Letters to the Editor

The initial experience with the wearable Baxter Novacor ventricular assist system

To the Editor:

The experience that has accumulated since the first successful Novacor (console-based) bridge to transplantation, together with extensive technologic development, has permitted the first clinical implantation of the wearable Novacor left ventricular assist system (LVAS) (Baxter Healthcare Corp., Novacor Div., Oakland, Calif.) as a prolonged bridge to transplantation. Delays imposed by Food and Drug Administration regulations, coupled with the active policy of Baxter Healthcare Corp. in March 1993, resulted in a spectacular diffusion of the technique.

A 44-year-old man was hospitalized on an urgent basis for an acute episode of cardiac decompensation after a 6-year history of dilated idiopathic cardiomyopathy. His condition first deteriorated in September 1992. At that time, the left ventricular ejection fraction was 9%. He responded favorably to medical therapy and returned to a normal life. On March 4, 1993, he was readmitted to the intensive care unit (ICU). Despite an increasing dosage of intravenous dobutamine and the addition of enoximone, his condition rapidly deteriorated over 5 days.

The patient was included on the transplant list and received the highest priority. His clinical condition further deteriorated: He became confused. Hepatic dysfunction (aspartate aminotransferase level 1280 μ/L) increased, renal function (creatinine concentration up to 180 mol/L) deteriorated, and hyponatremia (119 mEq/L) worsened. The decision to institute a mechanical bridge to transplantation was based on the lack of a positive response to reinforced medical therapy, the duration of maximal medical therapy, which was extending beyond the limits of a pharmacologic bridge to transplantation, and the lack of availability of a suitable donor. The Novacor LVAS was selected because of the low pulmonary resistance (315 dynes·sec·cm⁻²) and anatomic considerations (body weight 91 kg), which made rapid transplantation unlikely. The selection of the wearable Novacor configuration was based on the probability of a long period of assistance because of the patient's blood type (ABO group) and anatomy. The patient's hemodynamic condition is described in Table I.

The operation was performed on March 16, 1993. With the patient under general anesthesia and supported by extracorporal circulation, the pump was placed as a left ventricular apico-aortic bypass, according to the standard protocol. Two technical changes were used: (1) intravenous infusion of 2 million Kallikrein inhibitor units at the start of anesthesia and 2 million units in the pump prime; (2) preclotting of the Dacron outflow conduit after the connector had been excluded. The initial pump flow was 6.4 L/min at a rate of 95 beats/min, which allowed rapid weaning from bypass. No transfusion was required during the operation.

The immediate postoperative course was uneventful. The patient was extubated after 5 days. Total blood loss through the chest drain was 800 ml over 3 days. Bleeding from the pump pocket was 1600 ml. No packed red cells were required. The patient was weaned from all inotropic agents on day 9.

The patient started exercising within the room on day 7. He walked freely inside the ICU on day 12. On day 14, a slight reduction in pump filling volume was observed as a result of posterior left ventricular compression. The patient was transferred to the operating theater. After he had been sedated and given a local anesthetic, 350 ml of asanguineous fluid was removed from the pericardium and 600 ml of blood and clots from the pump pocket. The pump filling volume returned to normal immediately.

Mobilization of the patient was restarted on day 15. On day 18, he could walk within the department of surgery for up to 1 hour. He was discharged from the ICU and moved to a large private room within the department. He was trained in the use of the wearable controller and batteries. He was rapidly able to move freely inside the hospital and in the surrounding garden from day 25 to 59 for periods extending to approximately 4 hours. During that period, minimal medical care was required. The hemodynamic situation was normal at rest and during exercise. A stress test conducted at 100 W showed a pump flow of 7 L/min, a heart rate of 160 beats/min, and a pump rate of 140 beats/min. Maximal peak oxygen consumption was 32 ml/min. Right ventricular ejection fraction was 34% as assessed by isotope.

An adequate ABO-compatible graft was obtained on day 59. Cardiac transplantation was uneventful. The patient was discharged from the ICU on day 8. Active rehabilitation was started and the patient was discharged after 16 days. He is now back to his normal life as a farmer.

Since this first case, two other patients have been selected for

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Table I. Hemodynamic condition at time of Novacor LVAS implantation

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<tr>
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<th>AoP (mm Hg)</th>
<th>RAP (mm Hg)</th>
<th>PAP (mm Hg)</th>
<th>PCWP (mm Hg)</th>
<th>SVR (dynes·sec·cm⁻²)</th>
<th>PVR (dynes·sec·cm⁻²)</th>
<th>CI (L/m² per square meter)</th>
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</thead>
<tbody>
<tr>
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<td>120/60</td>
<td>12</td>
<td>50/15</td>
<td>18</td>
<td>1312</td>
<td>315</td>
<td>2.14</td>
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AoP, Aortic pressure; RAP, right atrial pressure; RVP, right ventricular pressure; PAP, pulmonary arterial pressure; PCWP, pulmonary capillary wedge pressure; SVR, systemic vascular resistance; PVR, pulmonary vascular resistance; CI, cardiac index.
implantation: one (42 years of age, AB blood type) is alive after 3 months, fully mobile, and still waiting for transplantation. He considers his life to be normal: he daily goes out of the hospital for shopping, dining in restaurants, or visiting to the Grand Louvre. His only concern is about the few days in the ICU he will experience after the transplantation to come . . . . one day.

The third patient (26 years of age, B blood type) joined the other patient 1 month ago. Return to a normal life is made easier by this daily cohabitation and the shared will to recover rapidly. In the meantime, a few European centers and two centers in the United States (Stanford and Pittsburgh) have started the program. The pace of development is rapid: as of February 1, 1994, less than 10 months after our first case, 30 patients have received the device (Lawson J. Wearable Novacor LVAS: update. In house reports, February 1, 1994. Personal communication).

These first three clinical cases illustrate perfectly the progress made by miniaturization of the external components of the system, making feasible their portability (Fig. 1). Elimination of the console facilitates nursing care in the immediate postoperative period, potential return to the operating room while chest drains are still in place, and rapid mobilization of the patient. The entire rehabilitation process is considerably facilitated by the low weight and small volume (a camera case) of the controller and batteries. General acceptance of this system and psychologic adaptation to the new way of life (full autonomy for extended periods) are spectacular. Full confidence in the system is frequently expressed by comments from the patients, such as: “Are you sure I need a transplant?” “There are more urgent candidates than me. Please, don’t rush!”

The benefit offered by the wearable LVAS is obvious with respect to recovery of physical capabilities. It becomes even more spectacular from the point of view of the quality of life of a patient supported by the device. This is particularly significant when compared with that observed in patients supported by external ventricular assist devices, who can theoretically be moved within their room, in the ICU, but who must remain hospitalized in the ICU under strict medical observation. When compared with the first (console-based) generation of the Novacor LVAS, the wearable system offers major advantages to both patients and hospital staff. The feeling of full autonomy, which extended to 4 hours in the first case, may account for the improved emotional and psychologic functioning.

The quality of life of patients awaiting transplantation with a wearable Novacor LVAS could be further improved by discharge to a residential facility, possibly close to the hospital, where tapered medical and technical support could be provided. Such a situation would allow a more active social and family life. The initial experience of the Pittsburgh group is encouraging in this respect.7

Fig. 1. The wearable Baxter Novacor LVAS. The wearable controller and batteries replace the external console.

REFERENCES


Valve thrombosis and strut fracture with the Björk-Shiley valve

To the Editor:

I read with great interest the article by Orszulak and associates7 from the Mayo Clinic on their long-term results with the Björk-Shiley tilting disc valve (Shiley, Inc., Irvine, Calif.). Their