However, 50% (four of eight) of the patients requiring dialysis were weaned and discharged.

Although different cannulation techniques and cannulas were used with this series of patients, the authors think that the ideal cannula for either inflow or outflow remains to be found and that this improvement alone may make a great difference in overall survival.

We believe the successful use of the Sarns, or any other VAD, depends upon good patient selection, early recognition of a need for the device, straightforward insertion techniques, maximum cardiac support with the device, appropriate use of anticoagulation, and appropriate timing of weaning and removal. These results demonstrate that success with the Sarns VAD is equal to that of other available devices and warrants continued clinical use in necessary instances.

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Hemopump Ventricular Support for Patients Undergoing High Risk Coronary Angioplasty

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Prophylactic implantation of a Hemopump (Johnson and Johnson, Skillman, NJ) has been evaluated in nine patients selected for high risk coronary angioplasty. They were unstable patients, refractory to maximal pharmacology, with indications for revascularization, but contraindications for surgery such as low ejection fraction and lack of material for bypass. In all, the target lesion was located on the last patent vessel. The pump was inserted under local anesthesia, without any graft. A specially designed occluder permitted avoidance of retrograde bleeding during implantation. The bypass flow ranged from 2.5 to 3.2 L/min, and permitted a rise in cardiac index from 2.05 to 2.55 L/min/m², with a drop in capillary wedge pressure from 13 (7–18) to 10 (7–13) mmHg. During balloon inflation, no electrocardiographic changes were observed, because only minor ventricular arrhythmias occurred. No significant hemolysis was seen (plasma free hemoglobin < 10 mg/dl in all) after 2 hr of pumping. The only limitation of the technique appears to be difficulty at the time of implantation from narrow, stenosed, or tortuous iliofemoral arteries (3 patients). This experience strongly supports the benefit of temporary left ventricular Hemopump support in high-risk situations and clearly shows the need for a smaller pump. *ASAIO Transactions* 1990; 36: M623–M626.

A new approach to the management of extremely sick patients with unstable myocardial ischemia selected for coronary angioplasty has been proposed.[1] It is based on mechanical assistance of the left ventricle, obtained by means of intraventricular implantation of the Hemopump® (Johnson and Johnson Intervention Systems, Skilman, NJ). The prophylactic implantation of this new type of axial flow blood pump, before the coronary angioplasty itself, reduces the risk and consequences of cardiac arrest during the pro-

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cedure. The current report of the first nine cases performed at Henri-Mondor's Hospital clearly shows the benefit and limitations of the technique.

Materials and Methods

The whole approach is based on the Hemopump. This newly designed,[2] arterial pump is based on the Archimedes screw principle and consists of a 21 F inlet cannula **(Figure 1),** an axial flow blood pump, a drive cable contained in a polymer sheat, and a rotor. The pump head is in the 21 F cannula and is actuated by a rotating electromagnetic field. The spiral vanes of the pump head **(Figure 2),** which rotates at a very high speed (20,000–25,000 rpm), permit the displacement of blood from the tip of the cannula placed in the left ventricular cavity, to the outflow port of the cannula in the ascending or horizontal aorta. Flow rates may be adjusted from 0 to 3.5 L/min. Insertion of the cannula into the ventricle is made under fluoroscopic control by way of the femoral artery. The technique of implantation has been considerably simplified, when compared with that originally proposed.[2] Under local anesthesia, the common femoral artery is exposed. A guide wire is first passed into the left ventricle under fluoroscopic control. This facilitates the rapid positioning of the cannula into the ventricle through the aortic valve. The femoral artery is clamped around the entry of the guide wire, 5 cm upstream from the level of the arteriotomy to be performed. The cannula is then inserted into the femoral artery, until the orifice is in the vessel. The femoral artery is then unclamped and the cannula advanced into the aorta. Retrograde bleeding through the cannula is avoided by a specially designed silicone occluder in the outflow port of the cannula **(Figure 3),** which is removed as the drive cable is inserted. A few interrupted Prolene® sutures close the arteriotomy around the drive cable, and the tip of the cannula is positioned in the ventricle. The pump is actuated as soon as the tip of the cannula is in the ascending aorta.

Immediately before cannula insertion, a Swan Ganz catheter is placed in the pulmonary artery. Cardiac output is measured by a thermodilution technique. Routine hemodynamic indices are continuously monitored and computed. As the pump is actuated at maximal speed, the percutaneous transluminal coronary angioplasty is performed using the conventional technique. Inflation time is 3 min, at 4 ATA pressure, three times for each stenosis. Premedication includes aspirin (250 mg daily, starting 2 days preoperatively), and heparin (1 mg/kg at the time of implantation of the Hemopump), maintaining the clotting at twice the control level for 24 hr.

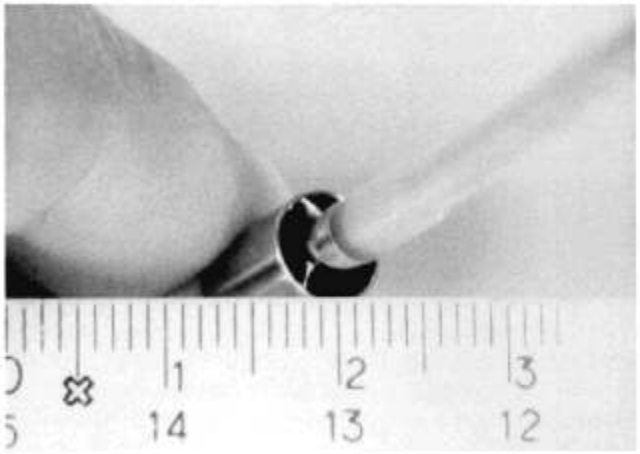

Figure 2. Outflow port of the ventricular cannula and the drive cable.

Clinical Experience

Criteria for inclusion in the protocol are as follows: evolving acute myocardial ischemia unresponsive to every medical therapy, related to significant stenosis, with patent distal run-off, in a patient who cannot undergo surgery or dilatation without a major operative risk.

Major surgical risks were advanced age > 75 years in two patients, ejection fraction below 20% in six patients, and

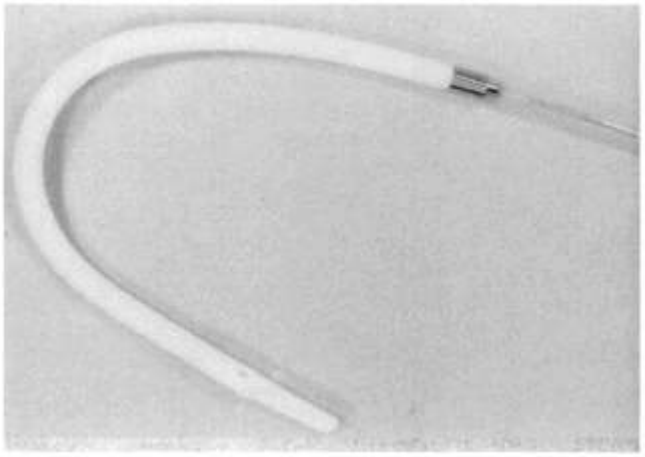

Figure 1. The 21 F Hemopump intraventricular cannula.

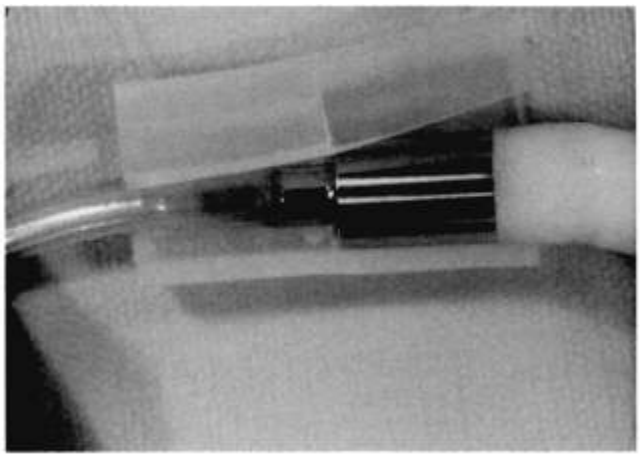

Figure 3. Homemade silicone occluder for the outflow port of the cannula, which prevents retrograde bleeding during implantation.

lack of any material available for bypass because of previous surgery in five patients. PTCA was considered a high-risk procedure because of uncontrolled, unstable myocardial ischemia in seven patients; ejection fraction below 20% in six patients; and, most importantly, the target lesion located on the last remaining patent vessel perfusing a major mass of viable myocardium. In three patients, the lesion was located on the left main artery, unprotected because of total occlusion of the right coronary artery.

The pump was successfully implanted in six patients. The size of the iliac artery in two patients, and an atherosclerotic stenosis in one patient, prevented insertion of the cannulae, but PTCA was nevertheless performed in one patient. The vessel was successfully reopened, but reocclusion occurred 5 min later, and the patient died despite new attempts at reperfusion. In the second patient, PTCA was not performed, and the patient died 2 weeks later of uncontrolled myocardial ischemia. The last patient underwent coronary artery bypass graft (CABG), as a compatible donor graft was available as a back-up. He actually benefited from CABG and could be successfully weaned from extracorporeal circulation. He is now symptom free after 6 months.

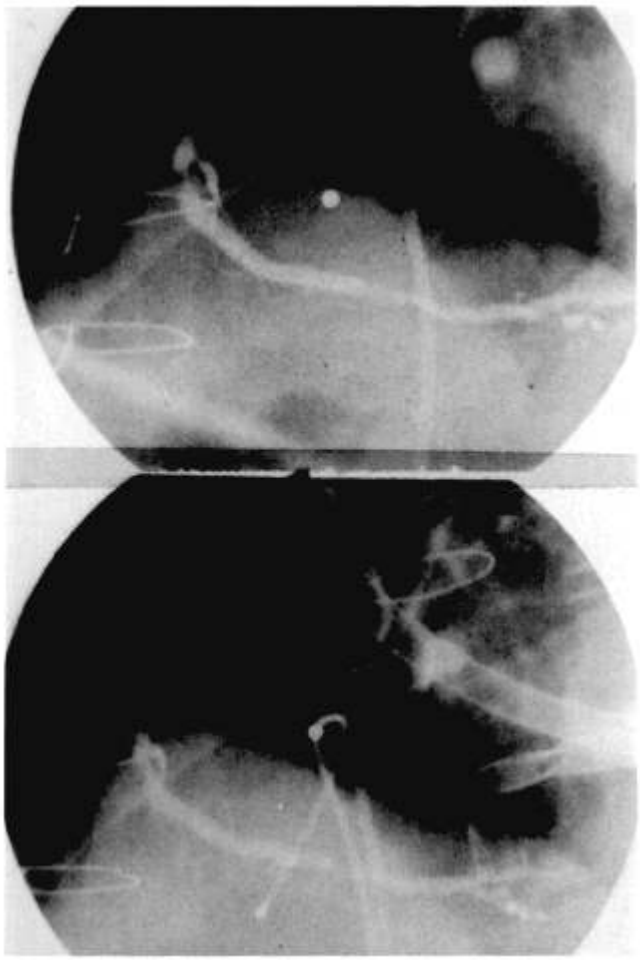

Figure 4. Pre- and post-percutaneous transluminal coronary angioplasty coronary angiograms of a right coronary subtotal occlusion in a patient with an occluded left main artery.

Table 1. Hemodynamic Changes During On/Off Maneuvers of the Hemopump

Patient	Pulmonary Capillary Wedge Pressure (mmHg) Off	Pulmonary Capillary Wedge Pressure (mmHg) On	Pump Flow (L/min)	CI* (L/min/m²) Off	CI* (L/min/m²) On
1	18	14	3.4	1.6	2.4
2	16	13	3.6	2.0	2.6
4	7	7	3.1	2.2	2.7
5	12	8	3.2	2.4	2.5
6	19	15	3.1	2.6	2.8

* Cardiac index (CI) assessed by thermodilution.

In the six other patients, dilatation was uneventful **(Figure 4).** During PTCA with native ventricular pumping, hemodynamic changes have been observed **(Table 1)** showing definite improvement in left ventricular function. Pump flow ranged from 3.1 to 3.4 L/min, and cardiac index increased by an average of 25% as the pump was actuated. Capillary wedge pressure dropped by 19%. The most striking observation was the lack of any clinical deterioration during balloon inflation in the last remaining patent vessel. Nevertheless, ECG monitoring revealed a prolonged atrioventricular block in one patient and ventricular tachycardia in three patients, with spontaneous return to normal sinus rhythm within a few minutes **(Figure 5).** No significant hemolysis was seen (plasma free hemoglobin < 10 mg/dl).

Five patients are currently under medical therapy and symptom free 5 to 15 months after following the episode of acute ischemia and PTCA. One patient, however, underwent subsequent elective surgical revascularization for class IV chronic angina pectoris, and is now also symptom free.

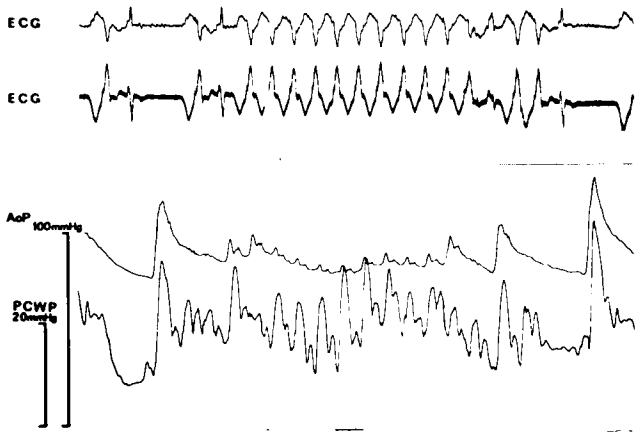

Figure 5. ECG, aortic pressure, and pulmonary capillary pressure during percutaneous transluminal coronary angioplasty, showing the circulatory support performed by the Hemopump during ventricular tachycardia.

Discussion

The current clinical experience clearly supports the concept of prophylactic noninvasive mechanical ventricular assistance for patients selected for high-risk PTCA. Simplicity, safety, and efficacy of the method based on the Hemopump is now well documented. Simplicity of implantation is emphasized by the current experience and is probably due to the fact that it was performed by cardiovascular surgeons used to rapid surgical exposure. The technique of cannula insertion has also been considerably simplified by our homemade silicone occluder. This device, which prevents retrograde bleeding during implantation, allows one to avoid implantation through a prosthetic graft sutured end to side to the iliac or femoral artery.[2]

Our approach differs from other approaches based on more invasive methods of ventricular support, such as systems using extracorporeal venoarterial shunting. These systems require full heparinization of the patient, sophisticated equipment, and trained pump technicians. Furthermore, they induce, as with all extracorporeal circulation, such deleterious effects as complement activation, thrombocytopenia, and bleeding.

The cause of reduction in risk during PTCA is probably complex. The most significant changes induced by Hemopump use are probably the drop in left ventricular dimensions, and external work. This leads to a drop in myocardial energy requirement, which is clinically helpful during balloon inflation. A second mechanism may be found in the improvement in perfusion through the nonoccluded vessels, although this is most likely minimal.

Introduction of the Hemopump into intensive care units will change the strategies used in the most critically ill patients. It should permit very early decompression of the left ventricle in massive myocardial infarction, with consequent increased chance of recovery of ischemic, noninfarcted areas. A reduction in the need for urgent cardiac replacement or invasive methods of support to the failing heart should also be seen. Further improvements in technology will facilitate these therapeutic changes, mainly by development of a percutaneous technique for implantation, and a more powerful device in term of outflow.

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Improved Survival After Hemopump Insertion in Patients Experiencing Postcardiotomy Cardiogenic Shock During Cardiopulmonary Bypass

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Immediate placement of a Hemopump® (HP) ventricular assist device was undertaken in nine patients (seven men, two women) after other attempts at weaning from cardiopulmonary bypass (CPB) after coronary bypass surgery had failed. All nine patients (100%) were successfully weaned from CPB, and six (63.3%) gradually improved enough to permit removal of HP support. Five (83.3%) of the six who were weaned from CPB survived beyond hospital discharge. HP support was evaluated in terms of vital organ function, incidence of complications, and clinical outcome. In both survivors (S) and nonsurvivors (NS), serial hemodynamic measurements were taken. Although there were few differences in hemodynamic parameters between groups at 4 hr, by 24 hr the S group had markedly improved cardiac index, Glasgow Coma Scale, urinary output, and pulse pressure and required far less inotropic support than did the NS group. All four patients who required high dose inotropic agents to maintain acceptable end-organ perfusion on HP support died; three were unable to tolerate weaning from the HP, and all died within 72 hr of surgery because of ineffective myocardial recovery. None of the survivors required additional early inotropic augmentation. Renal perfusion appeared to be well maintained, even with mean arterial pressures below 60 mmHg during HP sup-

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