Initial Clinical Experience With the Jarvik 2000 Implantable Axial-Flow Left Ventricular Assist System

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In this issue of *Circulation*, Frazier et al report their initial clinical experience with the Jarvik 2000 implantable axial-flow left ventricular (LV) assist system. This report is gratifying to me for several reasons. First, I have been involved in the development of devices to replace or assist the failing heart since the 1960s. I am also proud that the initial clinical work with this device was spearheaded by my colleague, Bud Frazier, who has worked tirelessly in this field since he was a medical student. Most important, however, is that this work gives hope to the 1 million patients with NYHA class III or IV heart failure who either die or suffer significant morbidity from their disease every year. New medications have helped delay the inevitable for some patients; however, a cure for chronic heart failure remains elusive. As heart failure worsens, medications become ineffective in treating the low contractility and pulmonary venous stasis that result from the increased dilatation of the heart. For patients with serious heart failure, the only hope is to unload the ventricle and augment the failing heart’s inadequate blood delivery. The Jarvik 2000 can do just that.

The Jarvik 2000 works differently than many other left ventricular assist devices (LVADs). Most of the LVADs currently in use were created as a result of an initiative by the National Heart, Lung, and Blood Institute (NHLBI) to develop a totally implantable long-term heart assist system. In 1977 and 1980, requests for proposals (RFPs) ultimately resulted in the first generation of all pulsatile blood pumps now used in clinical practice. These RFPs called for an LVAD capable of pumping up to 10 L/min of flow. At that time, it was thought that flow needed to be physiological, ie, fully pulsatile, to protect and enhance end-organ function. The very early clinical LVADs were associated with a number of complications, including hemolysis, infection, and patient discomfort. These problems have largely been overcome in the newer versions of the pumps. Special blood-contacting surfaces and highly engineered construction decreased the incidence of hemolysis and thrombosis. Electrical contacting surfaces and highly engineered construction decreased the incidence of infection, as has changing the location of the driveline exit site—particularly in the HeartMate, the most commonly used of these devices. Since their clinical introduction, pulsatile LVADs have proved themselves in thousands of cases as bridges to transplantation. More recently, they have been used as a means to rest the heart until ventricular function improves as well as for destination therapy. Why then do we need yet another assist device?

The successful clinical trial of the Hemopump in 1988 proved that it was possible to support the circulation with an axial-flow (or continuous-flow) pump. The advantages were obvious. Continuous-flow pumps can be made much smaller than pulsatile pumps, they can function without a compliance chamber, and they offered the real possibility of being totally implantable. Thus, in 1994, an RFP ("Innovative Ventricular Assist Systems") was issued for the development of innovative LVAD technologies. At that time, the Jarvik 2000 axial flow pump was already under development in our laboratories. The project had begun in 1989 through the collaboration of Dr Frazier and Dr Robert Jarvik and with internal funding. In 1994, the Texas Heart Institute and its engineering partners received 1 of the 6 awarded contracts from the RFP.

The Jarvik 2000 is an intraventricular pump, which makes it different from the other axial flow devices under development. Early in its development, Dr Frazier suggested keeping the pump inside the heart, which he felt would eliminate a number of potential problems, including inlet graft kinking, thrombosis, and pannus formation in the inlet graft, and inlet obstruction by the septum or lateral wall of the heart. In addition, intraventricular placement would avoid the altered rheology of negative pressures (suction) on the blood. Like other axial-flow devices, the Jarvik 2000 is small, which makes it available for more patients than its larger pulsatile cousins, including small women and children. In addition, the Jarvik 2000 can be implanted through a left thoracotomy, with or without cardiopulmonary bypass. Although it is not currently powered transcutaneously, this should not be difficult to accomplish with the technology available today. The Jarvik 2000, however, is not the indicated device for every patient with heart failure who needs mechanical circulatory support. Like pulsatile LVADs and the total artificial heart, the Jarvik 2000 gives physicians another means of treating serious heart failure.

As Frazier et al point out in their paper, uses and indications for the available pumps have become somewhat blurred. The pulsatile pumps, eg, the HeartMate (Thoratec Corporation) and Novacor (Baxter Healthcare Corporation), are really LV replacement devices. With these devices in place, the native heart seldom ejects. In contrast, the Jarvik...
2000 works in concert with the heart as a “true left ventricular assist device.” And, as the authors also explain, the best use of the Jarvik 2000 will be when native heart function needs augmenting, rather than complete unloading. Although it is a continuous-flow pump, the Jarvik 2000 should ideally allow the native heart to supply pulsatility. In fact, the best results with the Jarvik 2000 have been achieved when pump speed is set at a submaximal flow rate, which allows the aortic valve to open during systole.

Although this initial clinical experience was successful, the Jarvik 2000 has yet to prove itself a panacea for all patients in need of an LV assist device. Questions remain about thrombogenicity and adequacy of aortic root outflow. Frazier et al.\textsuperscript{1} believe that allowing the aortic valve to open during systole, which usually occurs at pump speeds between 9000 and 11,000 rpm, prevents stasis and decreases the incidence of thrombosis. This may be one of the reasons for their good results. Certainly, more follow-up by Frazier et al. and experience from additional centers is needed to determine the appropriate niche for this new physiology.

At this early stage, the Jarvik 2000 seems to hold much promise for many patients with heart failure. This series showed that it could safely support patients to transplantation. The low operative risk associated with this pump also may make it a possible destination therapy for patients who are either refractory to medical therapy or whose conditions deteriorate rapidly. As stated earlier, >1 million Americans have severe heart failure (NYHA Class III or IV)\textsuperscript{3} at any given time, and 70,000 will die\textsuperscript{3} from their disease because of the lengthy wait for a transplant or because they are not transplantation candidates. These patients are generally homebound and require numerous hospitalizations to treat their disease; their quality of life is poor. In the United States, we spend >$56 billion annually to treat them, 70% of which covers their hospitalizations. For the patients who do receive transplants, costs are also high and will not decrease. In contrast, with wider use, manufactured devices such as the Jarvik 2000 will become less expensive. Patients whose heart failure is treated by assist devices can return to their jobs and other normal activities—which also reduces lost wages, increases productivity, and confers numerous psychological and emotional benefits to patients and to their families. Thus, LVAD therapy with the Jarvik 2000 has the potential to convert these seriously ill patients with heart failure from nonproductive consumers of healthcare resources into productive consumers as they resume active, high-quality lives.

References

Keywords: Editorials transplantation heart-assist device heart failure
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Circulation. 2002;105:2808-2809
doi: 10.1161/01.CIR.0000021162.19008.F9
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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