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The PUCA Pump: A Left Ventricular Assist Device

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Abstract: Left ventricular assist devices (LVADs) that are being used clinically still have specific drawbacks. Therefore, a new concept for mechanical circulatory support was developed, the pulsatile catheter (PUCA) pump. It consists of an extracorporeally placed, pneumatically driven membrane pump that is connected to a valved catheter. The catheter is introduced into an easily accessible artery and positioned with its distal tip in the left ventricle. Blood is aspirated from the left ventricle and ejected into the ascending aorta. Potential advantages of the catheter pump are its simple design and its fast application with minimal surgery. Preliminary in vitro tests with a first prototype showed that it is possible to create a pulsatile flow of 3 L/min and proved that further developing the PUCA pump will be worthwhile. **Key Words:** Left ventricular assist device—Catheter pump—Temporary mechanical circulatory support.

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Temporary or prolonged mechanical circulatory support during the treatment of patients with severe heart failure can be a life-saving measure (1). Prolonged circulatory support (weeks to month) is mostly used as a bridge to heart transplantation. It is generally used with support systems that require major surgery (thoracotomy) such as the total (implantable) artificial heart or biventricular support systems. Temporary support (hours to weeks) can be necessary when patients need to be "bridged" to other forms of heart surgery aimed at alleviating severe ventricular failure such as mitral valve surgery after ischemic rupture of a papillary muscle or closure of a ruptured ventricular septum. It also can be used as an adjunct to pharmacological treatment of severe heart failure.

Requirements for an optimal short-term cardiac support system can be defined as follows: fast application with minimal surgery; no highly specialized personnel for operating the system; minimal chance of mechanical breakdown by minimizing moving parts inside the patient; output of at least 3 L/min; applicable for a period of several hours to a number of days; minimal chance for blood coagulation; and minimal blood damage (mechanical factors usually play a major role in these types of system).

The PUCA pump concept

A new concept for mechanical short-term circulatory support, the pulsatile catheter (PUCA) pump (2), was developed to meet the requirements mentioned above. It consists of a pneumatically driven pulsatile membrane pump located outside the body and connected to a catheter (Fig. 1). The catheter will be introduced into an easily accessible artery like the femoral or proximal brachial artery. The tip will be positioned in the left ventricle via the aorta. The tip is provided with inlet valves; outlet valves are located at such a distance from the tip that they will open into the ascending aorta. A radiopaque marker is incorporated to visualize the position of the tip and outlet valves visible under fluoroscopy during the introduction of the catheter. The mem-

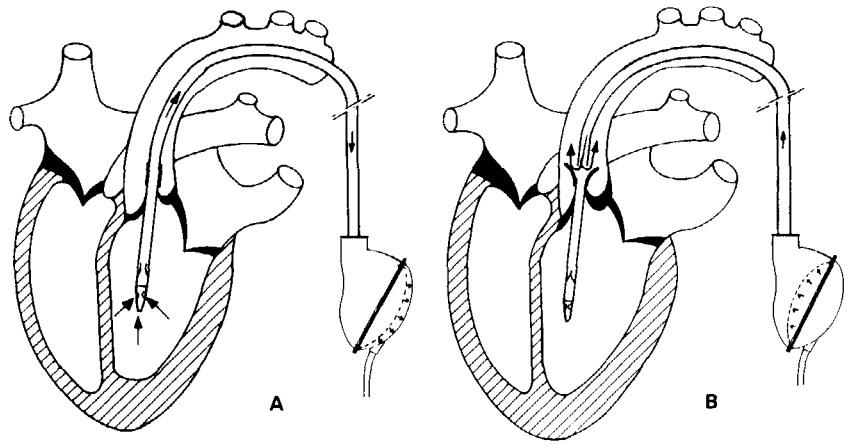

FIG. 1. Schematic drawing of the catheter pump during aspiration (**A**) and ejection (**B**).

brane pump aspirates blood from the left ventricle and ejects it into the ascending aorta thus ensuring adequate blood flow to the coronary arteries. The pump will be controlled by an electrocardiographic signal. In the case of severe cardiac arrhythmia or signal disorders, the pump will be automatically triggered by an independent internal source.

A limitation of the pressure in the air compartment to +700 mm Hg was advised by manufacturers of membrane pumps in order to avoid damage of the membrane. This limit will be checked in a later stage of the research. Blood damage by mechanical factors will be avoided by limiting the shear stress to 150 Pa (3) and limiting the pressure in the air compartment during aspiration to −460 mm Hg (4). High positive pressures will hardly cause blood damage (5). The (+) dP/dt will be limited to 4,500 mm Hg/s (6) and will be limited during valve closure to avoid cavitation. The limit depends on valve size, amount of valve leakage, and the stiffness of the seat (7). We intend to limit blood damage caused by interaction with the internal surface of the device by using a special heparin coating developed at the University of Twente, Enschede, the Netherlands (8).

Testing of the concept

Experimental setup

A first preliminary prototype with specially designed miniature inlet and outlet valves was built to investigate whether further development would be worthwhile. The catheter was made of polyethylene, had a length of 1.2 m and an internal diameter of 7 mm, and was mounted on a modified membrane pump with only one connection, a stroke volume of 100 cc, and a three-layer polyurethane membrane. The inlet valve, a single-hinge mechanism, was made of polymethyloxid. The outlet valves were made of polyethylene sheets glued to the outside of the catheter and covered little holes in the catheter wall (Fig. 1). The pump was driven by a pneumatic system (Cardiac Systems). The prototype was tested in vitro. The PUCA pump was placed in a two-compartment container with negligible preload and afterload and pumped 1 L of a water and glycerol mixture (61% and 39% by volume to provide the viscosity of blood) from one compartment to the other (Fig. 2). The flow was measured by an electromagnetic flow meter (Skalar) in the return tube.

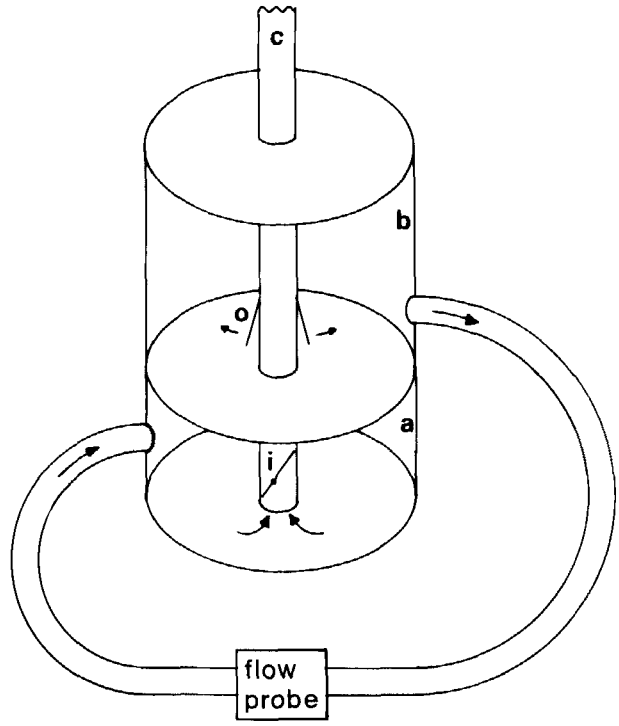

FIG. 2. Schematic drawing of experimental setup. The catheter (**c**) is placed in the cylinder. The inlet valve (**i**) is located in compartment **a**, outlet valves are located in compartment **b**.

A first series of two hemolysis tests were performed using the same experimental setup filled with 1 L of fresh heparinized bovine blood. An identical control container was filled with the same blood to investigate the influence of the material. For the first 25 min, a frequency of 30 bpm was used; for the last 15 min, 60 bpm was used. The total test time of 40 min simulated a 5 times longer use in vivo (humans) because of the 5 times reduced amount of blood that was used.

Results

It was possible to create the required flow of 3 L/min with the water-glycerol mixture. A pump frequency of 30 bpm, a systolic period of 50%, a pressure during aspiration of −340 mm Hg, and a pressure during ejection of +520 mm Hg were used. At 60 bpm, the required pressures were −350 and +540 mm Hg, respectively. All pressures that were applied did not exceed the maximum pressures. When using blood instead of the water-glycerol mixture, the same pressures were needed to obtain the required flow. Obviously, this first prototype was not optimal because in both tests severe hemolysis was found. During both in vitro tests, plasma free hemoglobin rose from 24 and 32 mg/L (baseline) to 1,357 and 1,037 mg/L (end of experiment). Potassium values did not increase significantly: 3.6 and 3.4 mmol/L (baseline) versus 3.6 and 3.6 mmol/L (end of experiment). There was also no significant increase in lactate-dehydrogenasis: 1,435 and 1,140 U/L (baseline) to 1,435 and 1,240 U/L (end of experiment).

Further development of the concept

In order to avoid developing the concept further by trial and error, using a large number of prototypes, a numerical simulation model (in which the flow mechanics will be described in mathematical terms) will be developed to find the minimal internal diameter that is required to get an output of 3 L/min while limiting mechanical blood damage, the optimal pressure profile for driving the pump, the influence of patient hemodynamics on the functioning of the pump, and the most efficient way to optimize the properties of catheter and pump. The optimal site for introducing the catheter in the patient and the matching maximum catheter diameter will be evaluated in postmortem studies. Results of the numerical model and postmortem studies will be published later.

Discussion

The situations in which LVADs have to be applied often constitute cardiac emergencies. Hence, they need to be applied expeditiously without requiring a difficult and time-consuming operation. Reliable functioning of these devices is necessary as the life of the patient generally depends on them.

Currently, the following minimal-surgery, short-term support devices are used most frequently: the Hemo pump, a coaxial flow pump with maximum flow rate of 3 L/min (9); the intraaortic balloon pump (IABP), which is in fact a counterpulsation device instead of a blood pump, whose contribution to the circulatory system is 0.75–1.25 L/min (10); and the cardiopulmonary support (CPS) system, in fact a small heart-lung machine that should ideally be operated by a perfusionist and can generate a flow up to 6 L/min (11).

In our opinion, the Hemo pump currently is the system that best meets the requirements for short-term circulatory support. However, the Hemo pump has a complicated and fragile driving system (9). Potential advantages of the PUCA pump are its simple and reliable design and its fast application without the need for major surgery. It may reduce the need for stand-by surgical support during high-risk interventions. It may also speed up the recovery of patients with severe heart failure and thereby shorten their stay in hospital. Another potential advantage is the pulsatile nature of the flow, which appears to be preferable to nonpulsatile flow (12).

During further development of the PUCA pump, special emphasis will be put on hemolysis reduction. The numerical simulation model will predict the minimal possible internal diameter and the optimal profile of the driving pressure. In our view, these parameters are the main factors in causing severe hemolysis. Other critical elements of the PUCA pump with regard to hemolysis are the high negative pressure, although it was of minor importance in other experiments (4), and the holes in the catheter wall, parts of the outlet valve. Holes can cause hemolysis in two ways. First, a hole causes a reduction of the cross-section of the blood flow and thus an increase of the blood velocity and shear stress (13). Second, turbulence past the holes can increase the incidence of red cell interactions with artificial surfaces (5). In the PUCA pump, however, the sum of the areas of the holes equals the area of the internal cross-section of the catheter. Consequently, the increase in mean blood velocity and shear stress in the holes will only be of minor importance. Turbulence will occur past the holes (this will be analyzed by flow visualization studies), but the amount of artificial surface and thus the chance for blood damage is minimal (the blood enters the ascending aorta through the holes).

With the results of the postmortem studies and the numerical simulation model, a strategy for introducing the catheter will be developed. If access via a superficial artery is possible, the consequences for the circulation distal to the site of introduction have to be examined. If a superficial artery cannot be used, introduction in the internal iliac artery or directly in the aorta could be considered.

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