Outpatients on Mechanical Circulatory Support

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Background. **As waiting periods for heart transplantation have lengthened, the application of long-term mechanical circulatory support (MCS) has become more common in patients presenting with cardiogenic shock. Anticipating increased long-term MCS, a policy to discharge patients home has been instituted. This study compares the results of outpatient on MCS to a group of patients remaining hospitalized.**

Methods. **We report our 10-year experience with 108 patients on MCS, who were supported for more than 3 months. Group A consisted of 38 patients (25 Novacor, 13 Berlin Heart) who underwent assist implantation from 1996 to 2001. They had a mean support time of 454 days (range 100 to 1074 days) and spent a mean of 326 days (range 20 to 769 days) at home. Group B consisted of 70 patients (24 Novacor, 46 Berlin Heart) who underwent assist implantation between 1991 and 2000. They had a mean support time of 234 days (range 95 to 795 days) and were not discharged. The patients were monitored for complications, hospital readmissions, and causes of death including infections and thromboembolic and bleeding events during the MCS time.**

Results. **Group A total mortality was 16% (6/38). Two patients died from cerebral embolism, one from cerebral hemorrhage, two from systemic infection, and one from multiorgan failure. Thirty-two patients (84%) required 95 readmissions to the hospital due to cerebral embolism (n = 9), bleeding (n = 1), wound infections (n = 23), coagulation disorder (n = 13) for heart transplantation (n = 5), and (n = 44). In group B the mortality was 43% (30/70) for noncardiac reasons and thus significant higher ($p = 0.004$, χ^2 test). Causes of death were cerebral embolism (n = 5), cerebral hemorrhage (n = 7), systemic infection (n = 14, significantly higher, $p = 0.04$, χ^2 test), and multiorgan failure (n = 4).**

Conclusions. **Our experience demonstrates that MCS can be used in outpatients without increased mortality and with an acceptable rate of readmissions (2.8/patient). It ensures the survival of the patient, enables recovery from multiorgan failure, and offers an acceptable quality of life.**

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Ventricular assist devices are mostly used as a bridge to heart transplantation or to recovery from postcardiotomy shock. The first mechanical circulatory support device (MCS) was implanted in 1963 [1]. At the Deutsches Herzzentrum Berlin (German Heart Institute Berlin) we started using pulsatile assist devices as a bridge to transplantation in 1987 [2]. Up until now more than 330 biventricular support devices and 280 left ventricular supports have been implanted in our institution. The initial inhospital experience with the Berlin Heart and the Novacor device demonstrated the technical reliability of these two support systems. Based on this observation, we felt comfortable in discharging patients on ventricular assist devices from the hospital.

Since 1996 patients who recovered from secondary organ dysfunction have left our hospital to spend the time following assist device implantation at home. Thanks to the reliability of the wearable electrical support systems patients were able to go to locations as far as 1000 km (675 miles) away from the hospital.

In the present study the course of 38 patients who were discharged from the hospital with MCS is described. The results were compared with those of a group of 70 patients who could not be discharged for psychologic, social and familial, or nonmedical reasons.

At the time of implantation all patients presented with severe heart failure and evolving multiorgan failure. They were dependent on maximal inotropic support and refractory to medical therapy. The MCS was initiated as a lifesaving procedure in all patients. The goal was mostly to bridge the patient to heart transplantation. However, some patients were later weaned from support or presented with contraindications to transplantation and MCS became permanent support.

The goal of this study is to report our experience with patients discharged from the hospital while on mechanical support. The incidence of thromboembolism, bleeding, infection, and lethal complications during the time out of hospital is documented.

Patients and Methods

The course of 108 patients who spent more than 3 months on MCS was analyzed. Two groups were compared (Table 1): Group A consisted of 38 patients who could

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Table 1. Two Groups of Patients

	Group A Discharged Home	Group B Not Discharged
Number	38	70
Date of implantation	1996–2001	1991–2000
Mean Age (in years)	48 (range: 17–76)	48 (range: 24–66)
Sex		
Women	2	9
Men	36	61
Diagnosis		
dilatative CMP	27	46
ischemic CMP	10	21
restrictive CMP	—	1
other	1	2
Time of support (days)	454 (100–1074)	238 (95–795)
Time at home (days)	326 (20–769)	—

CMP = cardiomyopathy.

leave the hospital, 36 men (95%) and 2 women (5%). The average age at time of implantation was 48 years (from 17 to 76 years). The indication for assist implantation was dilated cardiomyopathy in 71%, ischemic cardiomyopathy in 26%, and in 1 patient another heart disease. Twenty-five patients of this group received a Novacor system (World Heart Inc, Oakland, CA) and 13 patients a Berlin Heart system (Berlin Heart AG, Germany; left ventricular assist device [LVAD], n = 8; biventricular assist device [BVAD], n = 38). The patients had a mean support time of 454 days (range 100 to 1074 days) and spent a mean of 326 days (range 20 to 769 days) at home (up to 620 days in a row). Group B consisted of 70 patients who did not leave the hospital. There were 61 men (87%) and 9 women (13%) with an average age of 48 years old (from 24 to 66 years old). The indication for MCS was again mostly dilated cardiomyopathy (66%), followed by ischemic cardiomyopathy (30%), restrictive cardiomyopathy in 1 patient (1%), and another disease in 2 patients (3%). Twenty-five patients of this group received a Novacor system and 45 patients a Berlin Heart (LVAD, n = 8; BVAD, n = 5). Their mean support time was 238 days (range 95 to 795 days) and no patient from this group was discharged.

Before device implantation, all patients were in severe heart failure with evolving or complete multiorgan failure refractory to medical therapy. A complete recovery from secondary organ dysfunction after device implantation and a stable psychological and social situation were the preconditions for outpatient care.

Patients with two different devices are described [3]. The Novacor is an assist device for left ventricular support only (Fig 1), implanted into a pocket in the abdominal wall. It consists of a polyurethane sack that is compressed by two electrically powered magnet. The pump is connected by a transcutaneous cable with an external controller and two batteries allowing independence for a maximum of 4 hours. The blood is drained from the apex of the left ventricle and brought back to the ascending aorta. The Novacor has been implanted since 1993 at our institution and patients have been able to leave our hospital with it since 1996. This system is used in patients presenting with severe heart failure with beginning multiorgan failure refractory to medical therapy.

The Berlin Heart consists of a paracorporeal artificial ventricle made of polyurethane (Fig 2). The ventricle has a mutilaminated membrane that separates the blood from the air-filled chamber. The air is transported under pressure into the artificial ventricle, producing the movement of the membrane ejecting the blood. The polyurethane is coated with heparin on the inside [4], inhibiting formation of thrombus.

The Berlin Heart can be used for left, right, or biventricular support. The artificial ventricle of the left heart has a blood volume of 80 ml, that of the right heart 60 ml. Every device has two Björk-Shiley monodisc valves (Shiley, Inc., Irvine, CA), each with a diameter of 21 mm. The cannulas connecting the artificial ventricle with the heart are available in different diameters and with different angles. The cannulas have an outer surface of Dacron, allowing ingrowth of the skin and thus diminishing wound infections. The pumps are activated by an air compressor (Ikus/Siemens [Danvers, MA] or Heimes HD-7), which produces simultaneous or alternating left-right rhythm. This compressor has a battery, allowing mobility for up to 30 minutes (Ikus/Siemens) or 2 hours (Heimes HD-7). A new compressor (Excor), available since the year 2000, is smaller and has been constructed for use by outpatients. It has a battery allowing independence for up to 8 hours [5]. The Berlin Heart is used for left ventricular support by left thoracotomy (apical and descending aorta anastomosis) in preoperated patients presenting with severe heart failure with beginning multiorgan failure refractory to medical therapy. In patients presenting with severe heart and multiorgan failure it is used for biventricular support.

All patients received anticoagulation consisting of heparin, Coumadin (Du Pont Pharmaceuticals, Wilmington, DE), and platelet inhibitors [5]. During the early postoperative period i.v. heparin was administered; then the patient was switched to Coumadin. To inhibit platelet aggregation acetyl salicylic acid in low doses and dipyridamol in high doses were given. The platelet function was measured by thrombelastogram and platelet activation tests.

Before leaving hospital the patient and the patients family were intensively trained (Table 2). They were involved in the technical function of the assist device and the patient and one family member were trained in driver exchange in case of malfunction [6]. The ventricular assist device coordinator taught the patient and his caregivers sterile wound dressing and practiced this with them until the dressing had been changed three times without complications. The local family practitioner was instructed about the device and performed routine follow-up exams once a week (laboratory check: coagulation, blood count, kidney function, C-reactive protein) or when needed. If the patient had no family member who could be trained, the family practitioner would be trained

Fig 1. Patient on Novacor system (World Heart Inc, Oakland, CA).

in sterile wound dressing. Patients routinely returned to the hospital for follow-up examination at intervals of between 2 weeks and 3 months. In addition, a 24-hour phone support line for medical and technical problems was introduced.

Results

Patients in group A spent a mean of 326 days at home, corresponding to 71% of the time on support (Table 3). Twenty-two patients were transplanted (18 survivors, 2 died due to septicemia and 2 due to transplant failure), one patient could be weaned from VAD, 6 patients died, and 9 patients are still on support. Four patients received the system for destination therapy and 2 patients were no longer considered transplant candidates (due to insufficient compliance or the patient's decision). Thirty-two patients (84%) required 95 readmissions to the hospital. This corresponds to 2.8 readmissions per patient per year. The causes for readmission are illustrated in Table 4 (the readmissions due to heart transplantation are not included): two patients had to be readmitted because of cerebral embolism. Six other readmissions were due to transitory ischemic attacks in 6 patients and to prolonged ischemic neurologic deficit in 1 patient. One patient developed cerebral bleeding after intentionally overdosing his antivitamin K. He was on mechanical support for more than 1 year before his suicide attempt. Thirteen patients were readmitted for coagulation disorders. Twenty-three readmissions in 11 patients were due to wound infections presenting at the transcutaneous cannula. These infections, manifesting with reddening of the

Fig 2. Patient on Berlin Heart system (Berlin Heart AG, Berlin, Germany).

skin and with elevated temperature and leukocytosis, were treated with regular dressings and antibiotic drugs. The bacteria most often found were *staphylococcus coagulase negative*, followed by *staphylococcus aureus, corynebacteriae, enterobacteria*, and *enterococcus* [7]. They were never a contraindication for transplantation [8]. Forty-four patients had to be readmitted for non-MCS related reasons. These were patients with diarrhea, dental problems, ventricular tachycardia, muscle pain following physical exercise, for surgery of a Dupytren contracture, etc. There were no readmissions due to device related failures and none of the devices had to be replaced because of mechanical failure. Problems with the inflow valve or bearing wear were not seen. The cumulative events per outpatient month were 0.0024 for cerebral bleeding, 0.022 for cerebral embolism, 0.057 for wound infection, 0.031 for coagulation disorder, and 0.11 for non-MCS related causes.

Table 2. Conditions for Discharge

Wound dressing training
Anticoagulation training
Medical support 24 h/day
Technical support 24h/day

Table 3. Readmissions in Group A

Time at home	326 days
Patients readmitted	n = 32 (84%)
Number of readmissions	n = 95
2.8 readmissions/patient/year	

Group B, the nondischarged patients, consisted of 70 patients. Thirty patients received a heart transplant (20 survivors, 1 patient died due to septicemia, 2 patients died due to transplant failure, and 7 patients died due to other causes), 10 patients could be weaned from VAD and 10 patients died during support. No patient from this group is still on support. The reasons for nondischarge are illustrated in Table 5. Most patients (61%) could not leave the hospital because of nonavailability of a portable drive unit for the Berlin Heart device. The new compressor (Excor) became available only in 2000. Twenty patients with a Novacor LVAD implanted before 1996 did not leave the hospital because this was before we started our outpatient program. The other patients were not discharged because of psychologic problems (9%), and social and familial disorders (9%). One patient (1%) was weaned from MCS before leaving the hospital. None of the devices had to be replaced because of mechanical failure and there were no problems with the inflow valve or bearing wear.

Fatal Complications

In group A the mortality was 16% and significantly lower than the rate in group B, which was 43% (Table 6) ($p = 0.004$, χ^2 test.

Five percent of patients in group A suffered from fatal cerebral embolism, 2.5% from cerebral hemorrhage, 5% from systemic infections, and 2.5% from multiorgan failure during a mean support time of 422 days. In group B fatal cerebral embolism occurred in 7% and cerebral hemorrhage in 10%. The rate of systemic infections as cause for death was significantly higher ($p = 0.04$, χ^2 test) at 20% although the time of support was half as long (234 days). Multiorgan failure occurred in 6% of patients and did not differ significantly from the incidence in group A.

Table 4. Causes for Readmission

	Group A	
	Number of Readmissions	Percent of Readmissions
Cerebral bleeding	1	1
Cerebral embolism	9	9.5
TIA	6	6.5
PRIND	1	1
Apoplex	2	2
Coagulation management	13	14
Wound infection	23	24
Non-MCS related	44	46.5
Transplant studies	5	5
Total	95	100

MCS = mechanical circulatory support; PRIND = prolonged ischemic neurologic deficit; TIA = transient ischemic attack.

Table 5. Reason for Nondischarge in Group B

	Group B	
	Number	Percent
Weaning	1	1
Social/family	6	9
Psychologic factors	6	9
Novacor before 1996	14	20
Berlin Heart before 2000	43	61
Total	70	100

Comment

The mechanical circulatory support devices Novacor and Berlin Heart were implanted in patients presenting with terminal heart disease and secondary multiorgan failure. All 108 patients included in this study recovered from secondary multiorgan failure after device implantation. This was the precondition for mobilization, for leaving the hospital and for subsequent heart transplantation. It has been reported in several publications [2, 9, 10] that the results of heart transplantation are optimal when organ recovery is complete.

The 38 outpatients in group A spent a mean of 326 days at home, corresponding to 72% of their time on support. The number of readmissions per patient per year was 2.8. The most frequent cause was non-MCS related (46%), followed by wound infections (24%), cerebral bleeding (9%), and embolism (1%). Five percent of the readmissions were in order to prepare the patient for heart transplantation. The cumulative events per outpatient month were 0.0024 for cerebral bleeding, 0.022 for cerebral embolism, 0.057 for wound infection, 0.031 for coagulation disorder, and 0.11 for non-MCS related causes.

Richenbacher and colleagues [11] have recently reported results from 13 discharged patients on left ventricular assist devices (HeartMate; Thoratec Corp., Pleasanton, CA). On average, they spent 171 days (range 3 to 473 days) out of hospital. Eight of them required a total of 20 rehospitalizations. This corresponds to 3.28 readmissions per patient per year. The most frequent cause was in 40% device related infections, followed by 35% non-MCS related, 10% neurologic events, 10% device malfunction, and 5% epistaxis. Morales and coworkers [12]

Table 6. Fatal Complications (%)

	Group A	Group B
Cerebral embolism	5	7
Cerebral bleeding	2.5	10
Systemic infection	5[a]	20[a]
Multiorgan failure	2.5	6
Mortality	16[b]	43[b]

[a] Significant ($p = 0.04$, χ^2 test); [b] significant ($p = 0.004$, χ^2 test).

presented results of 44 patients on HeartMate discharged home for an average of 103 days. The cumulative event rate per outpatient month was 0.02 for bleeding, 0.0068 for thromboembolism, 0.053 for device infection, and 0.02 for major malfunction. Although their figures for bleeding are almost the similar to ours, their patients had a higher incidence of pocket infections and major device malfunctions. On the other hand the rate of cerebral embolism and of readmissions for non-MCS related causes was higher in our patient population.

Although no patient in group A died at home, the mortality rate was 16% during the support time. None of the discharged patients reported by Morales and colleagues [12] died. Frazier and coworkers [13] reported in a multicenter evaluation that in a group of 280 patient with an electrically vented HeartMate system the mortality rate was 29%. Most patients died of infection (40%), followed by bleeding (11%), neurologic dysfunction (5%), and thromboembolic events (6%). Although the rate of bleeding was equal to that observed by us, Frazier saw more infections and a lower rate of neurologic and thromboembolic events.

The mortality rate due to systemic infection was significantly lower in our outpatient group (5%) than for the patients who remained hospitalized (20%). The cause may be the number of opportunistic infections acquired in hospitals. Frazier [13] presented similar results with a morbidity of 40% due to infections.

The lifesaving effect of mechanical circulatory support in critically ill patients has been shown by several authors [1, 2, 6, 12–17]. In the Rematch trial [17] advantages using VADs could be shown. However, experience with discharging patients on VADs from the hospital is limited especially for those implanted with biventricular paracorporeal assist devices. With regard to using such devices as an alternative to transplantation, the observations made in discharging these patients on the transplant waiting list are of special importance. In particular, the issue of quality of life for these patients needs to be addressed [18, 19]. Although others have reported a considerable incidence of device-related technical problems in patients on certain LVADs, it is noteworthy that in our patient population using Novacor and Berlin Heart assist devices, not a single case of device malfunction occurred during the extended observation time.

The comparison of 38 patients discharged from the hospital while on MCS with 70 patients continously hospitalized demonstrates that discharging patients on left and biventricular support devices does not increase the risk of complications in particular the number of systemic infections. The mortality rate was remarkably reduced in patients who spent extended periods of time at home. A dedicated team of nurses, technicians, and physicians contributed to the success of the discharge program.

However, 16% of the outpatients died before they could receive a heart transplant. The reason for this lies not only in the medical and technical problems but also in the mismatch of the number of potential organ recipients and the number of hearts available, which makes a waiting period, and hence the mechanical systems for outpatients necessary. Unfortunately this mismatch is likely to increase in the future, making it a matter of urgency to decrease the potential risks of MCS by improving both the systems and the postimplantation care of these patients.

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DISCUSSION

DR O. H. FRAZIER (Houston, Texas): Did you have both the TCI and the Novacor patients on anticoagulants in Berlin?

DR LOEBE: No. The TCI patients were managed only with aspirin. But actually our TCI experience in Berlin, as you know, is somewhat limited (n = 24). Since these patients did not spend more than 90 days on the device, they did not qualify for the present report of more than 3-month support experience.

DR FRAZIER: Has the long-term patient that you had over there (568 days) been transplanted? Is there anything unusual about that patient's anticoagulation regimen?

DR LOEBE: No. This patient is actually ongoing. One of the reasons why we were able to generate such a long-term experience is that until very recently in the German organ allocation system a patient on assist device could not qualify for higher urgency, even with device-related problems. Therefore, these patients had to wait for this very long time with a mean waiting time of 1 year. I think it is another remarkable part of our experience that none of these patients experienced any device malfunctions despite the more than 1-year median support duration.

DR FRAZIER: We've introduced the same problem here. Have you discharged the MicroMed patients?

DR LOEBE: MicroMed is expecting to be FDA approved for hospital discharge soon, but so far patients on MicroMed DeBakey LVADs cannot be discharged in the USA. In Berlin/Germany, however, we have been able to discharge patients on MicroMed pumps home and they did very well.