

Invited Editorial

The Rotary Blood Pump: Lessons Learned and Future Directions

It is a pleasure to be here today addressing such a distinguished group of scientists and clinicians dedicated to saving and improving the lives of heart failure patients. Congratulations to the organizers for arranging such a fine Congress. In this presentation, we would like to review some of the developments that have led to the current status in the use of ventricular assist devices (VADs) for heart failure and to project into the future our vision and objective in this endeavor.

On May 6, 2003, we celebrated the golden anniversary of the first successful clinical use of the heart-lung machine, when Dr. John Gibbon performed closure of an atrial septal defect. On that date, one of us (M.E.D.) was invited to participate in the 50th anniversary celebration of the Gibbon Heart-Lung Machine at the Jefferson Hospital in Philadelphia (1). At that meeting, I related my first meeting with Dr. John Gibbon in the thirties, at which time he noted that one of the mechanical problems he had encountered in his research was with the pump. I told him about the roller pump that I had developed when I was a medical student and that I had used for direct blood transfusion when I was a resident in surgery (2). I then sent him a model of my roller pump, which he subsequently incorporated into his heart-lung machine and whose source he generously referred to in some of his published articles.

In my comments at this celebration, I stated that Dr. Gibbon's contribution "had a much more profound effect than the mere construction of a mechanical pump for temporary replacement of the function of the heart and lungs. Once he showed successfully that it could be used for that purpose, that success had a profound impact on the medical community, particularly on researchers who were interested in the cardiovascular field." I added, "he thus helped greatly to stimulate the developments in the past half century that have provided us the satisfying experi-

ence we have today in dealing with cardiovascular problems" (3).

Among important derivatives of the clinical experience was its stimulation of the development of VADs. This is exemplified by certain instructive observations made in the early period of the use of the heart-lung machine. At the time of operation, many of the patients were in some phase of heart failure, and after the corrective surgical procedure, it was sometimes difficult to wean them off the heart-lung machine. Some could be weaned off the heart-lung machine by allowing the heart-lung machine to support the failing heart over a period of 1–2 h, then gradually reducing the flow from the heart-lung machine. Other patients, however, despite prolonged support with the heart-lung machine, could not be weaned off the heart-lung machine—a problem that had fatal consequences. In the pioneering era of the use of the heart-lung machine, this was not an uncommon experience for many cardiac surgeons (4).

This experience led to a search for other methods of more prolonged support for the failing heart that could last for days or weeks, to allow the heart more time to recover. As a consequence, the concept of the VAD was developed. In the early 1960s, we began working in the experimental laboratory on mechanical models for this purpose. Our first clinical experience with such a device occurred in 1963 in a patient who developed cardiac arrest on the second postoperative day after aortic valve replacement and who had open resuscitation (5). The left VAD consisted essentially of an outer rigid tube with an inner compressible blood chamber with ball valves at each end to provide unidirectional flow. After resuscitation, this device was implanted in the patient to relieve severe pulmonary congestion; the inflow of the pump was attached to the left atrium, and the outflow to the descending thoracic aorta. It was most impressive—and encouraging—to observe dramatic relief of the pulmonary congestion within hours after the pump was installed. Although the patient remained free of pulmonary congestion for several days, he died presumably of brain damage that followed the

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cardiac arrest. This encouraging experience in relieving pulmonary congestion of a failing heart by mechanical support with this VAD stimulated our continued experimental laboratory research activities with this device.

Our next clinical experience with the latest experimental model of a VAD occurred in 1966 (4). This device consisted of an outer globular rigid housing with an inner mobile diaphragm separating the inner blood chamber from the outer gas chamber, which provided intermittent pressure to compress the diaphragm and thus pump blood with ball valves at the inner and outer opening to provide unidirectional flow. The patient in whom this VAD was used had developed heart failure from severe aortic and mitral valve disease. After surgical replacement of both valves, it was not possible to wean the patient off the heart-lung machine despite prolonged support with that device. We then used our VAD, whose supplemental use provided adequate cardiac output and permitted removal of the heart lung machine. After 10 days of support with this VAD, the patient's heart recovered adequate function to permit removal of the device. Her subsequent recovery was entirely satisfactory, and she later resumed normal activity. She was observed during annual checkups and found to have relatively normal heart function. Six years after the operation, however, she was tragically killed in an automobile accident.

The success of this procedure, along with a number of subsequent similar procedures, was extremely encouraging. Accordingly, in the 1970s we discontinued our experimental research efforts on the development of a total orthotopic cardiac prosthesis and focused all of our resources and experimental work on VADs. In the mid-1980s, we (M.E.D. and G.N.) performed a heart transplant on an engineer from the NASA Johnson Space Center in Houston, Texas. The patient obtained an excellent result and was able to perform his normal activities at that Center for almost 15 years. He became interested in our experimental work on VADs, and after my (M.E.D.) inquiry regarding the possibility of engaging some of his colleagues in hydraulic engineering, we showed them some of the ventricular assist models that we had developed in our laboratory, all of which were pulsatile. We asked about the possibility of making such a device much smaller than the bulky ones we had that would have a similar output of 5–10 L per minute. One of the engineers asked us if it had to be pulsatile, and we answered that it probably did not have to be. They then suggested using the axial flow principle with which they were very familiar because such a pump was used in some of their space engines.

This collaborative effort with the NASA engineers resulted in the development of a VAD using the axial flow principle (6). This pump consists of a flow tube measuring 68 mm long and 24 mm wide, within which there is an inducer-impellor (the only moving part) with a brushless motor rotor stator set around the middle of the flow tube where the impellor is located. Rare earth magnets embedded in the blades of the impellor act as the rotor of the brushless motor and make the impellor spin in a magnetic field. With the inducer-impellor spinning at about 10 000 rpm, the pump is capable of producing a flow of 5 L/min against 100 mm Hg pressure and requires less than 10 watts of input power. The efficacy and safety of this pump were demonstrated in calves with VADs implanted for as long as 6 months.

The licensing for the commercial production of this pump was obtained by MicroMed Technology, Inc., of Houston, Texas, which provided additional technologic development for its clinical application. This entailed, among other things, fabrication of the pump out of biocompatible materials; development of ancillary equipment, such as controllers, batteries, chargers, and data systems; manufacturing processes; and a regulatory strategy. MicroMed invested more than US\$50 million in developing and testing the DeBakey VAD. The device has earned the CE Mark in Europe based on the European trials that were begun in 1998, and MicroMed is now engaged in protocols approved by the Food and Drug Administration for both bridge-to-transplant and destination therapy in the US. Other rotary or axial flow blood pumps are also under development. While several are in preclinical stages, others are in various stages of human use. To date, more than 300 rotary or axial flow blood pumps have been implanted in patients, including more than 200 DeBakey VADs, 50 Incors from Berlin Heart (Berlin, Germany), 50 Jarviks (Jarvik Heart Inc., New York, NY, U.S.A.), and a couple of centrifugal pumps, such as the Coraid (Arrow International, Reading, PA, U.S.A.) and Ventrassist (Ventracor, Ltd., Chatwood, Australia) devices.

With more than 60 patient-years of experience with rotary or axial flow blood pumps as assist devices, we have accumulated considerable information. We now know that heart failure patients can be successfully supported for prolonged periods with continuous flow technology. We have seen patients supported for well over a year without untoward effect, maintaining good end-organ function and exercise activity on continuous flow support. Others have confirmed these observations (7,8).

Patient selection and the criteria used for this purpose have been found to be vitally important. As our

results continue to improve, we can justify using the devices earlier and in patients with less severe cardiac and end-organ failure. By implanting the device before irreversible end-organ damage has occurred, we will help more patients lead better lives and will lower the mortality rate. Of course, to justify using assist devices in earlier stages and in patients who are not as sick, we must obtain results that justify their earlier use.

We can do this with better patient management. Preventing bleeding and thromboembolic complications offers the greatest challenge, as well as the greatest hope, to improve clinical results. The miniaturization achieved by rotary blood pumps, especially of the axial flow variety, makes possible implantation with less surgical dissection because these devices need only a minimal pocket, and thus there is less raw surface to bleed. Of more importance, the advances in our knowledge about anticoagulation will allow better long-term anticoagulation management. We now have a better understanding of how the artificial surface and shear stresses in these blood pumps interact with platelets and the role they play in the anticoagulation scheme. Also, we have better drugs with which to inhibit the aggregation of platelets. Combining newer antiplatelet drugs with platelet monitoring technology, such as thromboelastography and platelet aggregometry, will allow us to individualize the anticoagulation regimen for patients on assist devices, making it both safer and more effective. As we look to support patients for longer periods in destination therapy permanent implantation, individualized anticoagulation regimens will become even more important.

We are probably nearing the limits of what can be accomplished for heart failure patients with standard pharmacologic treatment, and further major strides will come from other modalities. In the near term, left VADs represent that major stride for advanced heart failure patients, and these miniature blood pumps with the added mechanical reliability of their simpler design promise to lead the way. Other major strides will come in bridge-to-recovery strategies. Whether we look at pharmacologic cocktails to help the failing heart remodel and heal, muscle and stem cell implants, or various combinations, all will, for the foreseeable future, require mechanical unloading and support while their salutary effects take hold. Such combinations will require good teamwork between cardiologists and cardiothoracic surgeons.

Other patients for whom assist devices hold promise are those with acute myocardial infarction and children with heart failure. The simpler, miniaturized assist devices promise to bring to children the same

improvements in survivability and quality of life that adults are starting to receive from current continuous flow devices.

Adequate reimbursement and regulatory reasonableness, combined with the commitment shown by the leaders in the field, will allow rotary or axial pump technology to lead the way into the future for heart failure patients.

CONCLUSIONS

Considerable new knowledge has been accumulated with VADs during the past half century since the first successful clinical use of the heart-lung machine. The concept of ventricular assistance of the failing heart has been established, particularly through the bridge-to-heart transplant experience. We have also learned that patients in severe heart failure with reduced fixed cardiac output can be restored to reasonably normal activity by the implantation of a VAD. We have also found that rotary or axial flow VADs, such as the MicroMed DeBakey VAD, can achieve this objective and provide adequate support for reasonably normal activities for well over a year, with the advantage of its small size permitting its use in women and smaller patients, including children.

With increasing experience and continued technologic improvements, we can look forward to great expansion in the clinical use of these VADs in destination or permanent therapy for a substantial number of heart failure patients, in bridge-to-recovery in tandem with new cellular technology, and in certain forms of heart failure in children.

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