CARDIOPULMONARY SUPPORT AND PHYSIOLOGY

NOVACOR LEFT VENTRICULAR ASSIST SYSTEM VERSUS HEARTMATE VENTED ELECTRIC LEFT VENTRICULAR ASSIST SYSTEM AS A LONG-TERM MECHANICAL CIRCULATORY SUPPORT DEVICE IN BRIDGING PATIENTS: A PROSPECTIVE STUDY

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Objective: **Long-term mechanical circulatory support as a bridge-to-transplantation procedure and bridge to recovery is of increasing importance. The implantable left ventricular assist devices, Novacor N100 left ventricular assist system (Baxter Healthcare Corporation, Berkeley, Calif) and TCI HeartMate vented electric left ventricular assist system (Thermo Cardiosystems Inc, Woburn, Mass), have proved to be efficient devices in bridge-to-transplantation settings and for prolonged support. The two systems were compared with regard to reliability and morbidity.** ***Methods:*** **Between October 1996 and March 1998, a prospective, single-center study was done that included 40 patients, 20 of whom were treated with the Novacor system and 20 of whom were treated with the HeartMate device. The diseases were mainly dilated cardiomyopathy (13/9) and ischemic cardiomyopathy (6/10). There were no statistically significant differences between the two groups regarding age, sex, preoperative clinical blood chemistry values, hemodynamic data, or risk factors.** ***Results:*** **There were no statistically significant differences between the two groups with regard to postoperative hemodynamics, organ recovery, out-of-hospital support, and survival to heart transplantation. Mean duration of support was 235.3 ± 210 days for the Novacor group and 174.6 ± 175 days for the HeartMate group and mean out-of-hospital support was 241 ± 179 days and 166 ± 152 days for the two groups, respectively. Neurologic complications occurred significantly more often among the Novacor group, whereas the HeartMate group had a higher prevalence of infections and technical problems, which was statistically significant. Survival to transplantation was 65% for the Novacor group and 60% for the HeartMate group.** ***Conclusions:*** **Most patients had organ recovery with left ventricular assist system support, and a considerable number of patients in both groups underwent transplantation. However, both devices need revision to address the current problems, that is, thromboembolism for the Novacor device and infection and reliability for the HeartMate device. (J Thorac Cardiovasc Surg 2000;119:581-7)**

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Supported by the German Association of Organ Recipients (Registered Association).

Read at the Seventy-ninth Annual Meeting of The American Association for Thoracic Surgery, New Orleans, La, April 18-21, 1999.

Received for publication April 22, 1999; revisions requested May 18, 1999; revisions received Nov 5, 1999; accepted for publication Nov 8, 1999.

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0022-5223/2000 $12.00 + 0 **12/6/104340**

doi:10.1067/mtc.2000.104340

The number of patients with heart failure is steadily increasing with an estimated 400,000 new cases recorded annually in the United States.[1] Modern medical treatments with angiotensin-converting enzyme inhibitors and β-blocking agents have failed to improve the clinical performance of these patients to an acceptable level. Ninety percent of lethal outcomes are due to cardiac causes. Heart transplantation currently is the only accepted therapy for end-stage heart failure; however, it is restricted by the general shortage of donor organs, which results in prolonged waiting times. In addition to the bridge-to-transplantation application, the option of mechanical circulatory support applied as a bridge to recovery is getting more and more important. Apart from the nonimplantable Thoratec ventricular assist device (Thoratec Laboratories Corporation, Pleasanton, Calif), the implantable left ventricular assist devices (LVADs) are the Novacor N100 left ventricular assist system (LVAS) (Baxter Healthcare Corporation, Berkeley, Calif) and the TCI HeartMate vented electric (VE) LVAS (Thermo Cardiosystems Inc, Woburn, Mass), both of which have obtained Food and Drug Administration approval as bridge-to-transplantation devices. Many trials have proved the efficacy of both devices in bridge-to-transplantation settings and for long-term support. However, there has been no investigation so far comparing the two systems with regard to reliability and morbidity on the basis of organ function during support, and this constitutes the aim of the present study.

Patients and methods

In a prospective, single-center study done between October 1996 and March 1998, we compared the Novacor and the HeartMate devices in terms of morbidity and reliability after implantation. End points of the study were heart transplantation or death of the patient. After study approval by the local ethics committee was obtained, patients requiring mechanical left ventricular support as a bridge to transplantation alternatively received either the Novacor LVAS or HeartMate VE LVAS device. After patients were accepted into the study, the relevant data were obtained on a daily basis from data sheets. Forty patients were included in the study, 20 of whom received the Novacor system (19 Novacor, 1 Novacor plus Thoratec ventricular assist device) and 20 of whom received the HeartMate system (19 HeartMate, 1 HeartMate plus Medos right ventricular assist device [Medos; Hamburg, Germany]). Both subsets consisted of 19 men and 1 woman each, with mean ages of 55.7 ± 11 years for the Novacor group and 56.3 ± 11 years for the HeartMate group. The causes of heart failure in both collectives are summarized in Table I. There were no statistically significant differences between patients in the Novacor and HeartMate groups as to preoperative laboratory parameters and hemodynamic data (Tables II and III) and preoperative risk factors (Table IV).

Implantation procedures were done by the same surgical team in both the Novacor and HeartMate groups. Both devices are placed into a preperitoneal pocket and share the same inflow and outflow cannulation. Furthermore, the same protocols were applied with regard to antibiotic and infection management strategies and intensive care unit and regular ward management protocols. Anticoagulation regimens differed between the groups according to our previous experiences and the recommendations established by the manufacturers of the devices. In the first 24 hours after the operation the patients (both groups) received no anticoagulants. Thereafter, therapy was started with heparin according to the activated clotting time (1.5 × initial value). After removal of chest drains patients in the Novacor group received warfarin sodium (Coumadin) (dosage according to international normalized ratio 2.5-3.5). Two weeks after the operation, both patient groups received aspirin, 1 mg/kg of body weight.

Patients in both groups were discharged from the hospital with the device in place if they fulfilled our selection criteria for out-of-hospital support, which have been published elsewhere.[2] All patients followed the same home-management protocol, which included daily control of body weight and international normalized ratio self-test (in the Novacor group) and twice-daily controls of temperature, blood pressure, and pump output, as well as wound dressing changes according to a special protocol. Patients underwent transplantation when they reached New York Heart Association functional class I without organ failure, except patients with uncontrolled pocket infections and patients with major technical problems (pump failure).

Definition of complications. A bleeding complication was defined as blood loss of more than 1500 mL/m^2 in 24 hours. Major neurologic complications were defined as neurologic deficits proved and differentiated by computed tomographic scan. Infection definition included several parts: a pocket infection was defined as being associated with local signs of infection with purulent secretions necessitating lavage drainage and with positive bacterial cultures. Criteria for valved conduit endocarditis were signs of systemic infection despite adequate antibiotic therapy, increased central venous pressure, low pump output with a dilated left ventricle, and an abnormal Doppler echocardiographic image above the inflow cannula. The presence of a septic complication was indicated by a body temperature above 38.5°C, white blood cell count greater than 12,000 gm/dL, high output states, low systemic vascular resistance, and positive blood cultures. Failure of the right side of the heart was defined as a cardiac index less than 2.2 L · min^{-1} · m^{-2} despite a central venous pressure of 18 to 22 mm Hg and double-drug inotropic support in the absence of high pulmonary vascular resistance. Arrhythmic complications were defined as hemodynamically relevant rhythm disorders necessitating electrotherapy. The criterion for acute renal failure was the necessity of renal replacement therapy (hemofiltration or dialysis).

Statistical analysis. Statistical analysis of the data was done with the SPSS software (SPSS for Windows, SPSS Inc, Chicago, Ill). Variables are expressed as mean values with the

Table I. *Cause of heart failure*

	Novacor (n = 20)	*HeartMate (n = 20)*
Idiopathic dilated cardiomyopathy	13	9
Ischemic cardiomyopathy	6	10
Fulminant myocarditis	1	-
Valvular heart disease	-	1

χ^2: $P = .3$.

SD. The specific tests applied for different analyses are detailed below the respective tables.

Results

All patients survived the operation. Weaning from extracorporeal circulation was successful in both groups with the use of two positive inotropic agents (dopamine, phosphodiesterase III inhibitors) except in 6 patients in the Novacor group and 5 patients in the HeartMate group who required three inotropic agents for support of the right side of the heart (dopamine, epinephrine, phosphodiesterase III inhibitors) and in 1 patient of each group in whom failure of the right side of the heart could only be managed by the institution of an additional right ventricular assist device (Thoratec plus Novacor, Medos plus HeartMate).

No statistically significant differences between the groups were found with regard to postimplantation hemodynamics (Table III), median postoperative ventilatory support time (Novacor, 2 days, 25th and 75th percentiles 1.5 and 3.2, respectively; HeartMate, 2.5 days, 25th and 75th percentile 1.5 and 4.0, respectively), mean stay in the intensive care unit (Novacor, 16.7 ± 15.5 days; HeartMate, 12.2 ± 8.7 days, $P = .3$), mean duration of total hospitalization (Novacor, 55.6 ± 30.7 days; HeartMate, 58.6 ± 30.1 days, $P = .8$), and mean duration of support (Novacor, 235.3 ± 210 days; HeartMate, 174.6 ± 175 days, $P = .4$). Laboratory data obtained on postoperative days 1, 7, 14, and 30 reflected good organ recovery without any statistically significant differences between the groups (Table V).

Fifteen patients (75%) supported with the Novacor LVAS and 14 patients (70%) supported with the HeartMate LVAS were able to be discharged from the hospital to home while the device was in place, and 1 patient in the Novacor group was moved to a rehabilitation center because neurologic complications precluded home care. Ten patients in the Novacor group and 9 in the HeartMate group had to be readmitted to the hospital because of a variety of complications as detailed in Table VI. Tables VII and VIII, which show the general complications occurring during support, indicate that patients in the Novacor group were readmitted mainly because of neurologic disorders whereas in patients in the HeartMate group infections and technical problems were the main reasons. Five patients (3 Novacor, 2 HeartMate) were able to return to work. Mean duration of out-of-hospital support was 241 ± 179 days (range 20-642 days) for patients in the Novacor group and 166 ± 152 days (range 11-616 days) for patients in the HeartMate group ($P = .14$).

Table II. *Preoperative clinical blood chemistry values*

Parameter	*Novacor (mean)*	*HeartMate (mean)*	P *value**
BUN (mg/dL)	82 ± 39	76 ± 37	.7
Creatinine (mg/dL)	1.5 ± 0.6	1.6 ± 0.6	.9
Bilirubin (mg/dL)	2.0 ± 1.0	1.7 ± 1.1	.3
AST (U/L)	34 ± 27	43 ± 69	.7
ALT (U/L)	46 ± 62	91 ± 190	.4
γ-GT (U/L)	101 ± 79	67 ± 45	.1
AP (U/L)	187 ± 129	147 ± 61	.3
Lipase (U/L)	123 ± 80	155 ± 79	.2
Amylase (U/L)	28 ± 38	23 ± 21	.7
WBC (gm/L)	8.0 ± 5.4	7.4 ± 5.5	.8
Platelets	203 ± 92	227 ± 127	.6

BUN, Blood urea nitrogen; *AST,* aspartate aminotransferase; *ALT,* alanine aminotransferase; *γ-GT,* γ-glutamylcyclotransferase; *AP,* alkaline phosphatase; *WBC,* white blood cells.
*Unpaired *t* test.

Of the Novacor group, 13 (65%) have undergone transplantation and have left the hospital, 3 are still awaiting transplantation, and 4 (20%) died while receiving LVAS support (multiple organ failure/sepsis, n = 3; massive thromboembolism, n = 1). Of the HeartMate group, 12 (60%) have received a transplant, 2 are waiting, and 6 (30%) died while receiving LVAS support (multiple organ failure and/or sepsis, n = 5; cerebral bleeding, n = 1).

The prevalence of complications is detailed in Tables VII and VIII. Four patients in the Novacor group and 2 in the HeartMate group were completely free of complications during LVAS support.

Discussion

The Novacor LVAS and the TCI HeartMate VE LVAS are comparable systems available for left ventricular assistance, the efficacies of which have been reported by many authors.[2-9] In a comparative trial in which all patients underwent the same procedures in terms of surgical team, implantation technique, and postoperative protocols, we tried to determine the differences between the two devices.

As expected, hemodynamic outcome was comparable in the two subsets of patients. Both groups had a higher postoperative central venous pressure compared with preoperative measurements possibly resulting

Table III. *Preoperative and postoperative hemodynamic variables*

	Preop			*Postop*		
Variable	*Novacor (mean)*	*HeartMate (mean)*	P *value*[*]	*Novacor (mean)*	*HeartMate (mean)*	P *value*[*]
CI ($L \cdot min^{-1} \cdot m^{-2}$)	2.1 ± 0.4	2.1 ± 0.4	.9	2.9 ± 0.4	3.0 ± 0.6	.8
mPAP (mm Hg)	39 ± 7	38 ± 8	.7	30 ± 7	28 ± 5	.3
mCVP (mm Hg)	13 ± 6	14 ± 7	.9	16 ± 4	15 ± 3	.5
PVR ($dyn \cdot min \cdot cm^{-5}$)	281 ± 138	229 ± 91	.2	249 ± 72	236 ± 69	.6
SVR ($dyn \cdot min \cdot cm^{-5}$)	1187 ± 413	1018 ± 289	.2	795 ± 255	804 ± 135	.9
mPC (mm Hg)	24 ± 8	22 ± 9	.5	11 ± 4	9 ± 4	.1

Postop indicates value on admission to the intensive care unit. *CI*, Cardiac index; *mPAP*, mean pulmonary artery pressure; *mCVP*, mean central venous pressure; *PVR*, peripheral vascular resistance; *SVR*, systemic vascular resistance; *mPC*, mean pulmonary capillary wedge pressure.
[*]Unpaired *t* test.

Table IV. *Preoperative risk factors*

Risk factor	*Novacor*	*HeartMate*	P *value*[*]
Inotropic support (at least 2 drugs)	20	20	1
IABP	7	6	.7
Reoperation	3	2	.6
Renal failure	4	4	1
AICD	2	1	.5

IABP, Intra-aortic balloon pump; *AICD*, automatic implantable cardioverter-defibrillator.
[*]χ^2 test.

from insufficiency of the right side of the heart, which is a common problem after LVAD implantation, or from a relative volume overload of the right side of the heart. As reported by other authors,[3,5,9] bleeding still constitutes a problem after ventricular assist device implantation. In our trial we found a similar prevalence in both patient groups but a significantly higher amount of blood loss in the Novacor collective, which might result from the more aggressive anticoagulation protocol. The prevalence of reoperation because of bleeding was similar between groups, with 6 patients in the Novacor and 4 patients in the HeartMate groups. The prevalence of bleeding noted in Table VIII included 3 cases of late bleeding (2 Novacor, 1 HeartMate) that occurred after aspirin medication, which in our primary experience was given 4 to 5 days after the operation after removal of chest drains, when the patient had been moved to the regular care ward. We therefore have changed our anticoagulation protocol and now start to administer aspirin 2 weeks after the operation. Despite the high amount of blood loss, this complication did not impair patient outcome.

In accordance with the data reported by various other authors,[5,6,10] patients supported with the Novacor LVAS showed a higher prevalence of neurologic disorders despite the aggressive anticoagulation protocol. Thromboembolic events were found in 4 patients and occurred on postoperative days 14 to 67 (mean 29 days). However, in 2 of these patients, anticoagulation was only suboptimal at the time of the event. It is highly recommended that anticoagulation in patients with the Novacor LVAS be carefully monitored and that attention be paid to the optimal balance between a possible bleeding complication and the risk of thromboembolism. One other explanation for the increased thromboembolic risk may be the configuration of the Novacor inflow and outflow grafts, which have a diameter of 22 mm compared with 18 mm in the HeartMate device, and the longer inflow graft, which might favor the development of thrombi. Cerebral bleeding was found in 1 patient of each cohort and resulted from a decompensated coagulation because of a septic attack. These results show that from the neurologic point of view, the HeartMate device is superior to the Novacor system.

In contrast, the number of patients who had system-related infections, which occurred on postoperative days 30 to 111 (mean 58 days), was significantly higher in association with the HeartMate LVAS, although implantation was done by the same surgical team and the same antibiotic protocols and wound care management were applied. It is suggested that because of the rotary movement of the pump there is an increased reaction between the pump housing and the surrounding tissue, leading to an increased secretion involving a higher risk of infection. To reduce device infection, we have modified our technique of implanting HeartMate devices.[11] Conduit endocarditis was found in 3 patients, 1 of whom had both Novacor and Thoratec support and in whom both inflow and outflow conduits were replaced. This patient underwent cardiac transplantation later and survived. The other 2 cases of conduit endocarditis occurred in 2 patients in the HeartMate group: in 1 case it was discovered at autop-

Table V. *Postoperative clinical blood chemistry values*

	Novacor (mean)				*HeartMate (mean)*				
Parameter	*POD 1*	*POD 7*	*POD 14*	*POD 30*	*POD 1*	*POD 7*	*POD 14*	*POD 30*	P *values*[*]
BUN (mg/dL)	74.4 ± 30.3	65.6 ± 45.4	42.0 ± 24.6	43.8 ± 41.4	71.6 ± 24.6	72.3 ± 46.9	54.0 ± 34.6	45.5 ± 15.8	.3
Creatinine (mg/dL)	1.6 ± 0.7	1.1 ± 0.5	0.9 ± 0.4	1.0 ± 0.4	1.5 ± 0.5	1.2 ± 0.6	1.2 ± 0.6	1.0 ± 0.3	.1
Bilirubin (mg/dL)	3.0 ± 1.6	4.5 ± 4.6	3.9 ± 3.8	3.2 ± 5.2	3.1 ± 1.9	4.7 ± 6.3	9.2 ± 15.5	2.9 ± 6.4	.8
AST (U/L)	60.4 ± 35.3	34.5 ± 20.3	36.1 ± 26.7	23.1 ± 9.6	62.1 ± 59.2	34.5 ± 20.3	31.9 ± 23.1	24.4 ± 26.2	.9
ALT (U/L)	32.0 ± 35.1	20.7 ± 18.9	24.1 ± 22.6	18.7 ± 11.0	46.1 ± 73.2	18.7 ± 14.3	29.6 ± 27.5	21.9 ± 27.0	.5
γ-GT (U/L)	35.8 ± 23.7	143.4 ± 123.2	141.7 ± 112.7	105.0 ± 79.0	27.5 ± 17.8	76.2 ± 47.7	89.3 ± 63.7	104.4 ± 75.2	.5
AP (U/L)	99.7 ± 17.8	262.2 ± 173.4	275.3 ± 139.3	281.8 ± 148.8	95.6 ± 23.2	202.2 ± 111.4	244.8 ± 125.1	285.6 ± 148.1	.8
Lipase (U/L)	154.5 ± 89.2	212.0 ± 128.1	213.2 ± 157.6	277.1 ± 112.0	152.3 ± 162.4	198.1 ± 101.5	342.3 ± 252.9	208.2 ± 142.9	.4
Amylase (U/L)	30.7 ± 31.2	31.7 ± 16.1	24.0 ± 15.1	35.9 ± 19.5	27.9 ± 28.5	22.7 ± 15.2	37.7 ± 26.6	22.9 ± 12.9	.8
WBC (gm/L)	7.9 ± 6.4	9.8 ± 6.4	14.6 ± 14.0	7.1 ± 2.5	6.7 ± 6.0	7.8 ± 5.8	9.4 ± 5.8	5.3 ± 1.9	.9
Platelets	115.9 ± 64.6	137.8 ± 64.1	273.0 ± 134.8	357.9 ± 176.8	124.4 ± 47.1	134.1 ± 68.5	261.4 ± 169.4	255.5 ± 116.6	.9

Abbreviations same as for Table II.
[*]GLM (general linear model for repeated measures).

Table VI. *Causes for readmission of out-of-hospital patients (several causes per patient possible)*

Complication	*Novacor (n = 10)*	*Event/patient mo*	*HeartMate (n = 9)*	*Event/patient mo*	P *value*[*]
Neurologic	5	0.042 (0.006-0.078)	1	0.013 (–0.012-0.038)	.4
Driveline infection	2	0.017 (–0.006-0.04)	1	0.013 (–0.012-0.038)	1
Pocket infection	2	0.017 (–0.006-04)	5	0.065 (0.01-0.12)	.1
Technical	1	0.008 (–0.008-0.024)	3	0.039 (–0.004-0.082)	.3
Gastrointestinal tract	1	0.008 (–0.008-0.024)	-	0.013 (–0.012-0.038)	
Miscellaneous	1	0.008 (–0.008-0.024)	1		

Linearized rates of complications are calculated as the number of complications per patient month in a given time frame (95% confidence limits).
[*]Fisher exact test.

sy and in the other case the patient subsequently underwent transplantation and survived. Pocket infections could usually be managed by local irrigation. If signs of systemic infection become obvious, antibiotics are given for at least 4 weeks. Two patients with pocket infection died during support, 1 of sepsis (HeartMate) and 1 of massive thromboembolism (Novacor). The systemic infections were mainly episodes of infections with positive cultures revealing the same pathogens obtained from the pocket or driveline.

In terms of reliability, the HeartMate device compared badly with the Novacor LVAS. Minor problems were controller exchanges, which were a result of software faults and after some modification were eliminated. Driveline cracks in both groups were associated with an extended duration of support (>300 days) and were found in very active patients putting major stress on the material. The cracks could be sealed without hazard to the patient. Unfortunately, all pump failures at this institution in our total HeartMate VE LVAS collective (n = 27) occurred in the current study population. In 1 patient, who was mobile on the regular care ward, pump failure occurred 8 weeks after implantation because of fluid in the motor component. The nature of the fluid was the subject of controversy between the manufacturer and us. According to their statement, the fluid had a red-brown appearance, but it was not analyzed with regard to heme. In the second patient, pump failure happened at home after 14 months of support. This patient was admitted to the hospital on an emergency basis and received support with the pneumatic system before undergoing exchange of the pump and being discharged from the hospital to his home again, where he is still waiting for cardiac transplantation. On examination, minor cracks were found in the membrane, which made the transition of blood into the motor chamber possible, thus causing a standstill. In another case occurring after 2 months of support the failure was patient related and resulted from a disconnected infusion cannula with blood leaking into the pump filter and

Table VII. *Neurologic complications and device-related infections during support*

Complication	*Novacor*	*Event/patient mo*	*HeartMate*	*Event/patient mo*	P *value*[*]
Neurologic					
Thromboembolic event	4 (20%)	0.026 (0.001-0.051)	—		.1
Cerebral bleeding	1 (5%)	0.006 (–0.006-0.018)	1 (5%)	0.009 (–0.008-0.026)	1
TIA	7 (35%)	0.045 (0.012-0.078)	1 (5%)	0.009 (–0.008-0.026)	.1
Infections					
Driveline	4	0.026 (0.001-0.051)	9	0.078 (0.029-0.127)	.09
Pocket	2	0.013 (–0.005-0.031)	5	0.044 (0.006-0.082)	.1
Conduit endocarditis	1	0.006 (–0.006-0.018)	2	0.017 (–0.007-0.041)	.6
Patients with device-related infections	4 (20%)	0.025 (0.001-0.051)	11 (55%)	0.096 (0.042-0.15)	.02
Technical					
Controller exchange	2	0.013 (–0.005-0.031)	14	0.122 (0.062-0.182)	<.001
Driveline crack	3	0.019 (–0.003-0.041)	2	0.017 (–0.007-0.041)	.6
Pump failure	—	—	4	0.035 (0.001-0.069)	.03

Linearized rates of complications are calculated as the number of complications per patient month in a given time frame (95% confidence limits). *TIA*, Transient ischemic attack.
[*]Fisher exact test.

Table VIII. *Other complications during support*

Complication	*Novacor*	*HeartMate*	P *value*[*]
Bleeding	8 (40%)	7 (35%)	.7
Blood loss (mL)	5245 ± 2220	2340 ± 2245	.01
Reoperation for bleeding	6 (30%)	4 (20%)	.5
RHF necessitating RVAD support	1	1	
RHF with medical treatment	4	2	.4
Gastrointestinal tract	2	2	
Sepsis/MOF	3	5	.4
Arrhythmia	1	1	
Systemic infection	4 (20%)	9 (45%)	.1

RHF, Right heart failure; *RVAD*, right ventricular assist device; *MOF*, multiple organ failure.
[*]Unpaired *t* test.

causing the failure. The patient was immediately switched to support with the pneumatic system. He died later of multiple organ failure and sepsis. The fourth patient was at home as well when pump failure occurred. He was admitted to the intensive care unit immediately and support was switched to the pneumatic console before the patient underwent heart transplantation. It was determined that the electronic commutator was malfunctioning, probably because of static discharge, so that it only operated at its fallback position, which is basal rate. Subsequently, all existing pumps were protected with the TCI-provided Static Protect Adaptor.

Apart from the patient-related failure, we had 3 device-related failures of the HeartMate VE LVAS in a total of 27 patients (11%) compared with no pump failures in a total of 76 patients supported with the Novacor device at our center. In accordance with the findings of McCarthy and colleagues,[3] infection and reliability of this device are major problems and still have to be addressed.

Gastrointestinal tract complications comprised mesenteric ischemia, cholecystectomy, pancreatitis, and ileus.

Despite the multimorbidity and the hopeless situation of the patients before device implantation, most of them had organ recovery with support and a considerable number of patients in both groups could be discharged from the hospital to await cardiac transplantation at home. Some of these patients were even able to return to work, which added to their quality of life. The results achieved are promising regardless of the complications. Both devices are undergoing revisions to address the current problems, that is, the thromboembolism associated with the Novacor LVAS and the infection and reliability problems found in the HeartMate device. If the devices can be successfully improved in these terms, the application of implantable LVADs should be considered as an alternative to cardiac transplantation.

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Discussion

Dr Verdi J. DiSesa *(Chicago, Ill).* You certainly have had more frequent technical failures with the HeartMate than we have seen. I would still maintain that avoiding anticoagulation and neurologic events has some advantages even if the device must be changed, although perhaps some of the new software and the new techniques you are using can obviate that.

Dr Edward B. Savage *(Chicago, Ill).* This represents a nice comparative series, and you have a large experience with these devices. I am concerned about the conclusions drawn in your abstract. Both of these devices were in the development phase during your protocol and they have undergone many changes, which you have outlined. To conclude that one device might be superior to another is a little premature, particularly since many of the device deficiencies that you cited have been addressed.

Dr DiSesa. Would you care to respond?

Dr El-Banayosy. I think no response is needed.

Dr DiSesa. Are you continuing to use both devices?

Dr El-Banayosy. Yes, we are continuing to use both of the devices. What we are trying to do now is select patients for the two devices by estimating the levels of proteins C and S before implantation of the devices. Patients having abnormal levels of these proteins are supported with the HeartMate device, and patients with normal levels receive the Novacor device. That is what we are trying to do, but I have no data as yet from this new study.

Dr Thierry G. Mesana *(Marseille, France).* You mentioned that most of the thromboembolic accidents occurred at a certain period with the Novacor device and occurred mainly with the Novacor LVAS. Did you observe at the same time some specific biologic modifications to explain that, such as inflammatory response or higher parameters?

Dr El-Banayosy. The incidence of the four major neurologic complications was independent of the inflammatory response in these patients. However, in 2 of our patients, anticoagulation was suboptimal at the time of the event.

Dr Boulos Asfour *(Muenster, Germany).* I have a question regarding the thromboembolism you had and the anticoagulation. Did the neurologic complications in the Novacor population occur early? I ask this because you mentioned that you also had more blood loss in the Novacor group. My guess is you do the same as we do in these patients: begin administration of anticoagulants rather late when you remove the chest tubes and not before.

Dr El-Banayosy. In the past we started aspirin administration on the fourth or fifth postoperative day after removal of chest drains and that is why we had more bleeding in these patients. We have now changed our strategy and we give aspirin beginning on postoperative day 14.

Dr Asfour. You said you had more bleeding because of aspirin, but now you say that you start rather late. Was the therapy begun at the time the chest tubes were removed?

Dr El-Banayosy. Yes.

Dr Asfour. When did you find these neurologic complications? Were there early complications in the intensive care unit before the start of aspirin therapy or were the complications late?

Dr El-Banayosy. They occurred during aspirin and warfarin (Coumadin) therapy.

Dr Asfour. They were late, not in the intensive care unit?

Dr El-Banayosy. Later, yes. I mentioned that these complications happened between postoperative days 14 and 67, and the mean was 29 days.

The Journal of Thoracic and
Cardiovascular Surgery
March 2000