

# LVAS Provides Bridge to Eligibility for Transplant

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PHILADELPHIA — Implantation of a left ventricular assist device in patients with a relative contraindication for heart transplantation can buy patients time for the rehabilitation therapy they need to become eligible to receive an organ.

Using an assist device this way has been dubbed “bridge to eligibility.”

In a subgroup analysis of 87 patients who received a Novacor left ventricular assist system (LVAS) when they were clinically ineligible for a heart transplant because of a relative contraindication, about two-thirds subsequently improved sufficiently on the device to become eligible for listing and went on to receive a trans-

**Patients who are contraindicated for transplant can have successful transplant outcomes when managed as bridge-to-eligibility patients.**

planted heart, James B. Young, M.D., reported at the annual meeting of the International Society for Heart and Lung Transplantation.

In contrast, in a control group of 12 patients who did not receive the LVAS, only a third of the patients subsequently became eligible for a heart transplant, reported Dr. Young, chairman of the division of medicine at the Cleveland Clinic Foundation.

These findings came from a study that was sponsored by WorldHeart, which makes the Novacor device.

Although bridge to eligibility works clinically, the Food and Drug Administration has yet to approve it as a formal indication for an LVAS. In June 2004, the FDA reviewed the same data that Dr. Young reported at the meeting and rejected a proposal from WorldHeart to change the wording of the device's approved indications. The LVAS could continue to be used as a bridge to transplant or as destination therapy, but not as a bridge to eligibility.

Dr. Young took issue with this decision.

“The indication for these devices should be for carefully selected and appropriate patients with end-stage heart failure, with absolutely no tie to whether it will be as a bridge to transplant, bridge to eligibility, or destination therapy,” he said. “We should recognize the robust data that we have that says that we can rehabilitate many patients. We need to plumb the concept of using LVAS for ill patients and then deciding which direction to take the patient.”

By not having an approved indication of bridge to eligibility, some insurers have refused to cover the cost of placing an LVAS in a patient who has relative contraindications for a heart transplant at the time of treatment, Dr. Young said.

According to formal definitions, any patient listed as a transplant candidate should be ready to receive a donor heart as soon

as it's available. The reality is that “many patients get LVAS and are said to be transplant candidates even if they have relative contraindications because it's reasonable to expect some contraindications to dissipate while the patient is on an LVAS,” said Dr. Young.

The most common contraindications that can potentially resolve with LVAS treatment are renal insufficiency, pulmonary hypertension, hepatic dysfunction, and obesity.

The data that Dr. Young reported came from the 225-patient pivotal trial for Novacor; 190 of these patients were randomized to receive an LVAS, and the remaining 35 patients served as control subjects.

Among the 225 patients, 87 had relative contraindications for heart transplant at the time they entered the study. LVAS treatment was used on 75 of these patients; the other 12 served as controls.

During the study, 49 of the 75 patients

with an LVAS (65%) improved so that they could receive a heart transplant, compared with 4 of 12 patients in the control group (33%).

In addition, following heart transplantation, the rate of survival was similar among the patients who initially had contraindications and those who did not, showing that the patients can have successful transplant outcomes when managed as bridge-to-eligibility patients, Dr. Young said. ■



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