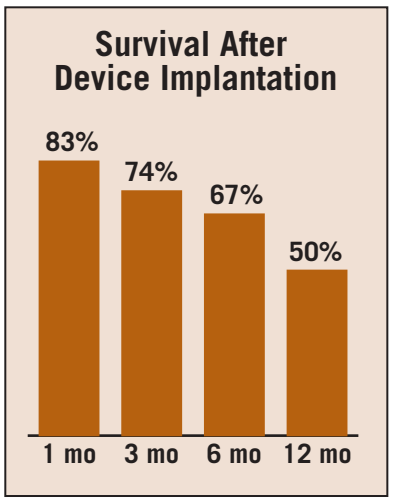
Assist Devices Stabilize Patients Awaiting Heart Transplants

BY MITCHEL L. ZOLER
Philadelphia Bureau

PHILADELPHIA — The bridge-to-transplant approach for stabilizing patients prior to heart transplantation is working.

Of patients who received a mechanical circulatory support device as a bridge to heart transplant in 2002-2004, half (50%) of those over age 50 and three-quarters (74%) of those under 30 survived to receive a heart transplant during the first year after receiving the device, Marshall I. Hertz, M.D., said at the annual meeting of the International Society for Heart and Lung Transplantation.



"The findings show, in a nonanecdotal way, that you can get a lot of patients to [heart] transplant who otherwise wouldn't get transplanted, said Dr. Hertz, professor of medicine at the University of Minnesota in Minneapolis, and medical director of the International Heart and Lung Transplant Registry.

"The results of several studies have shown that patients who have a heart transplant after receiving a ventricular assist device can do better than patients who are transplanted with no device. It's paradoxical, because the sickest patients get devices, but then they are stabilized and they can get physical rehabilitation and improved nutrition, and they become better candidates for heart transplantation a few months later. The bridging idea started as a last ditch effort for patients, but now it's viewed as interim therapy," Dr. Hertz said in an interview.

Starting in January 2002, the registry began a voluntary program for submitting case reports for patients who received a mechanical circulatory support device, and as of Dec. 31, 2004, 699 patients were registered. They had received a total of 831 devices at 60 centers worldwide. Follow-up data were available for 655 patients, including 513 who had received a device as a bridge to transplant and 78 patients who received a device as destination therapy. Also, 35 patients received a device as a bridge to recovery, and 29 patients had received a device with an unspecified purpose.

Among all patients who received a device, the actuarial survival rate was 83% after 1 month, 74% after 3 months, 67% after 6 months, and 50% after 1 year.

Survival was linked with age in patients who received a device as a bridge to transplant. Among 292 patients who were aged older than 50 years, mortality was 37% during the first year after they received the device. In contrast, among 52 patients aged younger than 30 years, first-year mortality was 13%, reported Dr. Hertz. A similar analysis was not reported for the remaining 169 patients who were aged 30-50 years.

"The survival to 12 months is not as good as we'd want; additional technical improvements are needed," said Dr. Hertz.

During 12 months of follow-up of the entire group of 513 patients who received bridge-to-transplant devices, 501 patients had infection episodes, 302 had bleeding episodes, and 75 has thrombotic episodes. The high rate of infection was not surprising, said Dr. Hertz. Infections occur primarily as a consequence of the transcutaneous catheters that devices currently require.

Most of the 78 patients in the registry who received devices as destination therapy were ineligible for heart transplants either because of advanced age (49%) or comorbidity (36%). An additional 10% received a device without listing for a transplant because of fixed pulmonary hypertension.

The long-term prognosis for these patients was not good, especially among older patients. Of the 41 patients in the registry who received destination therapy and were at least 65 years old, 52% died within 6 months of receiving the device, and 74% died within 1 year. Among the 37 patients aged younger than 65 years, 13% died within 6 months and 39% were dead after 1 year. ■

Advanced Age Shortens LVAS Survival Time

BY MITCHEL L. ZOLER
Philadelphia Bureau

PHILADELPHIA — Older patients are much less likely to survive their first year on a ventricular assist device than are younger patients, according to a review of 1,365 patients who have received such devices.

But many patients who are at least 60 years old can often benefit from a left ventricular assist device, Peer M. Portner, Ph.D., said at the annual meeting of the International Society for Heart and Lung Transplantation.

"Age is likely a surrogate marker for comorbid conditions at the time of the implant. Left ventricular assist systems [LVAS] can produce a strong survival benefit, even in the oldest patients. This underscores the importance of patient selection for destination therapy," said Dr. Portner, of the department of cardiothoracic surgery at Stanford University in Palo Alto, Calif., and developer of the Novacor LVAS.

"We have an idea of which patients will do better, but it's been hard to collect the data that could help" identify the patients who will have the best outcomes after receiving an LVAS, he said.

The analysis reported by Dr. Portner came from a registry of patients who received the Novacor LVAS in 1984-2003. During that period, 1,461 patients received the device at 98 centers worldwide. This analysis excluded 70 patients who received the device as destination therapy and 26 patients with inadequate follow-up data, which left 1,365 patients who received the device as a bridge to transplant. The average period of implantation prior to receiving a heart transplant was 144 days for the entire group, but today the average period during which the implant is in place is about 1 year.

Outcomes data were analyzed by the patients' age, and the database was divided into four groups that had similar numbers of patients: those aged 12-39 years (316 patients), aged 40-49 years (353), aged 50-59 years (451), and aged at least 60 years (245).

A logistic regression analysis showed that death during the first year with the device was directly linked to age. Patients in the oldest subgroup (at least 60) had a 2.4-fold increased risk of death compared with all other patients. In contrast, the youngest patients (younger than 40) had a 50% lower risk of death compared with the other patients. The two intermediate age groups had mortality risks between these two extremes.

Expressed another way, the survival rate at 1 year was 75% in patients younger than 40, 70% in those aged 40-49 years, 60% in patients aged 50-59 years, and 40% in those aged at least 60 years. Although mortality was high in older patients, the data also showed that a significant number of older patients could survive beyond 1 year on a LVAS.

"It's unfortunate that we're stuck in the United States with having a separate indication for destination therapy," said Dr. Portner. "The decision on the ultimate outcome of a recipient of an assist device should depend on how they progress." ■

BNP Better Than Guidelines at Guiding Heart Failure Treatment

ORLANDO, FLA. — Using serial plasma B-type natriuretic peptide levels to guide medical therapy in patients with systolic heart failure significantly reduces heart failure–related deaths and hospitalizations, Patrick Jourdain, M.D., said at the annual meeting of the American College of Cardiology.

Half of 220 patients in a 21-center French randomized trial received state-of-the-art, clinically guided medical therapy in accord with practice guidelines. The other half underwent monthly B-type natriuretic peptide (BNP) measurement for 3 months, then three times per year thereafter. The goal in the BNP group was to titrate doses of ACE inhibitors, β-blockers, and diuretics until plasma BNP dropped below 100 pg/mL.

During a median 15 months of follow-up there were three heart failure–related deaths in the BNP group and nine among the clinically managed patients. The primary composite end point in this unsponsored trial—heart failure–related death or hospitalization for heart failure—occurred in 25 patients in the BNP arm and 57 in the control group. This translates to a highly significant 54% reduction in relative risk when BNP was used to optimize medical management, noted Dr. Jourdain of Hôpital Rene Dubos, Pointoise, France.

—Bruce Jancin

Men Are More Likely Than Women to Receive Defibrillators for Heart Failure

BY SHARON WORCESTER
Tallahassee Bureau

ORLANDO, FLA. — Men with heart failure and/or bundle branch block are preferentially treated more aggressively with implantable devices than are women with similar health status, a review of nearly 11,000 cases suggests.

The 10,931 patients, of whom 4,138 (38%) were women, were listed in an administrative database and represented consecutive admissions to any of numerous hospitals owned by Hospital Corporation of America. All had a diagnosis of heart failure, bundle branch block, or both, and underwent a primary procedure of pacemaker, cardiac resynchronization therapy pacemaker (CRT-P), implantable cardioverter defibrillator (ICD), or cardiac resynchronization therapy defibrillator (CRT-D) implantation, Robert Fishel, M.D., said at an international conference on women, heart disease, and stroke.

Women received 52% of the pacemakers, 33% of the CRT-Ps, 22% of the ICDs, and 21% of the CRT-Ds implanted, said Dr. Fishel of the J.F.K. Medical Center, Atlantis, Fla. Logistic regression analysis showed that men were significantly less likely than women to receive a pacemaker (odds ratio 0.35) and more likely to receive an ICD (OR 1.34) or CRT-D (OR 1.48). There was no significant difference in device utilization of CRP-Ps between sexes.

After controlling for device, diagnoses, age, and comorbidities, there were no significant differences between men and women in measured clinical outcomes, including mortality, postoperative stroke, postoperative infection, or ICD or pacemaker mechanical malfunction. However, further research is needed to determine if these differences in device use have any long-term effects on outcomes in women, he said. ■