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PRECLINICAL STUDIES

An Expandable Percutaneous Catheter Pump for Left Ventricular Support

Proof of Concept

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OBJECTIVES We sought to evaluate the performance of a newly designed percutaneous catheter with expandable pump.

BACKGROUND The device was designed as a percutaneously insertable temporary support system for patients with acute left ventricular failure.

METHODS The pump catheter (introduction diameter 9-F) is positioned in the left ventricle. The rotor is driven by an external motor through a flexible drive shaft. A model circuit was used to assess pump performance, hemolysis tests, and particle image velocimetry. The feasibility of the catheter placement and pump operation were examined in 12 anesthetized sheep. Cardiogenic shock was induced in seven of the animals. Cardiac output (CO) and mean aortic blood pressure (MAP) were recorded before and during shock, and during catheter pump action.

RESULTS The catheter pump delivered a flow of 4.1 l/min at a differential pressure of 60 mm Hg. The average modified index of hemolysis was 11.6 (optimum, 1.8). Fluoroscopically and echocardiographically guided in vivo placement and deployment of the device were quick and uncomplicated. Under simulation of acute left ventricular failure (CO 43 ± 22% and MAP 55 ± 16% of the baseline value), the catheter pump significantly improved CO to 67 ± 12% and MAP to 74 ± 18%. Maximum in vivo duration of operation was 6 h (average, 3.1 ± 1.4 h). These animal studies revealed: 1) no significant hemolysis (average plasma-free hemoglobin 26 ± 4 mg/l after 3 h); 2) no thrombotic deposits at rotor or pump housing; and 3) no damage to the endocardium or aortic valve.

CONCLUSIONS A percutaneously insertable, expandable catheter pump is technically and clinically feasible. Our first experimental results are encouraging. (J Am Coll Cardiol 2005;45:1856–61)

Mortality rates resulting from cardiogenic shock, which is the state of inadequate tissue perfusion resulting from acute myocardial infarction, and other causes of heart failure remain in the 50% to 80% range, despite coronary interventions (1). During the past two to three decades, no significant change in the incidence of cardiogenic shock as a complication of acute myocardial infarction has been observed (2). However, patients selected to receive early revascularization with percutaneous transluminal coronary angioplasty or coronary bypass grafting during this time had lower in-hospital mortality rates than those not selected (3). The rate of mortality of the critically ill with acute left ventricular failure is mainly due to multiple organ failure caused by inadequate tissue oxygenation.

Temporary left ventricular support may increase myocardial oxygen supply and improve oxygen delivery to dependent organ systems, thereby preventing multiple organ dysfunction and subsequent death. A non-surgical, percutaneously implantable device may save time and resources because it could be managed by interventional cardiologists while executing percutaneous coronary intervention. The purpose of this project was the development and initial experimental evaluation of a percutaneously insertable blood pump for temporary left ventricular support.

MATERIALS AND METHODS

Percutaneous catheter pump. The expandable pump unit is located at the tip of the catheter and consists of an expandable rotor, concentrically located within an expandable housing. Both of these components are made of the shape memory alloy (Nitinol, Euroflex, Pforzheim, Germany). The middle segment of the housing, between inflow and outflow tracts, has a polyurethane coating that extends to the catheter shaft as a tubing with outlet slits (Fig. 1). The rotor is connected to a flexible shaft, driven by an external motor unit with a rotation speed of 32,000 rpm. The device is introduced via the percutaneous femoral arterial route. A 9-F delivery sheath is placed with its tip in the left ventricle, and the device is pushed through the

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Abbreviations and Acronyms

CO = cardiac output
MAP = mean aortic blood pressure
MIH = modified index of hemolysis
PFH = plasma-free hemoglobin
TEE = transesophageal echocardiography

sheath. Consecutively, the compressed pump unit, at the catheter tip, is released by partial withdrawal of the sheath. The correct positioning of the pump unit is assisted by a fluoroscopic or transesophageal echocardiography (TEE) guidance. The inflow tract of the pump unit and the expanded pump housing (diameter, 6.5 mm) are placed within the left ventricle, the outlet tubing in a transvalvular aortic position, and the outflow tract (tubing slits) in the ascending aorta (Fig. 2). Before its removal, the pump unit is compressed by withdrawing it back into the sheath. The sheath with the pump unit is removed, and the puncture site closed via manual compression.

Hydraulic and hemolysis bench test. The catheter pump was evaluated using bench tests for compressibility and expandability of the pump unit, pump performance, and hemolysis. It was delivered via a 9-F sheath into a flow model. Within the test loop, the device was operated at different rotation speeds to determine the flow-differential pressure relationship and the hemolysis rate. Hemolysis was determined by the modified index of hemolysis (MIH), which represents the ratio of red blood cells destroyed during passage through the pump to the total number of red blood cells in the system, according to the American Society for Testing and Materials regulations (4).

In vitro flow field studies. To assess the flow condition of the pump (stall, vorticity, backflow) tests were performed using particle image velocimetry in a translucent test circuit (Fig. 3). The rotor was positioned along the center line of a transparent pump housing. The central part of the flow channel had an inner diameter of 6 mm and a divergent nozzle at the downstream end to simulate outflow conditions at the downstream end of the catheter. To reduce flow disturbances upstream, a flow straightener and a contraction nozzle were placed in the inflow chamber. A water-glycerine mixture of 30% vol glycerine was used as a test fluid with a viscosity of 3.6 cP (similar to human blood at 37°C). A thin laser sheet was focused in axial planes, which crossed the rotor blade at different angles during rotation. Small fluorescent tracer particles were added to the fluid and recorded in the light sheet with a digital double-shutter camera (PCO Optics, Munich, Germany). The motion of the tracer particles was frozen by a double-pulse of the laser onto two separate images of the camera and digitally processed with cross-correlation methods to obtain the vector field of velocity distribution.

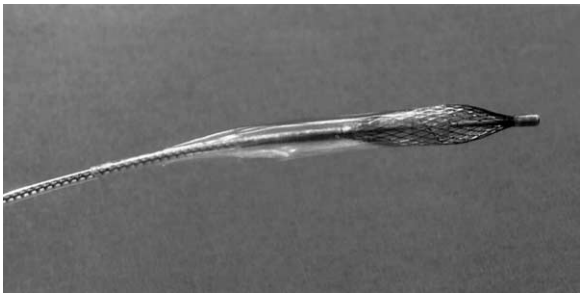

Figure 1. Catheter pump with expanded pump housing (expanded diameter, 6.5 mm; introduction diameter, 9-F).

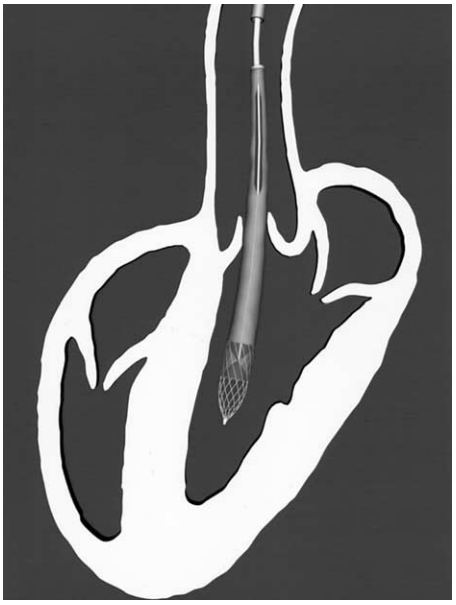

Figure 2. Schematic drawing of catheter pump position: expanded pump housing with inlet tip within the left ventricle, outlet tubing with the outlet slits in the aortic root. The **dark shadow** within the pump body indicates the position of the impeller.

Animal trials. The catheter pump was tested in 12 sheep (average body weight 73 kg). Approval for the study was obtained from the regional council in accordance with the German Animal Welfare Act. The animals were premedicated with natriumpentobarbital (20 to 30 mg/kg intravenously), intubated, and mechanically ventilated (isofluorane 0.5 to 1.5%, supplemented with oxygen and N_2O). Surface electrocardiographic leads were attached, and a gastric tube inserted. All investigations were performed with the animals in a supine position.

In 5 of the 12 sheep, pump delivery, deployment, and operation, as well as the resulting hemolysis were tested. In seven of the animals, a 4-mm balloon catheter was placed in the left anterior descending coronary artery and inflated to induce myocardial infarction (Fig. 4). For measurement of cardiac output (CO), a Swan-Ganz catheter (131F7, Edwards Lifesciences, Irvine, California) was inserted into the pulmonary arteries. Measurements were performed in triplicate using ice-cold saline solution. Successful implementation of acute cardiac insufficiency was confirmed by a subsequent reduction of CO.