USE OF CIRCULATORY-ASSIST DEVICES IN THE FAILING HEART

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To date a variety of mechanical devices have been used to support the circulation in those patients requiring cardiac transplantation who are in cardiogenic shock. These include devices which produce either a pulsatile or nonpulsatile blood flow pattern. Of the former, the intraaortic balloon pump is the most frequently used, however, it augments but does not replace the function of the left ventricle. At the Ottawa Heart Institute, orthotopic replacement of both ventricles with a total artificial heart has proven to be a reliable and effective bridge to transplantation in selected patients. Heterotopic ventricles, known as ventricular-assist devices, may also be used to replace the function of one or both ventricles and are increasingly being used to maintain the circulation. The future of nonpulsatile devices for mechanical support remains unclear as the long-term effects of this unphysiologic flow pattern are as yet undefined. As refinements in circulatory support devices continue and as patient selection and timing of device insertion become more clearly defined, it is anticipated that in the 1990s the results in these patients will approach those of elective cardiac transplantation.

IN THE LAST DECADE the experience gained with cardiac transplantation has demonstrated that approximately 20% of patients awaiting transplant died before a donor heart became available.1 The quest for a simple yet safe means of circulatory support to function as a "bridge to transplantation" therefore continues. Currently, available cardiac-assist devices are used either as a "bridge to recovery," such as in a patient with a depressed myocardium following cardiac surgery (until myocardial recovery is sufficient to sustain adequate cardiac function) or as a "bridge to cardiac transplantation," for those patients awaiting cardiac transplantation in cardiogenic shock. 2-9

Donor hearts are a scarce resource that must be used with anticipation of optimal results. Therefore, the success of transplantation in patients with assist devices should approach that of elective cardiac transplantation. To attain this goal, patient selection and timing of device implantation are crucial. Patients being considered for a

"bridge to transplantation" should fulfill the standard criteria for elective cardiac transplantation. Life-threatening infection, major neurological impairment, consumption coagulopathy, or dysfunction of two or more secondary organs are generally considered a contraindication to transplantation and therefore should contraindicate the implantation of an assist device as a "bridge to transplantation." Finally, during circulatory support these patients must be thoroughly evaluated to ensure they continue to remain candidates for transplantation. The timing of device implantation is equally important to achieving a successful outcome. The hemodynamic criteria for implantation of a cardiac-assist device are shown in Table 1. Essentially, these patients are all in cardiogenic shock despite maximal pharmacologic support.

Table 1. Hemodynamic criteria for insertion of a cardiac-assist device.

1. Cardiac index < 1.8 mUsq m.
2. Systolic blood pressure < 90 mm Hg.
3. Left and/or right atrial pressure > 20 mm Hg.
4. Urine output < 20 mml/hr (adults).
5. Systemic vascular resistance > 2100 dyne/stem-So
6. Maximal pharmacological support with adequate filling pressures.

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However, what constitutes maximal pharmacologic support remains controversial and often varies among institutions. This variability includes both the nature and duration of pharmacological support. The former pertains to defining which drugs should be used and in what dosage before the criterion of maximal support has been met. Experience, however, has shown that the period of pharmacologic support before mechanical support is instituted should not be unduly long as this adversely affects patient outcome.

Pulsatile-Assist Devices

Intraaortic Balloon

Intraaortic balloon counterpulsation has been the most commonly employed cardiac-assist device both to support patients as a "bridge to transplantation" and as a "bridge to recovery." While it is simple to use, inexpensive, and effective in many patients, it augments but does not replace the function of the left ventricle only. Our own experience with the use of the intraaortic balloon as a bridge to transplantation is shown in Table 2. Of our first 97 cardiac transplant recipients, 34 (35%) were in cardiogenic shock prior to transplantation. Of these, 16 (47%) were supported with the intraaortic balloon with a 70% survival rate following transplantation.

Orthotopic Ventricles

These devices are partially implantable total artificial heart systems with the artificial left and right ventricles being implanted orthotopically following excision of the native heart. The ventricles are then connected to a bedside pneumatic or electric drive unit by transcutaneous lines. Originally developed as a permanent replacement for the human heart, the Symbion (Jarvik) pneumatic total artificial heart has been subsequently used as a "bridge to transplantation." At the Ottawa Heart Institute, we have utilized the Symbion heart for temporary circulatory support in 13 patients with profound cardiogenic shock with good results. Our own experience with this device has shown it to be a reliable and effective temporary replacement for the heart. However, the world experience has shown that infection is a serious limiting problem with the use of the total artificial heart.1~14 Currently, the Symbion total artificial heart is not approved for clinical use in the United States. While other designs of total artificial heart have been developed, predominantly in the United States and Europe, none is currently available commercially.

Heterotopic Ventricles

Commonly known as ventricular-assist devices (VADs), these devices can be used for support in patients with either univentricular right or left ventricular failure or in biventricular failure. In most of the clinically-used systems, the ventricle(s) also remains outside the body and is connected in parallel to the native heart by cannulae. In many patients in cardiogenic shock, however, an effective univentricular left ventricular support is often sufficient to maintain adequate circulatory support.2,3,7,15 Right ventricular dysfunction, if not severe, can frequently be managed by pharmacological means.

While orthotopic artificial hearts are currently much less frequently used for circulatory support than heterotopic ventricles, there are certain clinical situations where the former are indicated. These include the presence of (1) ventricular septal defect which may occur following acute myocardial infarction involving the septum, (2) intraventricular or intracavitary thrombus, and (3) severe valvular dysfunction.

Nonpulsatile-Assist Devices

Centrifugal Pumps

These bedside-assist devices provide a nonpulsatile flow of blood when connected in parallel to the native heart by cannulae. For left ventricular support the pump is connected between the left atrium and the aorta; for right ventricular support the pump is connected between the right atrium and pulmonary artery. These devices can there

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Table 2. Cardiac transplantation - Ottawa Heart Institute patient group.

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<thead>
<tr>
<th></th>
<th>Elective</th>
<th>IABP</th>
<th>TAH</th>
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<tbody>
<tr>
<td>No. patients</td>
<td>63</td>
<td>23</td>
<td>13</td>
</tr>
<tr>
<td>No. survival</td>
<td>54</td>
<td>16</td>
<td>7</td>
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<tr>
<td>% survival</td>
<td>86%</td>
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IABP = intraaortic balloon; T AH = total artificial heart.
fore provide either univentricular or biventricular support. Though relatively inexpensive, these devices are, however, not recommended for use for more than 10 days. Prolonged use is associated with serious bleeding, renal failure, infection, hemolysis, and respiratory insufficiency. 16.17

**Hemopump**

This is a miniature cable-driven axial flow pump which provides active left ventricular assistance and is capable of generating flows of up to 3 L/min. This pump is introduced into the aorta through the femoral artery and is passed retrograde across the aortic valve. It is connected to a portable bedside controller. The obvious benefits of size and simplicity and the relative ease of insertion are the main advantages of this system. However, cost, pump dislodgement, cable breakage, and inability to insert in small patients or in patients with peripheral vascular disease are significant problems with this device. IS

Table 3 shows the survival rates for the patients entered into the Registry of the International Society for Heart Transplantation as of December 1989 with various modes of cardiac circulatory support. The survival following transplantation is 80% and 65%, respectively, following "bridging" with a heterotopic univentricular (left) VAD and a biventricular VAD and approximately 50% with the total artificial heart. However, it is important to recognize that enrollment in the registry is entirely voluntary and that this does not represent a prospective randomized comparison of various modes of cardiac assistance.

LV AD = left ventricular-assist; RV AD = right ventricular-assist; BIVAD = biventricular-assist (heterotopic); TAH = total artificial heart (orthotopic).

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**Conclusion**

It is obvious that there are many limitations to the above devices. In many cases this includes the large size of the devices, the size and complexity of the driving consoles, and the subsequent lack of patient mobility. In collaboration with the University of Utah, we are currently developing a totally implantable univentricular electro-hydraulic left VAD. The future of cardiac-assist devices in the 1990s appears to be very bright. The basis of future successes is dependent not only on technological refinements in the development of new devices but also on continued research into the physiological effects of mechanical circulatory support.

**References**