Counterpulsation Therapy Benefits Heart Failure

BY BRUCE JANCIN
Denver Bureau
ORLANDO — A standard 7-week course of enhanced external counterpulsation therapy in patients with heart failure who are on optimal pharmacotherapy improves their exercise duration, quality of life, and New York Heart Association class for at least 6 months afterward, according to the results of a randomized trial presented at the annual meeting of the American College of Cardiology.

“We believe these results suggest that EECP provides adjunctive therapy in patients with New York Heart Association (NYHA) class II-III heart failure receiving optimal pharmacologic therapy,” said Arthur M. Feldman, M.D., chairman of the steering committee for the Prospective Evaluation of EECP in Congestive Heart Failure (PEECH) trial.

EECP involved 187 patients with systolic heart failure (HF) and a mean ejection fraction of 26% who were randomized to 29 medical centers to optimal drug therapy alone or in combination with 35-hour-long EECP sessions over 7 weeks.

Patients were unblinded as to their treatment allocation, as were their treating physicians; however, a separate group of blinded investigators performed all patient evaluations, explained Dr. Feldman, professor and chairman of the department of medicine at Thomas Jefferson University, Philadelphia.

The primary study end point was at least a 60-second improvement in exercise duration at follow-up 6 months after the last EECP session. This was achieved in 45% of the EECP group and 25% of controls, a significant difference.

However, there was no between-group difference in a predefined alternative primary end point, the percentage of patients achieving at least a 1.25 mL/kg per minute increase in peak oxygen consumption (VO2). Exercise duration improved by a mean of 25 seconds in the EECP group, whereas it declined by 10 seconds among controls. To put this 35-second difference into perspective, EECP was well tolerated, although one patient developed a pulmonary embolism that investigators believed was therapy related.

Discussant Andrew D. Michaels, M.D., characterized the PEECH results as “mixed.”

FDA Panel Narrowly Votes Down AbioCor Artificial Heart

BY RICHARD A. PIZZI
Contributing Writer
GAITHERSBURG, MD. — The Abiomed Inc. AbiCor total artificial heart did not meet the Food and Drug Administration’s humanitarian-device exemption requirements, according to the FDA’s Circulatory Systems Devices Panel. The vote was 7-6 against, with one abstention.

The committee determined that the device maker Abiomed’s submission under the humanitarian-device exemption standards was inadequate. Concerns were based on undefined anticoagulation treatment protocols and the lack of quality of life data. The panel stressed the need for more extensive studies demonstrating the device’s safety.

The Abiomed Implantable Replacement Heart is the first fully implantable artificial heart for severe end-stage heart failure patients who are younger than 75 years, improves their exercise duration at the time of assessment, and in biventricular failure not treatable by a destination-therapy left ventricular-assist device. The device is designed as a last resort for a small patient population with a poor prognosis of survival within 30 days.

Abiomed submitted data from a clinical trial spanning slightly more than 3 years, from 2001 through 2004. The device was implanted into a total of 14 patients. The trial was initially designed to assess patient survival at 2 months.

Two patients died during implantation, and two others died before the 60-day end point. Three of the patients who survived more than 60 days had strokes prior to 60 days. A device failed in one patient at 5 months, another patient, the device wore out unexpectedly at 17 months. (The average run time during bench tests was 18.8 months.) Patients were unblinded as to their treatment allocation, as were their treating physicians; however, a separate group of blinded investigators performed all patient evaluations, explained Dr. Feldman, professor and chairman of the department of medicine at Thomas Jefferson University, Philadelphia.

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The panel was concerned about the lack of quality of life data, and they stressed the need for more extensive safety studies because of a high stroke incidence.

“The trial met one of two primary end points. It’s somewhat concerning that the end points that were met—namely increased exercise duration, improved quality of life, and improvement in NYHA class—were all subject to the placebo effect,” added Dr. Michaels of the University of California, San Francisco.

Dr. Feldman said that although EECP resulted in a significant gain in VO2 in an earlier pilot study, the PEECH population may have been biased against realizing a similar benefit because they were predominantly NYHA class II and hence didn’t have a long way to go to reach an essentially normal response.

EECP utilizes a series of ECG-synchronized inflatable cuffs wrapped around the legs. The cuffs swiftly inflate at onset of diastole and rapidly deflate at onset of systole, providing hemodynamic effects similar to intraaortic balloon counterpulsation, including increased coronary artery blood flow along with afterload reduction.

EECP is approved for the treatment of stable angina and the average physician payment under Medicare is $138.34 per session.

Both Dr. Feldman and Dr. Michaels are consultants to Vascularmedical Inc., which markets EECP systems and sponsored the PEECH trial.