Original Article

The Novacor Left Ventricular Assist System: Lessons Learned

Louis E. Samuels, MD*; Marla S. Kaufman, BA*; Rohinton J. Morris, MD*; Susan C. Brozena, MD#; Carol Twomey, CRNP#, MS; Stanley K. Brockman, MD*

*Department of Cardiothoracic Surgery, Allegheny University Hospitals, Hahnemann Division, Philadelphia, PA; #Department of Medicine, Division of Cardiology, Allegheny University Hospitals, Hahnemann Division, Philadelphia, PA

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ABSTRACT

The purpose of this investigation is to identify the factors influencing the outcome of the Novacor left ventricular assist system (LVAS) as a bridge to transplant. Novacor LVASs were placed for transplant candidates refractory to medical therapy. All LVASs were performed on cardiopulmonary bypass without aortic cross clamping. Postoperative care was instituted per protocol. From October 9, 1993, to October 29, 1996, 17 Novacor LVASs were placed as a bridge to transplantation. There were 15 male and 2 female patients. The mean age was 52 years (16-66 years). The mean time interval from listing for orthotopic heart transplantation (OHT) to LVAS insertion was 55 days (1-307 days). The mean cardiopulmonary bypass time was 108 minutes (53-300 minutes). Ten (59%) patients were subsequently transplanted. Prior to transplant, seven (41%) patients expired of neurologic sequellae, right ventricular failure, or sepsis syndrome. The mean duration of LVAS support to transplantation was 31 days (1-76 days). The average blood loss for the first 24 hours was 4096 ml (500-16,105 ml). Eight patients remain alive at a mean follow-up of 13 months (1-22 months). Two patients expired of heart failure following transplantation. Preoperative cardiogenic shock and infection result in poor outcome following LVAS insertion. Severe right ventricular (RV) dysfunction requires prompt RVAD placement. Correction of preoperative coagulopathy and meticulous hemostasis are critical.

Address correspondence to:
Louis E. Samuels, MD
Allegheny University Hospitals, Hahnemann Division
Broad and Vine Streets, MS 111
Philadelphia, PA 19102-1192

INTRODUCTION

The introduction of ventricular assist devices (VAD) into the armamentarium of heart failure management has enabled patients to be successfully bridged to transplant who would have otherwise expired waiting for a donor organ. Over the past two decades, several devices have been designed and implanted with variable degrees of success. The Novacor left ventricular assist devices (LVAS)[a] was originally designed for long-term support of patients awaiting transplant.. The first implant was in September 1984 at Stanford University, Stanford, CA (1). Since then, this heterotopic, electronically driven device has been employed in over 277 cases in the United States, 506 worldwide (2). At Allegheny University Hospitals, Hahnemann Division, Philadelphia, PA, we have implanted 17 Novacor devices. We have identified several features regarding preoperative selection, intraoperative techniques, and postoperative care which directly influence outcome. The purpose of this report is to offer suggestions in prevention, identification, and management of problems encountered during the use of Novacor LVAS as a bridge to transport.

MATERIALS AND METHODS

One hundred forty-seven orthotopic heart transplantations (OHTs) were performed at Allegheny University Hospitals, Hahnemann Division, Philadelphia, PA, over a six-year period. Seventeen Novacor left ventricular assist devices (LVAS) were placed as a bridge to transplantation from October 9, 1993, to October 29, 1996. Patient inclusion and exclusion criteria appear in Table 1.

All LVASs were performed on normothermic cardiopulmonary bypass. The aorta was not cross clamped. The woven Dacron outflow conduits to the aorta were either removed and baked in albumin prior to insertion or replaced with a 22mm knitted double velour Dacron graft[b] that did not require preclotting. All inflow conduits were placed in the left ventricular apex. Right ventricular assist devices[c] were placed if right ventricular failure prevented weaning from cardiopulmonary bypass. Initially, protamine was given to reverse half the heparin dose. Now, complete protamine reversal is instituted. The postoperative anticoagulation protocol appears in Table 2.

Patients were weaned from the ventilator using standard extubation criteria. Antibiotic coverage was with cefazolin or vancomycin (if penicillin allergic) for forty-eight hours. Alternate antibiotic coverage was determined by the infectious disease staff. Dressing changes were performed daily with sterile gown, gloves, and mask. Patients were allowed out of bed to ambulate when clinically and hemodynamically appropriate.

Table 1: Inclusion/exclusion criteria

Inclusion Criteria:

1. acceptable transplant patient
2. age between 15 and 65 years
3. BSA between 1.5 and 2.5 m^2
4. NYHA functional class IV
5. signed informed consent
6. must meet two or more of the following hemodynamic (Section A) and/or pharmacologic (Section B) criteria:

Section A:	CI<2 L/min/m^2
	Systemic BP< 65 mmHg
	LAP (PCWP) ≥ 18 mmHg
	PAD ≥ 18 mmHg
Section B:	Dopamine ≥ 10 mcg/kg/min
	Dobutamine ≥ 10 mcg/kg/min
	Epinephrine ≥ 0.02 mcg/kg/min
	Isoproterenol ≥ 0.05 mcg/kg/min
	Amrinone ≥ 10 mcg/kg/min
	Other equivalent drug at similar toxic dose
	Intra-aortic balloon pump support

Exclusion Criteria:

1. primary right ventricular (RV) failure or RV failure secondary to pulmonary disease
2. renal dysfunction not explained by underlying heart failure and not reversible
3. hepatic dysfunction not explained by heart failure and not reversible
4. infection
5. pulmonary parenchymal disease and/or fixed pulmonary hypertension
6. diagnosed primary coagulation or platelet disorder
7. symptomatic cerebrovascular disease
8. symptomatic peripheral vascular disease
9. prosthetic aortic valve
10. cancer with metastasis
11. patients who have had previous open heart surgery
12. patients with known left ventricular aneurysm

RESULTS

From October 9, 1993, to October 29, 1996, seventeen Novacor LVASs were placed as a bridge to transplantation (Table 3). There were eleven patients with idiopathic dilated cardiomyopathy, five with ischemic cardiomyopathy, and one with viral cardiomyopathy. Prior to LVAS insertion, all patients were on inotropic agents. Fifteen patients were on dobutamine, 13 on milrinone, 6 on dopamine, and 2 on epinephrine. Four patients were on single, 7 on double, and 6 on triple inotropic therapy preoperatively. Four patients had intraaortic balloon pump (IABP). The hemodynamics on the day of LVAS insertion were: PAD 28 mmHg (15-36 mmHg), CVP 13 mmHg (1-27 mmHg), CI 2.2 L/min/m^2 (1.3-4.4 L/min/m^2). The mean crea-

a Baxter Healthcare Corporation, Novacor Division, Oakland, CA
b Hemashield, Meadox Medicals, Inc., Oakland, NJ
c Abiomed Cardiovascular, Inc., Danver, MA

tinine was 1.8 mg/dL (0.7-3.3 mg/dL). The total bilirubin was 1.2 mg/dL (0.3-3.4 mg/dL). The mean protime was 14.7 seconds (12.5-18.4 seconds) (Table 4). One patient required ventilator support prior to LVAS insertion. The mean time interval from listing for OHT to LVAS insertion was 55 days (1-307 days). Ten (59%) patients were successfully transplanted. Seven (41%) patients expired (four neurologic sequellae, two RV failure, one sepsis syndrome) prior to transplant. Eight of the ten patients (80%) who were bridged to transplant were discharged from the hospital. Two patients expired following OHT from heart failure.

Intraoperatively, all procedures were performed with normothermic cardiopulmonary bypass without aortic cross-clamping. Standard ascending aortic and right atrial cannulation were utilized. In twelve cases, the woven Dacron outflow graft was preclotted with baked albumin and sewn to the aorta with 3-0 polypropylene suture. In four cases, the outflow graft was replaced with a 22 mm knitted double velour Dacron graft which did not require preclotting and was sewn to the aorta with 4-0 polypropylene suture. In one case, hemodynamic instability prevented sternal closure. In one case, the outflow graft was too long and required revision. Abiomed BVS 5000 right ventricular assist devices were required in three cases. The mean cardiopulmonary bypass time was 108 minutes (53-300 min).

Postoperatively, the average blood loss through the chest tubes for the first 24 hours was 4096 ml (500-16,015 ml). All patients required blood products within the first 24 hours with an average of 11 units PRBC (0-48 units), 6 units FFP (0-23 units), 8 units platelets (0-32 units). The mean interval from device implantation to transplantation or expiration was 18.9 days (1-76 days). For patients who expired, the mean time interval was 3.4 days (1-5 days). The causes of death were neurologic in four patients, right ventricular failure in two, and sepsis in one. Morbidity occurred in all patients. There were six wound complications (three sternal infections, two abdominal infections, one pocket hematoma). There were five neurologic complications (four CVA, one TIA). Four patients developed multiple organ system failure. There were three respiratory tract infections. In three patients with excessive blood loss, the chest was reopened in the Intensive Care Unit. There was one line sepsis, one colitis, one pancreatitis, and one upper gastrointestinal blood. One patient developed heparin-induced thrombocytopenia.

Eight patients remain alive following OHT at a mean follow-up of 13 months (1-22 months). Two patients expired of heart failure post-transplant.

DISCUSSION

In 1995, there were 6966 patients on the waiting list for cardiac transplant in the United States. There were 2362 heart transplants performed. There were 770 patients who expired waiting for a suitable donor (3). In an effort to decrease the number of

Table 2: Postoperative anticoagulation protocol

Phase I -	Early postoperatively (usually within 12 hours), low molecular weight dextran IV (10% 40 at 25 ml/hr)
Phase II -	When bleeding from chest drains is <30 ml/hr for three consecutive hours (usually within 12-72 hours), heparin continuous IV drip to a target PTT of 1.5-2.0 x control. Once target PTT achieved, discontinue dextran
Phase III -	When chest tubes removed, begin aspirin 80 mg PO daily
Phase IV -	When oral administration of agents tolerated, coumadin PO to achieve INR of 2.0-3.5. Once target INR achieved discontinue heparin. Chronic maintenance of aspirin 80 mg PO daily and coumadin to maintain INR at 2.0-3.5.

Table 3: Age, outcome, and complications for patients with the Novacor LVAD

Novacor	Age/Sex	Outcome	Duration: Implant-Expiration or OHT	Complications
1	53/M	E (right ht fail)	1 day	bleeding
2	16/M	E (RV fail, sepsis)	5 days	renal failure, ARDS, bacteremia
3	37/M	OHT	17 days	line sepsis, stroke, resp. tract infection
4	41/M	OHT	20 days	pump pocket hematoma
5	60/M	OHT	28 days	stroke, sternal wound infection
6	52/M	E (neurological)	3 days	right ventricular failure
7	47/F	OHT	63 days	pneumonia, abdominal wound inf, colitis
8	50/M	E (neurological, cardiopulm. collapse)	5 days	multiple organ system failure
9	45/M	E (neurological)	3 days	
10	66/M	OHT	19 days	stroke, wound infection
11	62/F	OHT	1 day	
12	53/M	OHT	76 days	TIA, HIT
13	61/M	E (sepsis)	2 days	multiple organ system failure
14	54/M	E (neurological)	5 days	seizures, stroke (CT-)
15	47/M	OHT	24 days	wound inf
16	58/M	OHT	31 days	wound dehiscence,pancreatitis,up.GI bleed
				Exp-post-transplant right heart failure
17	64/M	OHT	18 days	Exp-post-transplant- heart failure

Legend:
OHT= Orthotopic heart transplant
E= expired

patients who expire while waiting for an organ, ventricular assist devices have been developed and implanted as a bridge to transplantation (4, 5, 6). The results have been encouraging (1, 7-11). From September 1984 to November 1996, the Novacor LVAS has been implanted in 277 patients in the United States and 506 worldwide (2). Sixty percent of the patients supported with the LVAS were transplanted and ninety percent of those transplanted were discharged from the hospital (2). As a result of this success, a steady increase in the use of Novacor LVASs has occurred. With improvement in design, wearable units (12-16) have permitted more patients to be ambulatory, translating into improved exercise capability and survival statistics (17, 18). Out of hospital protocols have been instituted (19, 20). Experimental work in totally implantable units (21-23) and consideration towards use as an alternative to transplant (1, 24, 25) are being recognized. Despite these excellent results, complications both related and unrelated to the unit occur (24-26). In our experience, these complications can be divided into preoperative, intraoperative, and postoperative categories.

Preoperatively, patient selection is critical in the decision-making to implant a VAD as a bridge to transplant (27, 28). The Novacor LVAS is no exception. As outlined in the Materials and Methods section, strict guidelines are necessary to determine candidacy. Deviation from these criteria is subject to problems intraoperatively and postoperatively. Although severe cardiac dysfunction despite medical therapy is within the parameters of LVAS insertion, cardiogenic shock with hemodynamic compromise is an undesirable condition in which to perform implantation. As demonstrated in two cases (patients #8, 9), the ultimate outcome following LVAS insertion in this setting was multiple organ system failure and death. Both patients were taken to the operating room on massive inotropic support – one with additional mechanical support (IABP), one on the ventilator – and both returned to the ICU with adequately functioning VADs but irreversible end-organ damage. In our opinion, these patients should not be candidates for Novacor type devices. Consideration toward insertion of less permanent type VADs (i.e. Abiomed BVS) could be argued with conversion to Novacor LVAS if the patient recovers. Another preoperative condition in which a fatal outcome is likely to occur is infection. Although this appears intuitively obvious, recognition and appreciation of local and/or systemic infection is not always apparent. Pneumonia may be masked by pulmonary-vascular congestion from congestive heart failure. Fever and elevated white blood count (WBC) may be manifestations of post-infarction pericarditis or allergic reactions to medications. Infection may be occult and only apparent following surgery. Nonetheless, if infection is suspected, then it is imperative that it be proven or disproven prior to LVAS insertion. In a desperate attempt to salvage one patient (patient #13) with fever, elevated WBC, and pulmonary infiltrate, the cause of death post-LVAS insertion was sepsis syndrome. Broad spectrum antibiotic coverage is not a realistic solution to this problem. Finally, a preoperative condition that is iatrogenically induced which influences the intraoperative and postoperative course is coagulopathy from anticoagulants. As shown in Table 2, the majority of patients had elevated protimes (PT) prior to LVAS insertion. Postoperative blood loss within the first 24 hours was unacceptably high. Indeed, four patients (#1, 6, 9, 13) required their chests opened in the intensive care unit because of cardiac tamponade from hemorrhage. Not only does massive blood product transfusion potentially introduce infectious elements, but the immunologic consequences can be disastrous. In addition, the volume loads place a significant strain on the right ventricle. As experienced in one case (patient #6), postoperative hemorrhage and massive transfusion overloaded the right ventricle and RVAD insertion became necessary. This patient ultimately expired, as did four of the five patients whose drainage exceeded 5 liters in the first 24 hours. The important message from this observation is to correct coagulopathy preoperatively. With respect to renal and hepatic dysfunction preoperatively, we could not demonstrate a correlation with postoperative outcome. Our impression, however, is that significant multiple organ system

Table 4: Pre-VAD implantation hemodynamics

Novacor	PreVAD PAD (mmHg)	PreVAD CVP (mmHg)	PreVAD CI (L/min/m2)	PreVAD Creatinine (mg/dL)	PreVAD Protime (sec)	PreVAD Bilirubin (gm/dL)	Drain Outputs (mL) Within 24 hours
1	34	16	2.4	1.1	13.1	0.8	11250
2	28	12	2.2	1.9	14	1.4	500
3	24	16	1.9	1.7	14.6	3.4	2500
4	36	16	3.3	2.1	13.5	0.9	1110
5	15	2	4.4	2.5	15.8	0.4	1960
6	17	1	3.1	1.3	16	1.2	16420
7	25	11	1.5	0.7	13.4	0.3	1540
8	26	13	2.4	3.3	13.9	0.8	1540
9	36	27	1.9	0.9	13.1	1	8660
10	37	13	1.9	1.9	17.3	1	585
11	37	15	1.9	2.6	14.6	1.8	4945
12	23	6	2.2	1.1	18.4	1.8	2250
13	18	8	2.7	1.1	12.5	0.7	6250
14	30	18	1.4	1.4	16.4	1	3580
15	19	14	2.8	1.4	13	0.7	1930
16	33	17	1.7	3.3	14.8	0.8	730
17	31	15	1.3	1.9	15.7	1.9	3840
Mean	27	13	2.4	1.8	15	1.2	4069
Range	(15-37)	(1-27)	(1.4-4.4)	(0.7-3.3)	(12.5-18.4)	(0.3-3.4)	(500-16,015)

dysfunction preoperatively will negatively impact on postoperative outcome.

Intraoperatively, we discovered several technical maneuvers which have made implantation simpler, safer, and more efficient. First, the outflow tubing that comes with the device is a woven Dacron that is very stiff and requires preclotting. One author (LES) substitutes a 22 mm knitted double velour vascular graft which is much more pliable and requires no preclotting. Not only does this translate into easier use and is less time consuming, but the risk of thromboembolic debris from the baked albumin is eliminated. In our study, four deaths (patients #6, 8, 9, 14) were neurologic. In three of the four, the outflow grafts were preclotted. In the fourth (patient #9), the Hemashield graft was substituted. However, the neurologic status of the patient (patient #9) was questionable preoperatively. He was on a ventilator with incessant ventricular tachycardia, hemodynamically unstable, and taken to the operating room in extremis condition. All neurologic morbidities (3 CVA, 1 TIA) were in patients whose outflow grafts were preclotted (patients #3, 5, 10, 12). Other theories regarding thromboembolic sequellae from VADs have been postulated. Several investigators (29, 30) have examined the hemorrheology in patients on VADs and some (31-33) have postulated that abnormal rheology may be responsible for thrombus formation and embolic phenomenon. Although there are several possible explanations for neurologic complications, including aortic debris, ventricular thrombus, inadequate deairing, and clot formation within the device (34), we feel that substitution of graft material with avoidance of preclotting is a simple maneuver to prevent this possible source of emboli. Another intraoperative point is recognition of right ventricular (RV) dysfunction with the need for RVAD placement. In most of our cases, particularly those with dilated idiopathic cardiomyopathy, RV dysfunction is significant. Although LVAS implantation frequently relieves the RV by unloading the left ventricle (35-37), this is not always the case. In fact, we have observed the opposite in several cases (patients #6, 9, 17). As observed by Kawai et al (38), RV failure following the LVAS implantation may be explained by the degree of fractional area change of the septal portion of the RV. Several investigators (39-41) have examined the relationship between LVAS performance, RV status, and pulmonary pressures. According to Miyamota and others (39), pulmonary vascular resistance (PVR), right ventricular stroke work index (RVSWI), and pulmonary capillary wedge pressure (PCWP) were the most important factors with respect to LVAS filling volumes. Kormos and colleagues (40, 41) found similar results with univentricular support in mortally ill cardiac transplant candidates. Whatever the mechanism, RV dysfunction is important to recognize early, because optimal LVAS function is dependent upon adequate RV function. Although RV function may improve after LVAS insertion or the addition of inotropic agents, when these maneuvers fail, RVAD implantation must be promptly entertained. In our early experience, right heart failure contributed to the cause of death in two patients (patients #1, 2). Finally, absolute surgical hemostasis is mandatory prior to sternal closure. Upon careful inspection with exploration for excessive bleeding, we have observed the heel of the aortic anastamosis to be a particularly vulnerable point. Because of this discovery, we now reinforce the suture line in this area with a teflon pledget. Since anticoagulation is instituted postoperatively, it is imperative to secure all cannulation sites and meticulously inspect all cut surfaces for bleeding points. Packing procoagulant materials around suture lines is not acceptable. As mentioned earlier, correction of coagulopathy is important preoperatively. Aggressive correction of coagulation factors with fresh frozen plasma (FFP) and reversal of platelet dysfunction with platelet transfusion may be required. Although several of our patients were on coumadin preoperatively, blood loss was not always excessive even in the face of a markedly elevated PT (patient #10). If an RVAD is inserted, surgical hemostasis becomes even more imperative since these additional suture lines and cannulation sites add to the possible sources of postoperative blood loss. Our experience with RVADs has demonstrated that the atrial cannulation site is often the culprit in terms of bleeding. Therefore, it is important to make sure the pursestrings used to fix the atrial cannula are well placed and secured. In addition, if hemostasis is initially achieved and bleeding suddenly appears postoperatively in the intensive care unit, early exploration is critical since the source is usually a suture line or cannulation site. Prompt intervention is necessary to avoid transfusion related complications.

Postoperatively, two important factors to focus on are LVAS performance and RV function. Since the two are influenced by each other, it is crucial to recognize conditions which both optimize and interfere with their function. Volume and contractility states influence outcome. Fluid overload will result in RV failure with subsequent LVAS failure. Inotropic support should not be discontinued following LVAS insertion since RV support is still necessary. Inotropes may be weaned only if there is evidence of RV improvement. If, on the other hand, increasing levels of inotropic support become necessary in the postoperative period, then early consideration toward RVAD insertion should be made before hemodynamic instability occurs and/or end organ damage ensues. Since bleeding is the most common early postoperative problem, a high index of suspicion for cardiac tamponade should be entertained, particularly when LVAS output decreases and central venous pressure (CVP) rises. Lavee et al (42) outlined the hemodynamic features of early and late cardiac tamponade in patients with LVASs. Late tamponade was characterized by a minor change in MAP, mild reduction in LVAS output and stroke volume (SV), with a marked elevation in CVP. An enlarged cardiac silhouette and an increased mediastinum on plain roentgenography are usually present if significant accumulation of blood is present. Bedside echocardiography is also helpful in determining if intracardiac or extracardiac mechanical problems exist. Irrespective of these results, if there are any concerns that a mechanical problem exists, then surgical exploration should be performed. This scenario was apparent in one of our patients (patient #17) in which LVAS perfor-

mance suddenly decreased on the seventeenth postoperative day. Upon exploration, evacuation of a mediastinal clot was performed and bleeding from around the right atrial cannulation site of the RVAD was controlled. Finally, strict adherence to the anticoagulation protocol is imperative to avoid thromboembolic or hemorrhagic complications. Studies of the pathophysiologic role of contact activation in bleeding followed by thromboembolic complications with implantation of a VAD have been described (43). Lastly, meticulous wound care and attention to vascular access sites is critical to avoid local as well as systemic infection. As outlined by Reedy et al (44, 45), meticulous nursing care is required for successful management of patients on prolonged mechanical circulatory support. Patients who have been hospitalized for several weeks for heart failure management prior to LVAS insertion are at an increased risk for hospital acquired infection. We believe these patients should be brought to the attention of the infectious disease service for appropriate antibiotic coverage.

In summary, our experience with the Novacor LVAS as a bridge to transplant has been a favorable one. Sixty percent of our patients supported with the device were bridged to transplant. Eighty percent of those transplanted were discharged. The lessons learned from this series include preoperative selection, with avoidance of patients who are in cardiogenic shock with hemodynamic instability, as well as those who may be infected. Intraoperative adherence to absolute surgical hemostasis and assessment of RV function to determine the need for RVAD assistance are critical before sternal closure. Postoperatively, emphasis on volume and contractility states to optimize performance with a high index of suspicion for intracardiac or extracardiac mechanical problems is necessary in order to determine whether surgical reintervention is necessary. With further experience and improvements in VAD technology, we hope to minimize the complications and maximize the outcome in the mechanical management of cardiac failure.

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