First Human Use of the Hemopump, a Catheter-Mounted Ventricular Assist Device

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The Hemopump, a catheter-mounted, temporary ventricular assist device, consists of an external electromechanical drive console and a disposable, intraarterial axial-flow pump (21F). Power is transmitted percutaneously to the pump by a flexible drive shaft within the catheter. The device is positioned in the left ventricle by way of the femoral artery approach or through the ascending aorta. Blood is drawn from the left ventricle through the transvalvular inlet cannula and pumped into the aorta. As of December 1988, the Hemopump had successfully supported the circulation of 7 patients (5 men, 2 women) ranging in age from 44 to 72 years (mean age, 59 years) and suffering from cardiogenic shock (cardiac index <2.0 L/min/m^2). Indications for use included failure to be weaned from cardiopulmonary bypass in 4 patients, acute myocardial infarction in 1, severe cardiac allograft rejection in 1, and donor heart failure in 1. Duration of support ranged from 26 to 113 hours (mean, 66 hours). Although 5 patients demonstrated transient hemolysis, none experienced infection, thrombosis, or vascular injury. Hemodynamic variables improved in all patients during support by the device. As of December 1988, 5 of the 7 patients were alive more than 30 days after support had been discontinued, and 3 of these patients were discharged from the hospital. On the basis of our initial clinical results, the Hemopump, which does not require a major surgical procedure for insertion, provides effective, temporary circulatory support in patients with potentially reversible cardiac failure.

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In 1964 DeBakey [1] was first to insert a mechanical cardiac assist pump in a procedure that required an open chest operation. The clinical application of the intraaortic balloon pump by Kantrowitz [2] in 1967 simplified the implementation of mechanical assistance, and its widespread use since then has shown that ventricular recovery can be achieved in many instances of postcardiotomy or postmyocardial infarction ventricular compromise. In 1975 Norman and associates [3, 4] introduced an abdominal left ventricular assist device that was used only in patients who suffered total loss of ventricular function after an open heart operation. Ventricular function invariably improved in patients who survived 48 hours of support; however, patients did not recover because of complications related to the major operative procedure required to implant the device. The results of left ventricular support are expected to improve with one of the most recent assist devices developed, the Hemopump (Nimbus Medical, Inc, Rancho Cordova, CA) [5], an intraarterial transvalvular axial flow pump that is undergoing initial clinical trials. This device supplements left ventricular function, providing blood flows of 3.5 to 4.0 L/min, markedly decreasing ventricular work while supplying the basic circulatory requirements of the body at rest. The pump can be implanted with a minimal operative procedure [6] and has had few complications associated with its use. In this report, we review our initial clinical experience with the Hemopump.

Material and Methods

From April 23 to December 31, 1988, 7 patients with cardiogenic shock (cardiac index <2.0 L/min/m^2) were treated with the Hemopump. These patients included 5 men and 2 women, whose ages ranged from 44 to 72 years (mean age, 59 years). Body surface area ranged from 1.68 to 2.13 m^2 (mean, 1.86 m^2). All patients were entered in the study according to the following specific guidelines:

Inclusion Criteria
- Pulmonary capillary wedge pressure >18 mm Hg
- Systolic aortic pressure <90 mm Hg or mean aortic pressure <60 mm Hg
- Cardiac index <2 L/min/m^2
- Failure of maximal drug and volume therapy

Exclusion Criteria
- Aortic valvular or aneurysmal disease
- Significant blood dyscrasia
- Approved cardiac transplant candidate
- Prosthetic aortic valve
- Aortoiliac occlusive disease

Informed consent was obtained in accordance with the guidelines of the Food and Drug Administration and the Institutional Review Board of the Texas Heart Institute/St. Luke's Episcopal Hospital. The specific indication for the use of the Hemopump in each patient is listed in Table 1,

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Table 1. Hemopump Patient Profiles

Patient Demographics					
Patient No.	Age (yr)	Sex	BSA (m^2)	Indications	Operative Procedures[a]
1	62	M	1.89	Severe cardiac allograft rejection	None
2	61	M	1.68	AMI	None
3	72	F	1.78	Failure to wean from CPB	Emergency reoperation, CAB × 3
4	50	M	1.92	Acute allograft failure, failure to wean from CPB	Orthotopic cardiac transplantation
5	44	F	1.76	Failure to wean from CPB	Emergency reoperation, CAB × 3 + LVA
6	66	M	1.88	Failure to wean from CPB	CAB × 3 + LVA + mitral valvoplasty
7	58	M	2.13	AMI, failure to wean from CPB	Emergency reoperation, CAB × 2

[a] Operations requiring CPB immediately before Hemopump implantation. [b] Less than 24 h before implantation. [c] IABP support not attempted. [d] Died of lymphoma after transplantation.

AMI = acute myocardial infarction; BSA = body surface area; CAB = coronary artery bypass; CPB = cardiopulmonary bypass; IABP = intraaortic balloon pump; LVA = left ventricular aneurysmectomy.

as is the status of the patient before pump implantation. The hemodynamic data for each patient at the time of implantation were as follows: patient 1 had a cardiac index of 1.85 L/min/m^2, and in patient 2 it was 1.96 L/min/m^2. Patients 3 through 7 could not be weaned from cardiopulmonary bypass and had no measurable cardiac output. Vasoactive drug therapy included intravenous infusions of epinephrine (7 patients), calcium chloride (6), dopamine (3), dobutamine (3), sodium bicarbonate (4), and other agents (4). All patients received some combination of at least three and as many as five of these agents.

Description of the Hemopump

The Hemopump consists of three basic elements: a pump assembly, a high-speed motor, and a control console. The disposable pump assembly (Fig 1) integrates all blood-contacting surfaces into a single system. The inlet cannula, which is made of flexible silicone rubber, measures 20 cm in length and 7 mm in diameter. It is reinforced with a helical spring to prevent kinking and has a beveled, radiopaque tip to facilitate placement across the aortic valve (Fig 2). The inlet cannula is connected directly to the blood pump housing, which has an outer diameter of 7 mm (21F) and is made of highly polished, thromboresistant stainless steel, as is the pump impeller. Power to the axial flow pump, located within the housing, is transmitted by a flexible drive shaft enclosed in a 9F polymeric sheath. The external end of the drive shaft is connected to an external reusable high-speed motor. When the device is activated, the pump impeller, which spins at 15,000 (pump speed 1) to 27,000 (pump speed 7) rpm, provides unidirectional, nonpulsatile flow. Blood is thus drawn from the left ventricle and propelled by the pump into the aorta. Maximum flow through the pump approaches 4 L/min and is primarily related to two variables: (1) external resistance to flow, ie, afterload or systemic vascular resistance, and (2) the inlet cannula position within the left ventricular cavity.

Also enclosed in the drive shaft sheath is a purge fluid system that uses 40% dextrose in water. This fluid lubricates the drive shaft and the hydrodynamic bearings, which support the rotating elements of the blood pump. Because of the high pressure of the purge fluid, generated by a roller pump on the console, flow across the drive shaft seal is outward. Thus, the purge fluid flow prevents the entry of blood into the drive mechanism. Because the purge fluid flow rate is low (approximately 200 mL/day) and because only a portion of the purge fluid flows across the seal into the systemic circulation, its effect on the intravascular volume is considered negligible.

The control console (Fig 3) powers and regulates the blood pump and the roller pump in the purge fluid system. Fail-safe mechanisms necessary for clinical use are also provided. These include warning signals for external alternating current power loss (an internal battery provides 30 minutes portable operation) and abnormal changes in motor current and purge pressure. To facilitate pump weaning, the console provides seven graded pump speeds, as well as visual display of calculated pump flow. This flow is calculated as a function of pump speed and mean aortic pressure. For example, at a pump speed of 7 (27,000 rpm) and a mean aortic pressure of 50 mm Hg, calculated pump flow is 4 L/min. The console, which weighs approximately 11.4 kg, can be easily carried or mounted on a rolling stand.

Methods of Implantation

The Hemopump was implanted through the femoral artery in 4 patients and through the ascending aorta in 3. The techniques have been described in detail [6]. After the pump has been inserted and the patient has been transferred to the intensive care unit, the position of the device is once again confirmed radiographically (Fig 4).

Anticoagulative Therapy

Heparin was administered intravenously to maintain an activated clotting time of 1.5 to 2 times control. If the patient had postoperative blood loss or coagulopathy, anticoagulative therapy was withheld until hemostasis was achieved.

Table 1. Continued

Status Before Implantation					Status After Implantation	
Duration of Shock (h)	Failed IABP	Acute Renal Failure	Cardiac Arrest[b]	Weaned From Hemopump	Survived (≥30 days)	Discharged
24	No[c]	Yes	No	Yes	Yes	Yes
24	Yes	Yes	Yes	No	No	No
12	No[c]	No	No	Yes	Yes	Yes
2	No[c]	Yes	Yes	Yes	Yes	No[d]
2	Yes	Yes	No	Yes	No	No
1	Yes	No	No	Yes	Yes	Yes
1	Yes	No	No	Yes	Yes	No

Hemodynamic Monitoring and Management

All patients were monitored with continuous electrocardiographic tracings, radial arterial lines, and pulmonary artery catheters. Cardiac output determinations were made using standard thermodilution techniques. All attempts were made to provide optimal pump flow, including maintaining adequate intravascular volume and left ventricular filling pressures and reducing systemic vascular resistance to the range of 600 to 800 dynes · s · cm^{-5}, primarily through a continuous intravenous sodium nitroprusside infusion. Additionally, the use of inotropic agents was minimized.

Hematologic Studies

All patients were carefully monitored for rheologic abnormalities using serial determinations of plasma free hemoglobin and serum haptoglobin levels, fibrin split products, fibrinogen levels, and platelet and hemoglobin levels. Peripheral blood smears were also routinely examined for evidence of hemolysis.

Device Weaning and Removal

Once the patient's heart has adequately recovered, ie, when the cardiac index is greater than 2.2 L/min/m^2 with minimal inotropic support, pump speed is gradually reduced from speed 7 to speed 1. The pump is not stopped until immediately before removal. Heparin is not reversed. The device is removed by way of the graft, after which the cannulation site is inspected for evidence of endothelial damage or thrombus formation. The arteriotomy/aortotomy is then repaired using a continuous polypropylene suture, and the remaining incision is closed in standard fashion.

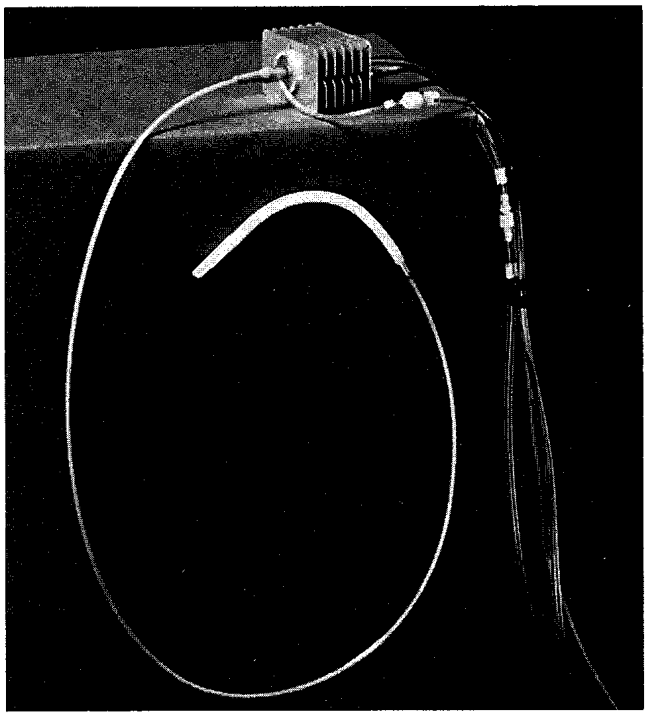

Fig 1. Disposable pump assembly consists of an inlet cannula, axial flow blood pump, flexible drive shaft enclosed in a polymeric sheath, and motor rotor.

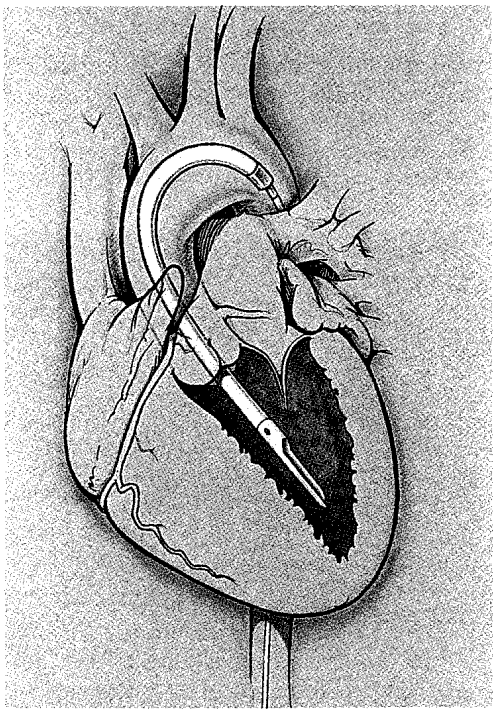

Fig 2. The beveled, radiopaque tip of the inlet cannula facilitates placement across the aortic valve.

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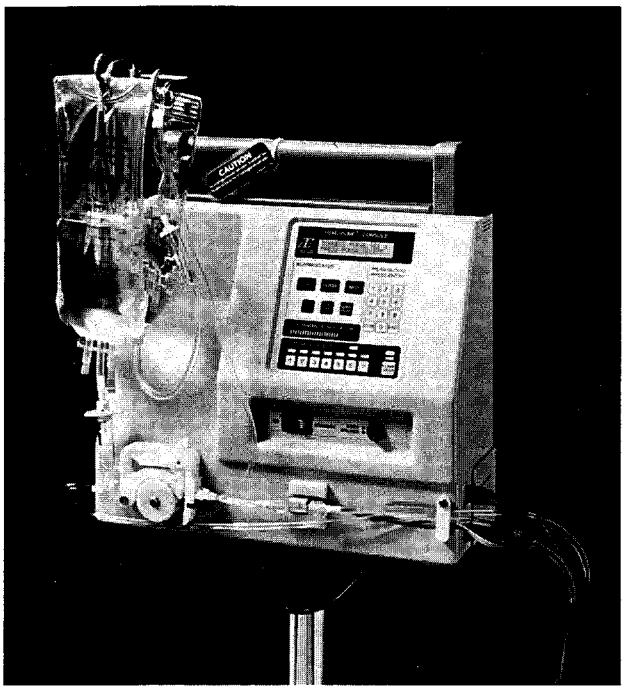

Fig 3. The control console, which provides power for the blood pump, also contains roller pumps for purge fluid delivery.

Results

The duration of Hemopump support ranged from 26 to 113 hours (mean, 66 hours). The operative time required for device implantation, including confirming the position of the pump by fluoroscopy, was approximately 15 minutes. All of the patients tolerated the implantation procedure well, and none experienced major surgical complications.

The hemodynamic status of each patient improved immediately on initiation of Hemopump support. The mean hemodynamic variables for all patients during the first 12 hours and during the last 12 hours of Hemopump support are shown in Table 2. The change in the vasoactive drug therapy of each patient during the course of Hemopump support included a decrease in inotropic drug therapy and an increase in afterload reduction therapy in 5 patients (Table 3). In 1 patient, vasoactive drug therapy remained fairly constant throughout the duration of Hemopump support. Increased inotropic support was required in only 1 patient (patient 3), although he also had increased afterload reduction therapy. Five of the 7 patients were alive more than 30 days after device insertion. Three of these patients have been discharged from the hospital and have returned to their normal activities. Neither of the 2 patients who died within 30 days of insertion were being supported by the device at the time of death. One patient was found to have irreversible biventricular failure and died four hours after the device was electively removed. A second patient, who had remained hemodynamically stable for two days after device removal, died unexpectedly of sudden cardiac arrhythmia.

Complications directly related to the use of this device were minimal. In 2 patients, the pump inlet cannula was ejected by the heart from the left ventricle; however, the cannula was easily repositioned at the bedside in both instances with no observed adverse effect. The drive shaft fractured in four cases, and pump support was terminated. In all cases, the fracture was contained within the central core of the drive shaft sheath. After removal of the device, all 4 patients remained hemodynamically stable. No clinical evidence of valvular damage or vascular injury was present, and no patients experienced thromboembolic episodes or infection. Device-related bleeding episodes resulting from anticoagulative therapy were dif-

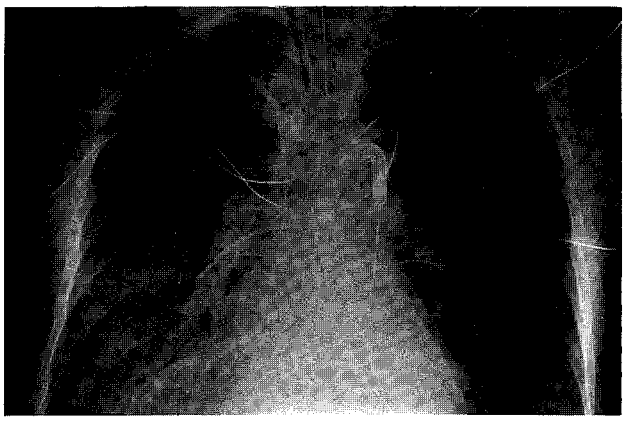

Fig 4. Roentgenogram of Hemopump placed by way of the femoral approach, revealing placement of the inlet cannula within the left ventricle and the pump in the descending thoracic aorta. When the aortic approach is used, the pump resides in the ascending aorta.

Table 2. Hemodynamic Variables During Hemopump Support

Variable	Initial 12 h[a]	Final 12 h[a]
Cardiac index (L/min/m^2)	1.73 ± 0.59	2.77 ± 0.36
Mean aortic pressure (mm Hg)	59 ± 13	69 ± 10
Mean pulmonary capillary wedge pressure (mm Hg)	17 ± 5	14 ± 4
Urine output (mL/h)	18 ± 21	74 ± 48

[a] Values represent mean ± standard deviation.

Table 3. Changes in Inotropic and Afterload Reduction Therapy During Hemopump Support

Patient No.	Inotropic Therapy	Afterload Reduction Therapy
1	Decrease	Increase
2	Decrease	Increase
3	Increase	Increase
4	No change	No change
5	Decrease	Increase
6	Decrease	Increase
7	Decrease	Increase

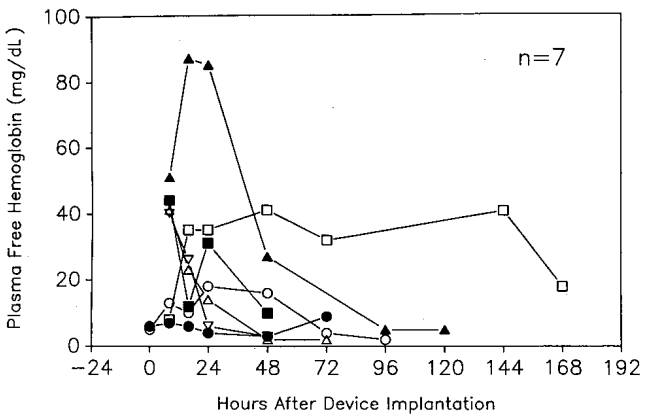

Fig 5. Plasma free hemoglobin levels in the 7 patients supported with the Hemopump.

ficult to distinguish from bleeding resulting from other causes, eg, prolonged cardiopulmonary bypass times in some surgical patients. In none of the patients did bleeding at the insertion site develop.

Hemolysis, as indicated by serial determinations of plasma free hemoglobin levels, was present in mild to moderate degrees in 5 patients during Hemopump support (Fig 5). Plasma free hemoglobin levels remained within normal limits (<10 mg/dL) throughout the course of Hemopump support in 2 patients. In all but 1 patient, plasma free hemoglobin levels returned to normal within 24 hours after device removal.

Comment

Our initial clinical experience with the Hemopump, a new left ventricular support system, has been encouraging. This system can be rapidly and safely implemented, and the circulatory support provided can be effective in allowing the ventricle to rest and potentially to recover.

Over the last decade, the ability to reverse some of the effects of acute heart failure using various cardiac assist devices has been shown [7, 8]. Because the implantation of many of these devices has required a major operative procedure in patients whose conditions are already severely compromised, survival has been adversely affected. For example, the common surgical problems of bleeding and infection are exacerbated by the need for prolonged cardiopulmonary bypass during device implantation.

Although less invasive support systems have been used, no device that can be implanted through the intraarterial approach has been as effective in supporting the circulation as the Hemopump [9, 10]. The intraaortic balloon pump only augments left ventricular function, whereas the Hemopump is capable of temporarily supplying circulatory requirements even in the total absence of effective left ventricular ejection (Table 1). In 4 of the 7 patients, intraaortic balloon pump support had been attempted and had failed. The hemodynamic status of all 7 patients improved quantitatively, and none died while being supported by the device. We believe that the patients' improvement was due specifically to the support provided by the Hemopump and subsequent ventricular recovery. All the patients had been in critical condition at the time of device implantation and had multiple risk factors for early operative mortality [11–13]. These risk factors included advanced age, emergency operation, complex operation, reoperation, multiple-vessel disease, acute renal failure, prolonged shock, and even prior cardiac arrest. Thus, the probability that any of these patients would have survived without some form of escalated mechanical circulatory support was minimal.

Optimal management of patients on the Hemopump is closely related to pump performance. Because the pump output varies inversely with mean aortic pressure, we have routinely employed intravenous infusion of sodium nitroprusside to maintain the mean aortic pressure at 50 to 60 mm Hg. At these pressures, pump flow typically ranges from 3.5 to 4.0 L/min. Concomitantly, such therapy minimizes native cardiac afterload and may thus effect cardiac recovery. Moreover, because the flow provided by the Hemopump appears adequate for the basic circulatory needs of most patients even without assistance from the heart, the requirement for catecholamine therapy is usually reduced. In this way, the adverse effects of prolonged, intense catecholamine therapy are avoided, and left ventricular recovery may be enhanced.

Device-related complications have been minimal. Evidence of hemolysis, which was a particular concern because of high pump speeds (maximum, 27,000 rpm), was minimal and occurred in 5 of the 7 patients. However, it should be noted that all of these patients had also undergone prolonged support with cardiopulmonary bypass, a well-documented cause of hemolysis. Thus, the extent to which hemolysis was due to the Hemopump remains uncertain. We are encouraged by the fact that in 2 patients in whom cardiopulmonary bypass was not used, plasma free hemoglobin levels remained within normal limits. This finding supports the results of our extensive preclinical animal studies, in which hemolysis specifically related to the Hemopump was inconsequential [5]. Bleeding specifically related to the Hemopump was not seen; the 2 patients in whom Hemopump implantation was the sole procedure performed did not experience bleeding. To correct the problem of drive shaft fracture, the inlet cannula has been lengthened from 20 to 26.7 cm. This modification allows the pump to be positioned in the descending thoracic aorta rather than in the aortic arch and eliminates severe bending of the drive shaft. No further drive shaft fractures have occurred. In confirmation of preclinical studies [5, 9, 10], transvalvular placement of the device did not cause aortic insufficiency or reduce coronary flow in this series of patients. Furthermore, injury to the aorta and the aortic valve, thromboembolic episodes, and infection were not evident.

A potential complication of this device, which we have not encountered, is the development of pump dependence beyond the current protocol limiting support to 14 days. If this were to occur, we would replace the initial Hemopump with either another Hemopump or another left ventricular support device [14, 15]. Right heart support is not currently available.

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Based on our early clinical experience, the Hemopump, with its small size, short insertion time, and minimal associated morbidity, is a useful tool in the treatment of patients with potentially reversible cardiac failure.

In the future, broader application of this device will be explored in settings such as cardiac catheterization laboratories or emergency rooms. Smaller versions of the Hemopump, designed for percutaneous insertion, are being developed and should further extend its application.

Addendum

Of the 5 patients who lived more than 30 days after Hemopump support, 1 died of lymphoma and 1 died of arrhythmia (2 months and 6 months, respectively, after device removal). The 3 patients who were discharged from the hospital were alive and well at follow-up in October 1989.

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