Newly Approved Total Artificial Heart Restores Hemodynamic and Clinical Stability

The Cleveland Clinic Heart Center has added the CardioWest total artificial heart to its armamentarium of treatments for patients with congestive heart failure awaiting transplantation. In March 2005, a Food and Drug Administration (FDA) advisory committee approved the artificial heart for implantation only in desperately ill patients at major transplant centers.

"CardioWest is appropriate for cardiac transplant candidates at risk of imminent death from non-reversible biventricular failure," says Cleveland Clinic cardiac surgeon Nicholas Smedira, M.D. Dr. Smedira is among the first transplant surgeons in the country to be trained and approved for implanting the CardioWest device.

"In properly selected patients, the artificial heart provides hemodynamic restoration and clinical stability," he explains. "This promotes more rapid recovery of organ function, making cardiac transplantation possible."

The Cleveland Clinic Heart Center has one of the largest heart failure and cardiac transplant programs in the country, performing 58 transplants in 2004. Dr. Smedira estimates that the total artificial heart may be appropriate for a few patients a year.

Candidates are those patients with New York Heart Association class IV disease in whom a left ventricular assist device or biventricular assist device is contraindicated due to aortic regurgitation, cardiac arrhythmia, left ventricular thrombus, irreversible biventricular failure or other complications. Due to the size of the CardioWest device, the patient must meet specific criteria for body surface area by computed tomographic scanning.

"The goal of treatment with the total artificial heart is to improve the rate of survival to transplantation in this very sick patient population," Dr. Smedira says. "Patients with these same indications who do not receive the artificial heart have a less than 50 percent survival to transplantation."

In a study of 81 patients reported in The New England Journal of Medicine (NEJM), 79 percent of artificial heart recipients survived to cardiac transplantation, compared with 46 percent of the 35 control patients who met the same criteria but did not receive the artificial heart. One- and five-year post-transplantation survival rates of 86 and 64 percent, respectively, for patients implanted with the CardioWest device were equal to those for transplant recipients who do not require the device, based on UNOS data.

CardioWest is a biventricular, pneumatic, pulsatile pump that totally replaces the patient's heart. Lined with polyurethane, it has a four-layer, pneumatically driven diaphragm. At maximum stroke volume, cardiac output with the device exceeds 9 l/min.

"The advantage of the artificial heart over the left ventricular or biventricular assist devices is that it replaces both the patient's ventricles and all the valves," Dr. Smedira says. "This virtually eliminates the risk of cardiac arrhythmia, valvular regurgitation, ventricular clots and other problems seen with the ventricular assist devices." Survival to transplantation in patients who receive a left ventricular assist device is 71 percent, UNOS reports.

Dr. Smedira notes that the artificial heart is not without risks, "although the major adverse events occur at rates similar to those found with left ventricular assist devices," he adds. The most significant of these are stroke (12 percent risk) and bleeding (28 percent risk). Seventeen of 81 patients in the NEJM study experienced an infection related to the device; however, in 80 percent of those patients, the infection neither delayed transplantation nor had a major clinical effect.

At present in the United States, the total artificial heart is powered by a large, wheeled console that necessitates in-hospital management, although in Europe the device is powered by a portable unit that allows discharge. In the NEJM study, average time from implantation of the device to transplantation was 79.1 days.

For more information about the CardioWest total artificial heart or to refer patients to Dr. Smedira for evaluation, contact him at 216/445-7052.