Counterpulsation Therapy Benefits Heart Failure

BY BRUCE JANCIN
Denver Bureau

OMAHA — 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 55% 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 15-second difference into perspective, in roughly a 50-second difference in exercise duration, compared with sham therapy.

Improvement in NYHA class was a secondary EECP end point. At 6 months, 31% of the EECP group, and only 14% of controls showed at least a one-class improvement.

Another secondary end point was quality of life as measured in terms of change from baseline in scores on the Minnesota Living with HF questionnaire.

One month after completion of the EECP sessions, treated patients had a mean 8.9-point improvement, compared with a 3.4-point gain in controls. The quality of life advantage favoring the EECP group remained significant at 3 months, but not at 6 months.

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.”

Dr. Feldman said randomized trials of cardiac resynchronization therapy show it typically results in roughly a 50-second difference in exercise duration, compared with sham therapy.

“Some of those patients were one year younger, were in NYHA class II and hence didn’t have a long way to go to reach an essentially normal response,” he said.

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 support 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 $138.54 per session.

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

FDA Panel Narrowly Votes Down AbioCor Artificial Heart

BY RICHARD A. PIZZI
Contributing Writer

GAITHERSBURG, MD. — The Abiomed total artificial heart did not meet the Food and Drug Administration’s humanitarian-device exemption standards, 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 designated 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 for 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 expectedly at 17 months. (The average run time during bench tests was 18.8 months."

Patients were unblinded after enrolling, bleeding requiring reoperation and neurologic events.

Two patients improved enough to be discharged from the hospital—one to the patient’s home and the other to a hotel near the hospital.

Although a humanitarian-device exemption is similar in both form and content to an FDA premarket approval application, requiring reasonable assurance of safety and probable benefit, it is exempt from the effectiveness requirements of a premarket approval. The sponsor’s representatives stressed this distinction among panel presentations to the panel and emphasized the groundbreaking nature of the technology.

The FDA prepanel offered a somewhat mixed evaluation of the device. Biomedical engineer Eric Chen, the FDA’s lead reviewer, asserted that the device met the humanitarian-device exemption’s requisite standards for biocompatibility, electrical safety, and manufacturing, but he said there are still concerns about reliability.

Julie Swain, M.D., leading the FDA’s clinical review team, said “This device is a real dilemma.” She asserted that the relationship between risk and benefit was very difficult to ascertain, “due to a lack of validated quality of life and functional data.”

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 panel and emphasized the groundwork necessary of the technology.

Dr. Lindenfeld said that she could not support the device because she was “unconvinced that we’ve settled the issue of bleeding and stroke.” Thomas B. Ferguson, M.D., of Washington University, St. Louis, spoke to concerns about anticoagulation treatment, telling the sponsor’s representatives that he would “like to be reassured that you are totally convinced that...all you are doing is improving for all the people who...are totally convinced of...all you are doing is improving for all the people who...are totally convinced of...all you are doing is improving for all the people who...are totally convinced of...all you are doing is improving for all the people who...are totally convinced of...all you are doing is improving for all the people who...are totally convinced of...all you are doing is improving for all the people who...are totally convinced of...all you are doing is improving...