of left ventricular assist devices (LVADs) early after acute myocardial infarction (MI) has traditionally been thought to be associated with high mortality rates due to technical limitations and severe end-organ dysfunction. At some experienced centers, doctors have refrained from earlier operation after MI to allow for a period of hemodynamic and end-organ stabilization.
- METHODS** We retrospectively investigated the effect of preoperative MI on the survival rates of 25 patients who received a Thermocardiosystems Incorporated LVAD either <2 weeks (Early) (n = 15) or >2 weeks (Late) (n = 10) after MI. Outcome variables included perioperative right ventricular assistance (and right-sided circulatory failure), hemodynamic indexes, percent transplanted or explanted, and mortality.
- RESULTS** No statistically significant differences were demonstrated between demographic, perioperative or hemodynamic variables between the Early and Late groups. Patients in the Early group demonstrated a lower rate of perioperative mechanical right ventricular assistance, but had a higher rate of perioperative inhaled nitric oxide use. In addition, 67% of patients in the Early group survived to transplantation and 7% to explantation, findings comparable to those in the Late group (60% and 0% respectively).
- CONCLUSIONS** This clinical experience suggests that patients may have comparable outcomes whether implanted early or late after acute MI. These data therefore support the early identification and timely application of this modality in post-MI LVAD candidates, as this strategy may also reveal a subgroup of patients for whom post-MI temporary LVAD insertion may allow for full ventricular recovery. (J Am Coll Cardiol 1999;33:1903-8) © 1999 by the American College of Cardiology
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Implantation of left ventricular assist devices (LVADs) early after acute myocardial infarction (MI) has traditionally been thought to be associated with mortality rates as high as 75% (1-8). Although initially indicated for both postcardiotomy shock and failure to wean from cardiopulmonary bypass (conditions often associated with a preoperative MI), LVAD insertion after MI has sometimes been delayed at experienced centers to allow for hemodynamic and end-organ stabilization before LVAD insertion. Although this strategy affords the possibility of ventricular recovery without the need for operation, the concomitant risks of ventricular decompensation and the development of malignant arrhythmias remain high (9).

As experience with the perioperative management of device recipients has grown, recent interest has focused both on the prompt implantation of LVADs soon after the development of cardiogenic shock, as well as on the use of LVADs as a so-called "bridge to recovery." With this has come a renewed emphasis on the timely implantation of LVADs early after MI to allow for the possible salvage of viable myocardium that may benefit from temporary ventricular decompression and mechanical circulatory assistance, thereby ultimately allowing for LVAD removal and full ventricular recovery.

METHODS

Between March 1991 and January 1998, 168 patients underwent insertion of a Thermocardiosystems (TCI) (Thermocardiosystems, Woburn, Massachusetts) LVAD at the Columbia-Presbyterian Medical Center in New York City. Of this entire cohort, 25 patients had an acute MI less

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Abbreviations and Acronyms

CABG	= coronary artery bypass graft proc
IABP	= intra-aortic balloon pump
LVAD	= left ventricular assist device
MI	= myocardial infarction
MSOF	= multisystem organ failure
RVAD	= right ventricular assist device
TCI	= Thermocardiosystems Incorporated

than three months before LVAD insertion. Myocardial infarction was defined by clinical history, serial electrocardiographic analysis, cardiac enzymatic evidence (isoenzymes of creatine phosphokinase) and echocardiography. These patients were divided on the basis of the interval from MI to LVAD insertion into cohorts of those who experience a MI less than two weeks (Early) or great than two weeks (Late) after MI. Patients with a MI more than three months before LVAD insertion were excluded from analysis.

Demographic/outcome variables. Demographic variables analyzed included age, gender, type of LVAD inserted (pneumatic or vented electric), preoperative assistance with an intra-aortic balloon pump (IABP) or temporary ventricular assist device, and presenting hemodynamics (central venous pressure, pulmonary artery pressure, pulmonary capillary wedge pressure and cardiac output). Perioperative outcome variables included the need for a right ventricular assist device (RVAD), the use of perioperative inhaled nitric oxide and overall perioperative hemodynamics (see above). Long-term outcome variables included number transplanted, number explanted, overall mortality and perioperative complications.

The TCI device. The TCI LVAD is a pusher-plate device with a maximal stroke volume of approximately 85 cc. It is implanted through a median sternotomy with the inflow graft and Teflon sewing cuff inserted into the left ventricular apex, and the Dacron outflow graft anastomosed to the ascending aorta after the institution of standard cardiopulmonary bypass (Fig. 1). The inflow and outflow conduits have 25-mm porcine valves to ensure unidirectional flow. The inflow cuff is sewn directly to the left ventricular apex, after removal of a "core" of apical tissue; in the postinfarction setting, particular attention is paid to placing large full-thickness, pledgeted bites in the ventricular myocardium through the infarct zone. The outflow graft is then anastomosed to the right lateral portion of the ascending aorta. A properitoneal pocket is created for the device in the left upper quadrant, before heparinization if possible. The device itself, when implanted in the left upper quadrant properitoneal pocket, allows for both the drive line and vent line also to exit the abdominal wall in the left lower quadrant.

The device is normally operated in the automatic mode, which programs ejection when the device is 95% full. The

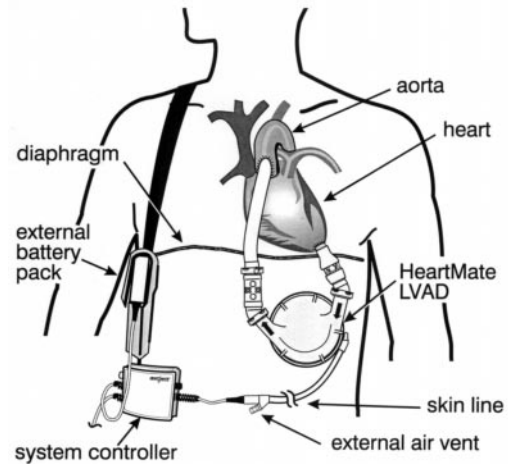


Figure 1. Illustration demonstrating the implantable Thermocardiosystems Incorporated vented electric left ventricular assist device (LVAD).

device may be actuated by a power source that is either pneumatically or electrically driven.

Statistics. All results were recorded as the mean plus or minus the standard deviation. Demographic and outcome variables were compared between the two cohorts by Fischer exact test for 2 × 2 tables. Statistical significance was defined as a p value less than 0.05.

RESULTS

Of the 25 patients who had experienced an acute MI before LVAD insertion, 15 (60%) patients made up the Early cohort (less than two weeks after MI) and 10 (40%) patients made up the Late cohort (greater than two weeks after MI). Four (25%) of the patients in the Early cohort and one (10%) of the patients in the Late cohort underwent LVAD insertion in the setting of postcardiotomy cardiogenic shock after failed coronary artery bypass graft (CABG) revascularization. Where available, peri-MI creatine phosphokinase values were 2,499.3 ± 1,945.5 in the Early cohort, and 1,758.5 ± 173.2 in the Late group; q waves on electrocardiogram were present in nine (60%) Early and six (60%) Late patients.

Demographic variables for the two cohorts are displayed in Table 1. There were no significant differences between Early and Late cohorts on the basis of initial demographic profiles. Patients in the Early cohort underwent device implantation 5.1 ± 5.1 days after MI (range 0 to 14 days); patients in the late cohort underwent device implantation 22.7 ± 8.0 days after MI (range 16 to 43 days). Patients in the Early group more often underwent LVAD insertion in the setting of postcardiotomy cardiogenic shock after failed CABG revascularization (26% vs. 10%) when compared with the Late cohort.

Patients in both cohorts had comparable preoperative support with IABPs, and two patients in the Early cohort

Table 1. Patient Demographics in the Early and Late Cohorts

Patient	Age (yr)	LVAD	MI→LVAD (days)	Preoperative Assistance	Operation	Duration of Support (days)	Right Ventricular Assistance	Ventricular Arrhythmia	Outcome
1	69	VE	0	IABP	LVAD	11			Death (MSOF)
2	59	VE	1	IABP	LVAD	15	RVAD/nitric oxide	Ventricular fibrillation	Transplant
3	49	VE	1	IABP	LVAD	60		Ventricular fibrillation	Transplant
4	58	VE	1	IABP	LVAD		Nitric oxide		Death (MSOF)
5	53	P	2	IABP	LVAD	87		Ventricular fibrillation	Transplant
6	65	VE	2	IABP	LVAD	74	Nitric oxide		Transplant
7	55	VE	2	Biomedicus	CABG pre-LVAD	128	Nitric oxide		Transplant
8	35	VE	2	IABP	CABG pre-LVAD	167			Transplant
9	48	VE	4	IABP	LVAD	48			Transplant
10	58	VE	5	Abiomed	LVAD	4	Nitric oxide		Death (MSOF)
11	47	P	8		CABG pre-LVAD	101		Ventricular fibrillation	Explant
12	52	P	11	IABP	CABG/LVAD	3			Death (PE)
13	39	P	12	IABP	LVAD	188			Transplant
14	63	VE	13	IABP	LVAD	35			Transplant
15	47	VE	14		LVAD	412			Transplant
16	57	P	16	IABP	LVAD	304			Death (CVA)
17	58	P	16	IABP	CABG/LVAD	54		Ventricular fibrillation	Transplant
18	54	P	17	IABP	LVAD	80	RVAD		Death (sepsis)
19	54	VE	19	IABP	LVAD	22			Death (graft dehiscence)
20	60	VE	21	IABP	LVAD	126			Transplant
21	63	VE	21		CABG/LVAD	48		Ventricular fibrillation	Transplant
22	56	P	23		LVAD	6			Death (MSOF)
23	62	VE	25	IABP	LVAD	205	RVAD	Ventricular fibrillation	Transplant
24	38	VE	26		LVAD	78		Ventricular fibrillation	Transplant
25	53	P	43		LVAD	48			Transplant

CABG = coronary artery bypass graft; CVA = cardiovascular accident; IABP = intra-aortic balloon pump; LVAD = left ventricular assist device; MI = myocardial infarction; MSOF = multisystem organ failure; P = pneumatic device; RVAD = right ventricular assist device; VE = vented electric device.

underwent temporary LVAD support with either a BioMedicus (Medtronic BioMedicus, Eden Prairie, Minnesota) or ABIOMED (ABIOMED Cardiovascular, Danvers, Massachusetts) LVAD. Preoperative hemodynamic profiles were not significantly different between the two cohorts, as reflected by pulmonary capillary wedge pressure (28 ± 5.0 vs. 29 ± 6.0 mm Hg, Early vs. Late) or by cardiac index (2 ± 0.5 vs. 1.8 ± 0.4 liters/min/m², Early vs. Late).

Patients in the Early cohort utilized fewer RVADs in the perioperative period (7% vs. 20%), but notably were administered inhaled nitric oxide (30%) more often than patients in the Late cohort (0%) for perioperative right-sided circulatory failure. Patients in the Early cohort were supported with mechanical left ventricular assistance for a mean of

90.3 ± 106.3 days (range 3 to 412 days); those in the Late cohort were supported for 97.1 ± 92.2 days (range 6 to 304 days).

Ventricular tachycardia and ventricular fibrillation afflicted four patients in both Early and Late cohorts. One patient in the Early cohort experienced cardiac arrest preoperatively secondary to ventricular fibrillation. The six other patients all experienced ventricular tachycardia and ventricular fibrillation in the immediate postoperative period after LVAD implantation; in all patients ventricular fibrillation was ultimately controlled with electrical cardioversion and medical management while on device support.

Patients were followed until the point of transplantation, explantation or death; mortality analysis was based on these

three censor criteria. The leading cause of death in both cohorts was multisystem organ failure (MSOF), most often related to sepsis. One patient in the early group died of MSOF four days after LVAD insertion, and another died of a pulmonary embolus three days after LVAD insertion. One additional patient in the Early group, who underwent a CABG procedure one day after MI, and an LVAD implantation seven days later, was successfully weaned from device support and underwent device removal 101 days after device support. At 24 months after explantation, he was noted to have a 50% estimated ejection fraction by nuclear ventriculography multigated acquisition scan; the patient ultimately died of a presumed (unwitnessed) fatal arrhythmia approximately 26 months after his LVAD removal.

DISCUSSION

Despite advances in the timely medical management of the syndrome and its sequelae, cardiogenic shock associated with acute MI remains a diagnosis associated with a mortality rate between 65% and 80% (10). In addition, the use of IABP counterpulsation as a temporizing measure while awaiting ventricular recovery continues to have a 30% to 75% mortality rate in the setting of acute MI, an outcome comparable to that associated with medical therapy alone (11-13). Although the success of both LVAD support for postcardiotomy cardiogenic shock and LVADs as a bridge to transplantation has been well established, their use for post-MI cardiogenic shock, either postcardiotomy or after medical management has failed, remains to be defined fully (14).

Since the first description of mechanical left ventricular assistance for acute MI in 1957, the application of LVADs and biventricular assist devices for this indication has continued to expand despite variable results (1-8). Early experience with LVAD insertion for acute MI revealed survival rates between 10% and 60%, a finding that discouraged the early application of mechanical ventricular assistance for this indication. However, later studies documenting both the beneficial influence of ventricular assistance on end-organ function, as well as the possibility of ventricular decompression allowing for full or partial myocardial recovery have led investigators to revisit the notion of early LVAD insertion for acute MI (15).

Experienced centers have sometimes refrained from earlier operation in this setting to allow for hemodynamic and end-organ stabilization before LVAD insertion. For these potential assist device recipients, the concomitant risks of infarction extension and malignant arrhythmia must be weighed carefully against those of the operation itself. Although in the early years of device support these risks were comparable, recent improvement in survival statistics for LVAD implantation has rendered the risks of the operation considerably less. Ventricular decompression and the restoration of blood flow to the myocardium have been demonstrated to limit infarct size and expansion, a finding

supportive of early LVAD insertion not only as a bridge to transplantation, but also as a bridge to recovery (16,17). In addition, the development of malignant arrhythmias due to infarction extension may be exacerbated further by medical management itself (which may also reduce ventricular function), and we and others have described successful long-term LVAD support for patients with active ventricular arrhythmias (17-20).

Several advances in surgical implant technique have also substantially improved LVAD recipient survival postinfarction. We have in recent years placed importance during implantation on the use of pericardial pledgeted sutures for the inflow cannula, with particular emphasis on the use of large, full-thickness bites of ventricular myocardium through the infarct zone. The short inflow cannula of the TCI device used is also advantageous in such patients, in that its shorter, wider inflow substantially reduces the residual left ventricular pressure, ultimately leading to fewer bleeding complications. Finally, our increasing use of therapeutic adjuncts, including inhaled nitric oxide and low dose intravenous arginine vasopressin, has undoubtedly dramatically improved the morbidity of this difficult patient population (21,22).

Our experience described herein is notable for a series of observations. First, patients in the Early cohort had a substantially decreased mortality (26%) when compared with those in the Late cohort (40%) ($p > 0.05$). Patients were more likely to have had an LVAD implanted early after acute MI in recent years, owing to a programmatic change in our sensibility over time; this change is reflected in the greater proportion of more recent vented electric LVADs implanted in the Early group. Although this tendency may, to some extent, have biased the data described, both groups notably comprised patients distributed throughout the time period studied. Furthermore, the overall survival rate to transplantation or explantation in the Early cohort (74%) is comparable to that described by us in previous reviews of our experience with the electric TCI LVAD, suggesting that this cohort of patients with ischemic cardiomyopathy is not at a significant survival disadvantage owing to the etiology of their heart failure (22).

Second, right-sided circulatory failure (defined as the need for either an RVAD, or the use of inhaled nitric oxide) remains a substantial source of morbidity for acute MI patients in the immediate post-LVAD setting, afflicting nearly one third of patients in both cohorts combined. The Early cohort enjoyed an increased use of nitric oxide (30%), and decreased use of RVADs (7%), when compared with the Late cohort (0% and 20% respectively), a fact that again likely reflects their more recent dates of implantation. We have previously reported the efficacy of inhaled nitric oxide in LVAD recipients for perioperative right-sided circulatory failure, and have noted a substantial decrease in our institutional use of RVADs as a result (23,24). The trends we report herein also parallel previous data reported from our institutional experience with the TCI device in 1990

through 1997, in which 27% of an overall cohort of 85 patients experienced intraoperative right-sided circulatory failure; 4/16 pneumatic device recipients, and 2/8 electric device recipients required RVAD insertion (compared with 3/16 and 6/8 requiring nitric oxide therapy respectively) (22). Moreover, these data refute the notion that biventricular failure may account for the discrepancy in survival between cohorts, as the overall use of therapeutic adjuncts for right-sided circulatory failure was in fact higher in the Early group.

Third, we demonstrated a 30% to 40% rate of malignant ventricular arrhythmias that developed within both cohorts (one of which accounted for a preoperative cardiac arrest in a patient in the Early group), suggesting that the risk of this occurrence in the perioperative period for LVAD patients after acute MI remains substantial. This finding is consistent with other published reports that document an incidence of post-MI ventricular tachyarrhythmias of as high as 65% (9). All patients who experienced ventricular fibrillation perioperatively underwent electrical cardioversion and subsequent medical management with antiarrhythmic medications. These patients tolerated their ventricular arrhythmias, and all eight patients survived to transplantation or explantation of their device.

Finally, the primary cause of death in the Early cohort was MSOF, most often due to overwhelming sepsis. It remains controvertible whether early implantation may not allow for scrutiny of all potential negative determinants of post-LVAD outcome (e.g., infection), as has been suggested by others (24). Arguably, those with "long-standing" (>2 weeks) ischemic cardiomyopathy should be at an increased risk of infectious and end-organ postoperative complications owing to prolonged hypoperfusion and in-hospital associated risks; however, these observations require a large prospective randomized analysis for confirmation.

Limitations. Several limitations are important to note with regard to these data. First, these results represent the findings of a retrospective clinical experience, rather than a prospective randomized trial. Second, although unexpectedly favorable outcomes are described for patients implanted early after MI, undoubtedly certain outcomes (e.g., the rate of survival to transplantation) may have been tempered in part both by the patients' clinical status, as well as by the prevailing practice patterns in transplantation; these results must therefore be viewed with caution. Despite this, the inherent characteristics of a presumably sicker cohort (those early after MI) should have biased these data against describing comparable outcome results; the lack of appreciable differences in preoperative characteristics in both cohorts argues against egregious differences in patient selection. The selection criteria (LVAD "screening scale") on which we have based our decision for implantation have been described previously (25). Clearly, the time interval since a prior MI, although an important factor, is but one of

many contributing demographic characteristics affecting overall outcome. Although these data do not promote the implantation of LVADs early after MI for all patients, they do suggest its feasibility and furthermore refute its position as either an absolute or relative contraindication.

Conclusions. These data support the early implantation of LVADs for acute myocardial infarction either postcardiotomy, or in the setting of decompensation despite maximal medical management. The comparable rates of survival to transplantation or explantation refute the notion of a two-week "recovery period," particularly in light of recent trends toward the use of mechanical ventricular assistance for myocardial recovery. Many of the patients in the Early cohort while receiving temporary IABP support were transferred to our institution for either LVAD insertion, or for weaning from IABP. We contend that for these patients, the aggressive implantation of IABPs or temporary assist devices—and the rapid referral to tertiary care centers for more long-term mechanical support—will allow for a greater percentage of patients who may be weaned completely after intermediate-term LVAD support, end-organ and hemodynamic stabilization, and partial or full ventricular recovery. Taken together, these findings support the notion of a seamless "bridge to recovery" program in which smaller hospitals with temporary device programs may refer patients (such as those who undergo temporary device insertion early after acute MI) to larger centers for longer term device support as a bridge to transplantation, destination or recovery.

Reprint requests and correspondence: Dr. Jonathan M. Chen, Department of Surgery, Presbyterian Hospital #295, 622 West 168th Street, New York, New York 10032. E-mail: jmc23@columbia.edu.

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