Counterpulsation Therapy Benefits HF Patients

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 that 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.

PEECH involved 187 patients with systolic heart failure (HF) and a mean ejection fraction of 26% who were randomized at 29 medical centers to optimal drug therapy alone or in combination with 35 1-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 35% of the EECP group and 25% of controls, a significant difference.

However, there was no between-group difference in a predefined alternate primary end point, the percentage of patients achieving at least a 1.25 mL/kg per minute increase in peak oxygen consumption (VO_2).

'EECP provides adjunctive therapy in patients ... receiving optimal pharmacologic therapy.'

DR. FELDMAN

Exercise duration improved by a mean of 25 seconds in the EECP group, whereas it declined by a mean of 10 seconds among controls.

To put this 35-second difference into perspective, randomized trials of cardiac resynchronization therapy show it typically results in roughly a 50-second differential in exercise duration, compared with sham therapy, he said.

Improvement in NYHA class was a secondary PEECH 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.

VASOMEDICAL

A patient wrapped in a lower-body cuff set receives EECP therapy while a medical technician monitors treatment data.

EECP was generally well tolerated, although one patient developed a pulmonary embolism that investigators believed may have been therapy related.

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

"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—are 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 VO_2 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 did not 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 has been approved for the treatment of stable angina. The average physician payment under Medicare is $138.34 per session.

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

FDA Panel Cites Missing Key Data, Nixes Mesh Cardiac Support Device

BY RICHARD A. PIZZI
Contributing Writer

GAITHERSBURG, MD. — By a vote of 9-4, the Food and Drug Administration's Circulatory Systems Devices Panel decided not to recommend the CorCap cardiac support device for approval, citing concerns about missing end-point data and uncertainty about the device's effectiveness.

The cardiac support device (CSD), made by Acorn Cardiovascular Inc., is a polyester mesh wrap that is implanted around both ventricles of the heart to stop cardiac enlargement caused by heart failure. It is intended to improve the heart's function by providing beneficial changes in cardiac structure and a decrease in the need for major cardiac procedures.

Acorn also claimed that patient quality of life would be improved significantly.

Acorn presented data from a prospective, randomized, controlled trial of 300 heart failure patients. The 193 patients in whom mitral valve repair or replacement was indicated were randomized to undergo surgery with (91) or without (102) CSD placement.

The remaining 107 patients were randomized to undergo a thoracotomy for placement of the Acorn device and continued medical therapy (57) or medical therapy alone (50).

The primary end point was a composite of survival, the need for additional major cardiac procedures, and change in New York Heart Association (NYHA) classification.

Of patients who were treated with CorCap, 38% improved, compared with 27% of control patients.

Additionally, 25% of CorCap recipients remained the same, compared with 28% of patients in the control group.

A total of 37% of CorCap recipients were reported to have worsened, compared with 45% of control group patients.

The FDA questioned both the company's statistical analysis and CorCap's clinical efficacy. FDA statistician Laura Thompson, Ph.D., raised concerns that more than a third of patients were missing primary end point measurements, and more than half were missing appropriate baseline NYHA class data.

FDA consultant Ileana L. Pina, M.D., professor of medicine at Case Western Reserve University, Cleveland, also highlighted the missing data and pointed out that the only component of the primary end point that was significant was that of major cardiac procedures; there were no significant differences between the CorCap group and the controls in mortality or rehospitalization.

Citing these concerns, the committee voted against approving the device. The FDA usually follows the recommendations of its advisory panels, but is under no statutory obligation to do so. ■

Cannula Obstruction, LVAD Regurgitation May Be Cause Of Recurrent Heart Failure

WASHINGTON — Cannula obstruction and inflow valve regurgitation of left ventricular assist devices may contribute to recurrent heart failure in long-term users of the devices, according to findings from a small review study.

Among 61 patients who have been implanted with a left ventricular assist device (LVAD) at Sharp Memorial Hospital, San Diego, since 1995, 6 have developed recurrent heart failure. On catheterization of the heart, LVAD, and cannulae, 3 of the 6 patients had inflow cannula valve regurgitation seen on LVAD angiography.

Those 3 patients had received their LVADs between 309 and 696 days prior to the diagnosis of regurgitation.

All 3 of the patients recovered following replacement of the LVAD cannula, David A. Miller reported during a moderated poster session at the annual conference of the American Society for Artificial Internal Organs.

In three other patients, a two-catheter approach helped to identify obstruction of the inflow cannula as a result of a pressure gradient between the LVAD and the left ventricle that was identified during the filling phase. Their duration of LVAD use ranged from 40 to 81 days before they were diagnosed with obstruction of the inflow cannula.

Although the three patients underwent surgical repositioning of the cannula, only one recovered from the surgery, said Mr. Miller, who was a research associate at Sharp Memorial. He is now at the University of California at Irvine.

A control group of four LVAD patients without symptoms of heart failure who were undergoing catheterization for other reasons did not show any dysfunction of the inflow cannula.

—Jeff Evans