Long-term support of 9 patients with the DeBakey VAD for more than 200 days

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Objective: Pulsatile left ventricular assist devices serving as mechanical circulatory support for patients with end-stage heart failure are associated with complications, including bleeding, thromboembolism, and infection. Axial-flow pumps might overcome some of these shortcomings. Here we report our experience with long-term application of the DeBakey VAD (MicroMed Technology, Inc, Houston, Tex).

Methods: Nine male transplant candidates (37 ± 14 years) with severe hemodynamic compromise (cardiac index, $1.6 \pm 0.5 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$; pulmonary capillary wedge pressure, 27 ± 6 mm Hg) and beginning end-organ failure despite inotropic and intra-aortic balloon pump support received the DeBakey VAD. Clinical outcome was evaluated.

Results: Cumulative support was 7.8 years, and the mean duration of support was 314 ± 75 days (range, 229–438 days). Eight patients were transplanted, and one died from intracerebral bleeding. Peripheral circulation and end-organ function recovered rapidly after implantation. Continuous flow was able to maintain adequate organ perfusion over the long term. Eight patients were discharged during support, with good quality of life. There were no early bleedings, but there were late bleedings in 3 patients caused by excessive anticoagulation and platelet inhibition. Neurologic events occurred in 4 patients. Three patients recovered completely from symptoms, and one had lethal intracerebral bleeding. Because of thrombus formation, the device was exchanged in 4 patients. With increasing experience, thrombolysis was performed in similar situations. All such patients underwent successful transplantation. Hemolysis occurred, with events indicating thrombus formation. Device-related infection was found in one patient.

Conclusions: The DeBakey VAD demonstrated its potential for long-term bridge to transplantation. The risk for thrombus formation needs to be addressed by improvement of pump technology and new strategies for platelet inhibition.

Since its introduction into the clinical arena, heart transplantation has been limited by a shortage of suitable donor hearts. Because of the resulting waiting time for transplantation, many patients deteriorated and died on the waiting list. Mechanical circulatory support provided those patients with an opportunity to survive until transplantation. After the first successful bridge to transplan-

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TABLE 1. Patient characteristics

Patient	Age (y)	Sex	Body surface area	Diagnosis	NYHA class	Cardiac index	PCWP	Catecholamines	IABP	Intubation	Renal dysfunction	Liver dysfunction
1	40	Male	1.71	DCM	IV	2.2	42	Yes	No	No	No	Yes
2	27	Male	1.81	DCM	IV	0.6	28	Yes	Yes	Yes	Yes	Yes
3	17	Male	1.68	DCM	IV	1.8	27	Yes	No	No	No	No
4	27	Male	1.86	DCM	IV	1.2	29	Yes	No	No	No	Yes
5	41	Male	2.06	ICM	IV	2.0	24	Yes	No	No	Yes	No
6	51	Male	1.90	Acute MI	IV	2.0	22	Yes	Yes	No	Yes	No
7	58	Male	2.07	ICM	IV	1.9	20	Yes	No	No	No	No
8	20	Male	2.07	DCM	IV	1.5	28	Yes	No	No	Yes	Yes
9	55	Male	1.85	ICM	IV	2.0	23	Yes	Yes	Yes	Yes	No

NYHA, New York Heart Association; PCWP, pulmonary capillary wedge pressure; IABP, intra-aortic balloon pump; DCM, dilated cardiomyopathy; ICM, ischemic cardiomyopathy; MI, myocardial infarction.

tation in 1969, remarkable improvements in technology were achieved that made mechanical circulatory support devices available for routine clinical use.^{1,2} Pulsatile left ventricular assist devices (LVADs) became the standard for bridging patients to heart transplantation. Their application in critically ill transplant candidates reduced mortality on the waiting list.³ However, pulsatile LVADs exhibit a number of disadvantages. Their big size requires large pump pockets that increase the risk for bleeding and infection and make them unsuitable for small patients. The pulsatile mechanism creates uncomfortable noise, and despite anticoagulation and platelet inhibition, the inner surfaces and prosthetic valves might be the origin of thrombosis and embolism.^{4,5} In the intention to eliminate some of these drawbacks, a new generation of blood pumps was developed. Nonpulsatile axial-flow pumps make little noise and, because of their small size, cause less bleeding and infection. The MicroMed DeBakey VAD (MicroMed Technology, Inc, Houston, Tex) was the first to be used in patients.⁶ The details of the pump have been described elsewhere.⁷ It was evaluated in a multi-institutional trial in which our center participated. Here we report our experience with long-term support using this new technology.

Patients and Methods
Patient Selection and Patient Characteristics

Patients were selected according to a multicenter clinical trial. To qualify for the study, the patients must have been listed for transplantation and have demonstrated profound cardiac failure, confirmed either by means of hemodynamics (pulmonary capillary wedge pressure of ≥ 18 mm Hg, with either a cardiac index of ≤ 2.0 L $\cdot$ min⁻¹ $\cdot$ m⁻² or a systolic blood pressure of ≤ 90 mm Hg) or the need for extraordinary inotropic support (≥ 2 catecholamines) or an intra-aortic balloon pump. Exclusion criteria resembled those excluding a patient from cardiac transplantation. For patients who our center considered suitable candidates for the study despite existing exclusion criteria, such as young age or increased creatinine or bilirubin levels, a special authorization was obtained by MicroMed. The study was approved by the local

institutional review board. Informed consent was obtained from the patients, their relatives, or both, depending on the patient's clinical condition. Over a period of 15 months, 22 patients qualifying for the study underwent implantation of the original uncoated DeBakey VAD. Nine (37 ± 14 years) of the 22 patients were supported for more than 200 days and are presented here. This support time was chosen because the waiting time for elective heart transplantation at our center frequently exceeds 200 days and extends up to 15 months. In addition, it might help assess the potential role of the pump for destination therapy. Patient characteristics are displayed in Table 1. Hemodynamics were profoundly compromised despite support with inotropics and the intra-aortic balloon pump (cardiac index, 1.6 ± 0.5 L $\cdot$ min⁻¹ $\cdot$ m⁻²; pulmonary capillary wedge pressure, 27 ± 6 mm Hg; systolic blood pressure, 80 ± 8 mm Hg). All but 2 patients had beginning end-organ failure involving the kidney, liver, or both.

Surgical Procedure
After a median sternotomy, a small abdominal wall pocket was formed underneath the rectus muscle. After standard cannulation of the ascending aorta and right atrium and initiation of cardiopulmonary bypass, the pump was implanted with the heart beating, as we have already described for Novacor LVADs.⁸ The inflow cannula was inserted into the left ventricular apex and oriented in parallel to the interventricular septum. The pump was positioned into the abdominal pocket, and the percutaneous cable was tunneled subcutaneously to exit on the contralateral side. The outflow graft was anastomosed to the ascending aorta. After deairing, the pump speed was gradually adjusted to provide sufficient pump flow, and administration of nitric oxide supported right heart function. Then cardiopulmonary bypass was stopped. The chest was closed in standard fashion.

Postoperative Management
In the early postoperative period, it was important to adjust pump speed, preload, and afterload to avoid suction and provide a pump index of 2.0 L $\cdot$ min⁻¹ $\cdot$ m⁻² or greater. Later, pump speed usually remained in each individual at the same level, which varied between patients from 8500 to 10,500 rpm. Positive fluid balance continued to be important.

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TABLE 2. Clinical outcome and adverse events

Patient	Clinical outcome	Duration of support (d)	Pump exchange	Pump 1 duration (d)	Pump 2 duration (d)	Thrombolysis	Bleeding	Neurologic events	Infection	Hemolysis
1	HTx	246	Yes	172	74	No	No	No	No	Yes
2	HTx	229	Yes	138	91	No	No	No	No	Yes
3	HTx	280	Yes	78	202	Yes (pump 2)	Yes	No	No	Yes
4	HTx	438	Yes	290	148	Yes (pump 2)	No	Yes	No	Yes
5	Death	253	No	253	—	No	Yes	Yes	No	Yes
6	HTx	299	No	299	—	Yes	Yes	Yes	No	Yes
7	HTx	412	No	412	—	No	No	No	Yes	Yes
8	HTx	274	No	274	—	No	No	No	No	Yes
9	HTx	399	No	399	—	Yes	No	Yes	No	Yes

HTx, Heart transplantation.

Figure 1. Recovery of preoperatively compromised peripheral organ perfusion, as indicated by lactate levels, after implantation of the DeBakey VAD (= day 0).

Anticoagulation and inhibition of platelet aggregation were adopted initially from our experience with pulsatile LVADs.⁹ Intravenous heparin at an activated partial thromboplastin time of 60 to 80 seconds was started on the first postoperative day (POD) and, after clinical stabilization, was switched to oral phenprocoumon (international normalized ratio, 2.5-3.5). Inhibition of platelet aggregation was started after removal of chest tubes, applying 300 mg of aspirin and 75 mg of dipyridamole daily. Specific monitoring of platelet inhibition was not available. After our initial experience with recurrent events indicating thrombus formation, anticoagulation was intensified, aiming at an activated partial thromboplastin time of 80 to 100 seconds during heparin therapy and an international normalized ratio of 3.5 to 4.5 after switching to phenprocoumon. For platelet inhibition, 75 mg of clopidogrel was administered in addition to 300 mg of aspirin and 75 mg of dipyridamol. The intensification of anticoagulation and platelet inhibition was applied in patients 6 to 9. One patient (patient 9) had heparin-induced thrombocytopenia for which anticoagulation was switched to danaparoid (Orgaran; target blood level, 0.3-0.6 U/mL). For thrombolysis, recombinant tissue plasminogen activator was used. After an initial intravenous bolus of 50 mg, a second intravenous dose of 50 mg was administered over a period of 2 hours.¹⁰

Results
Clinical Outcome

Operation time averaged 150 ± 21 minutes, and cardiopulmonary bypass time averaged 62 ± 4 minutes. Cumulative time of support was 7.8 years, and mean duration was 314 ± 75 days (range, 229-438 days). Three patients were supported for more than 300 days, and 2 of those were supported for more than 400 days. Eight patients underwent transplantation, and one patient died from intracranial bleeding (Table 2). Six patients (patients 2-4 and 6-8) spent most of their time on support at home, and 2 patients (patients 1 and 9) went home for weekends. Patient 5 was ambulatory in the regular ward, but because of the rather complicated course, he was not discharged home.

Hemodynamics

According to the pump and hemodynamic management described above, pump flows from 3.5 to 7 L/min were achieved, depending on the patient’s size and activity. This allowed cessation of nitric oxide and inotropic therapy within 24 to 48 hours after the operation, and in the later course, it enabled the patients to perform normal daily activities and exercise. Preoperatively compromised peripheral organ perfusion normalized rapidly (Figure 1). None of the patients had right ventricular failure, which would have required right ventricular assistance. Pulsatility was absent in all patients in the initial postoperative period. Within the first postoperative week, all patients regained pulsatility to a variable extent. Echocardiography demonstrated closure of the aortic valve at rest. In the later course, exercise caused the aortic valve to open.

Bleeding

There were no intraoperative or early postoperative bleedings. Later postoperatively, bleeding complications occurred in 3 patients after intensive anticoagulation and platelet inhibition were effective (Table 2). Patient 3 underwent a pericardiocentesis with placement of a pericardial tube for pericardial tamponade 11 days after device exchange. Five days later, a pericardial hematoma was removed through re sternotomy. Because of recurrent nose bleeding, the patient received a temporary nasal tamponade. In patient 5 a minithoracotomy was performed on POD 15 for bleeding in the left pleural cavity. On POD 35, pericardial and pleural drains were placed for effusion. In addition, the patient experienced recurrent episodes of nasopharyngeal bleeding that required several otorhinolaryngeal interventions. In patient 6 a hematoma of the device pocket was evacuated through re sternotomy on POD 13 and again on POD 17 for recurrence. All but 2 bleeding events occurred in patients 1 to 5 before the anticoagulation and platelet inhibition protocol was intensified.

Neurologic Events

Neurologic events occurred in 4 patients (Table 2). On POD 139, patient 4 experienced a transient episode of slurred vision resolving within 2 hours, which correlated with a small ischemic area in the left ventral thalamus on computed tomography. On POD 397, he experienced a visual field defect of the left lower quadrant on his left eye, which disappeared completely. Computed tomography revealed an ischemic zone in the area of the right posterior cerebral artery. In patient 5 a minor subarachnoidal bleeding around the left brainstem and left occipital lobe occurred on POD 157, which clinically correlated with diffuse headaches. On POD 226, he again experienced headaches and transient word-finding difficulties. Computed tomography showed

TABLE 3. Indices of hemolysis

Patient	PFH (mg/dL; normal, 0-8	LDH (U/L; normal, <240 U/L)
	mg/dL)	
1	10.2 ± 5.8 (3-31; 8)	685 ± 318 (192-1514; 575)
2	9.6 ± 5.4 (3-23; 7)	750 ± 309 (144-1442; 748)
3	14.1 ± 11.1 (4-61; 10)	940 ± 458 (306-2134; 760)
4	8.8 ± 4.1 (3-27; 8)	724 ± 280 (342-1897; 654)
5	11.2 ± 12.3 (2-77; 7)	648 ± 347 (165-1957; 553)
6	22.9 ± 28.0 (4-133; 11)	1396 ± 1233 (127-6320; 917)
7	8.0 ± 2.8 (3-16; 7)	430 ± 140 (227-1152; 411)
8	5.7 ± 2.1 (3-12; 6)	530 ± 135 (257-896; 536)
9	19.0 ± 32.7 (3-200; 9)	1132 ± 596 (349-3640; 928)

Data are presented as means ± SD (minimum-maximum; median) of the complete duration of support. PFH, Plasma free hemoglobin; LDH, lactate dehydrogenase.

ischemia of the left basal ganglia and a small anterior area of the right medial cerebral artery, as well as a small infarction with subsequent bleeding in the anterior region of the left medial cerebral artery. On POD 249, he had massive intracranial bleeding in the right hemisphere, which, despite all medical and neurosurgical measures, finally caused the patient’s death. Patient 6 complained of headaches on POD 250, correlating with a small ischemic infarction with subsequent hemorrhage in the left occipital lobe. Four weeks later, the bleeding was completely absorbed. On POD 50, patient 9 experienced intracranial bleeding in the right parieto-occipital area, causing headaches and hemianopia to the left. With resorption of the bleeding, the symptoms disappeared. On POD 284, he experienced a left thalamus infarction with subsequent right arm paresis. Clinical symptoms disappeared almost completely over time. On POD 355, he experienced bilateral amaurosis, corresponding with a right thalamus infarction and an ischemic zone in the posterior area of the left medial cerebral artery. Until transplantation, cortical blindness improved gradually. In total, patients 1 to 5 had 5 neurologic events. Under intensified anticoagulation and platelet inhibition, patients 6 to 9 experienced 4 neurologic events. In one patient (patient 9) the activity level was markedly reduced by neurologic symptoms (arm paresis and cortical blindness).

Pump Exchange and Thrombolysis

Because of suspected thrombus formation in the pump causing flow decrease of less than 1 L/min with severe compromise of hemodynamics, limiting activity level to bed rest, the pump was exchanged in patient 1 on POD 172, in patient 2 on POD 138, in patient 3 on POD 78, and in patient 4 on POD 290 (Table 2). Thrombus formation was found in the rear and front hub, around the bearing, and in the inflow cannula. Operations went uneventfully, and later, all patients underwent successful transplantation. With our increasing experience, we performed recombinant tissue

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Figure 2. *Left panel* (patient 2): hemolysis indicating thrombus formation. After device exchange, cessation of hemolysis was seen. *Right panel* (patient 7): no clinically relevant hemolysis at any time during support. Data are presented as means $\pm$ SD of a 1-month period after implantation. LDH, Lactate dehydrogenase; PFH, plasma free hemoglobin.

plasminogen activator lysis when such situations occurred (Table 2). In all cases normal pump function could be restored. Thrombolysis was not associated with adverse events. In patient 6 thrombolysis was applied on POD 296 and in patient 9 on POD 261. In patient 3 thrombolysis was performed on days 29, 116, and 179 after the pump was exchanged and in patient 4 on day 140 after pump exchange. In total, patients 1 to 5 experienced 8 events requiring pump exchange or thrombolysis, whereas in patients 6 to 9 only 2 such events occurred under intensified anticoagulation and platelet inhibition.

Hemolysis

All patients showed laboratory signs of hemolysis, as indicated by plasma free hemoglobin (PFH) and lactate dehydrogenase (LDH). In general, baseline levels of LDH were continuously increased 2- to 3-fold above the normal range, and PFH levels were between the upper normal limit and a 2-fold increase (Table 3). These increases of laboratory parameters were not associated with clinical events. Simultaneous increases of LDH and PFH to greater than these levels suggested thrombus formation associated with the pump. Some of these incidents led to device malfunction (Figure 2). There were some patients without any such increases (Figure 2). Two patients (patients 6 and 9) had jaundice after excessive increase of PFH (>100 mg/dL) and LDH (>3000 U/L). In all other patients, increases of PFH and LDH to greater than baseline values were not correlated with clinical signs of hemolysis nor did they require blood transfusion. Modification of the anticoagulation and platelet inhibition protocol did not seem to have an effect on hemolysis.

Infection

On POD 105, patient 7 presented with secretion from the driveline exit site and a small skin defect over the subcutaneous driveline channel. This resulted from mechanical irritation after the patient had pursued his hobby of fishing for several days. After antibiotic treatment, the secretion stopped, and skin ulceration healed (Table 2).

Long-Term Organ Function

Kidney function recovered in patients who were in acute renal failure preoperatively and stayed within normal limits until the end of support (Figure 3, patient 2). In patients without renal compromise at implantation, normal kidney function was maintained until transplantation (Figure 3, patient 3). After initial renal recovery, patient 5 experienced renal dysfunction in the scenario of prolonged multiorgan failure, despite sufficient pump flows of 4.5 to 7 L/min (Figure 3, patient 5). Preoperatively compromised liver function recovered within days after the operation and remained normal until termination of support (Figure 4).

Discussion

Our experience with the DeBakey VAD indicates that it is capable of providing adequate circulatory support in patients with severe heart failure. In the early postoperative phase, the normalization of lactate, as well as kidney and liver parameters demonstrates that the pump rapidly restores normal peripheral circulation and end-organ perfusion, even in patients with severely compromised preoperative hemodynamics. In the long term, normal function of peripheral organs is maintained for periods of more than 1 year. Patients can be discharged from the hospital, as has been

Figure 3. Renal function during support with the DeBakey VAD, as indicated by serum creatinine (day 0 = implantation). *Above* (patient 2): recovery of preoperative renal failure. *Middle* (patient 3): maintenance of normal renal function. *Below* (patient 5): after initial renal recovery, progressive renal failure occurred in the scenario of multiorgan failure.

practiced with patients receiving pulsatile LVADs.¹¹ This clinical experience contradicts the hypothesis that a pulsatile blood pressure profile is necessary to keep adequate peripheral perfusion in human subjects and confirms experimental studies that demonstrated tolerance of nonpulsatile blood flow in animals.¹² However, true nonpulsatile flow exists only in the initial phase. Within days, pulsatility returns to a variable extent in all patients induced by the recovering left ventricle, which transmits pulse waves through the pump.¹³ This phenomenon might contribute to the remarkable long-term tolerance of continuous flow. The pump has also shown its capability for long-term support of

Figure 4. Recovery of preoperatively compromised liver function, as indicated by serum bilirubin, after implantation of the DeBakey VAD (= day 0).

more than 1 year and thereby qualifies as a device for bridge to transplantation. Thus it can compete with pulsatile pumps that demonstrated their long-term durability repeatedly.^{14,15} Moreover, because of the small size and the low noise, the device provides good comfort and quality of life for the patient. This is of particular advantage in long-term assistance. One might argue that the required pump exchange in 4 patients indicates limited reliability and durability of the DeBakey VAD. These events, however, are attributed to the learning curve in our early patients. After it was realized that anticoagulation and platelet inhibition needed to be more intense than in patients with pulsatile devices and that thrombus formation could be managed with thrombolysis, all pumps were running for more than 250 days without the need for exchange.¹⁰ The intensification of anticoagulation and platelet inhibition resulted in a decrease of thrombotic events associated with the pump. Similar experiences with pump thrombus were made by other investigators who also approached the problem with pump exchange, thrombolysis, or outflow graft ligation.¹⁶⁻¹⁸ Embolic events occurred in the late course after 100 days of support and were

associated mainly with headaches, transient vision disturbances, and word-finding difficulties. Neurologic symptoms, such as arm paresis and cortical blindness, resulted in a reduction of the patient's activity level only in one patient. This was in the patient with heparin-induced thrombocytopenia, which might have contributed to its cause. Other ischemic occurrences, such as gastrointestinal ischemia, which is known to occur in patients with pulsatile devices, did not happen. In contrast to currently approved pulsatile devices, the rate of thromboembolic events appeared to be higher. In particular, the device cannot compete with the low frequency of embolic episodes in pulsatile pumps with textured inner surfaces (HeartMate), as seen in the REMATCH trial.^{5,19-21} However, the severity and extent of neurologic dysfunction was limited in most cases, perhaps because of the small size of particles being ejected from the pump.

There were no bleeding complications in the initial postoperative period, which is attributed to the small size of the pump requiring only limited dissection, little pump pockets, and short operation times. Bleeding episodes, however, occurred in the later course because of intense anticoagulation and platelet inhibition. Although chest and nose bleeds, as well as most intracranial bleeds, being small in size, did not affect patient outcome unfavorably, a fatal intracranial bleeding event caused the death of a patient, most likely resulting from the intense anticoagulation and triple platelet inhibition.

The bleeding events together with the thrombotic and embolic episodes emphasize the most important and as yet unsolved problem of how to manage anticoagulation and platelet inhibition in patients on axial-flow pumps. Various protocols were applied by using varying dosages of anticoagulation and platelet inhibition,¹⁶⁻¹⁸ but none of those approaches reduced thrombotic and bleeding events to a satisfying extent. This might be explained, at least in part, by the damage to blood cells, in particular platelets, by the fast rotating impeller of the axial-flow pump, which has not been seen to this extent in patients with pulsatile LVADs.²² Strategies are needed to reduce blood activation by such impeller pumps and establish efficient therapy for platelet inhibition. Specific monitoring of platelet inhibition seems to be required to adjust antiplatelet therapy individually. This was not feasible in our patients and might be considered a limitation of the study. However, the experience obtained here prompted us to establish such methods for guidance of antiaggregation therapy in future patients receiving mechanical circulatory support. In addition, improvement of pump technology and mechanics is needed to reduce its thrombogenicity.

Injury of blood corpuscles by the pump also caused a certain extent of hemolysis throughout the duration of support. Most of the time, this was clinically irrelevant. In-

creases in hemolysis indicated thrombus formation associated with the pump. Varying amounts of hemolysis were also reported by other groups.¹⁶⁻¹⁸ Similar to our experience, they also found hemolysis to be correlated with thrombus formation.¹⁷ Thus reducing the incidence of thrombus formation will also decrease the extent of hemolysis.

Although the series of patients is small, it seems that the device is associated with a low incidence of infection. Similar findings were described by other investigators of patients with axial-flow pumps.^{16-18,23} This advantage becomes even more evident if one considers the long cumulative support time of several years in our patients. Moreover, the reported infection might not have occurred without provocation by means of mechanical irritation. The low rate of infection appears to be due to the small size of the pump resting motionless in the pocket and the flexibility of the percutaneous cable.

In summary, the DeBakey VAD has been shown to provide adequate circulatory support to bridge patients over the long-term to heart transplantation. Compatibility of continuous blood flow with sufficient tissue perfusion and overall maintenance of life could be demonstrated. The new dimension of patient comfort grants improved quality of life. Its advantages are contrasted by thrombotic events associated with the pump. New strategies in managing anticoagulation and platelet inhibition and improvement of pump technology are needed to overcome these shortcomings.

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