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SEISMIC STUDY ISSUES GLUM REPORT ON CELL THERAPY

In patients with heart failure, symptoms improved but not heart function

CHICAGO, Ill. (April 1, 2008) — A study in which interventional cardiologists injected muscle cells into scarred areas of the heart using a needle-tipped catheter has reported mixed results in patients with congestive heart failure. The Safety and Effects of Implanted (Autologous) Skeletal Myoblasts (MyoCell) using an Injection Catheter (SEISMIC) study showed some improvement in patients' symptoms but no evidence that the heart was able to pump blood more effectively. In addition, heart size did not improve.

The SEISMIC study results are being reported today in a Late-Breaking Clinical Trials session at the SCAI Annual Scientific Sessions in Partnership with ACC i2 Summit (SCAI-ACCi2) in Chicago. SCAI-ACCi2 is a scientific meeting for practicing cardiovascular interventionalists sponsored by the Society for Cardiovascular Angiography and Interventions (SCAI) in partnership with the American College of Cardiology (ACC).

The study is testing the safety and effectiveness of a treatment that, it is hoped, will replace inactive, scarred areas of the heart with the patient's own skeletal muscle cells, or myoblasts, creating functioning tissue that contributes to the heart's ability to contract and pump blood.

For the study, Patrick W. Serruys, MD, Erasmus University Medical Center, Rotterdam, the Netherlands, and his colleagues recruited 47 patients with heart failure, randomly assigning them to cell injection or to the best available medical therapy. Patients in the cell-therapy group underwent a biopsy of skeletal muscle from the front of the thigh. The muscle tissue grew in culture until there were hundreds of millions of muscle cells. Then, after threading a special needle-tipped catheter into the heart, researchers repeatedly injected millions of muscle cells at approximately 1-cm intervals throughout the area of scarring.

At the beginning of the study, the average left ventricular ejection fraction—or the portion of blood the heart is able to pump from the left ventricle with each contraction—was 41.5 percent. At six-month follow-up, the left ventricular ejection fraction was 29.2 percent in the cell-therapy group and 32.9 percent in the control group. Similarly, the enlarged hearts did not shrink as hoped in response to myoblast injection. Instead, at six months, the diameter of the left ventricle was larger in the cell-therapy group than the control group (54.5 mm vs. 39.4 mm, respectively, at the end of each contraction).

However, cell therapy was associated with an improvement in the distance patients were able to walk in six minutes (an additional 60.3 meters in the cell-therapy group vs. an additional 0.4 meters in the control group), but it was not statistically significant. Similarly, in the cell-therapy group, three patients (17.6 percent) experienced some relief of heart-failure symptoms as gauged by a one-step improvement in New York Heart Association (NYHA) functional class; one patient treated with cell injection (5.9 percent) experienced a worsening of NYHA class. By comparison, in the control group, one patient (8.3 percent) experienced an improvement of NYHA class, while five patients (41.7 percent) experienced worsening of heart failure status.

The researchers concluded that injection of cultured skeletal muscle cells in patients with heart failure is feasible and may improve symptoms, but had no detectable effect on heart function or size.

Dr. Serruys will present the results of the "Safety and Effects of Implanted (Autologous) Skeletal Myoblasts (MyoCell) using an Injection Catheter" (SEISMIC) study on Tuesday, April 1 at 11:15 a.m. CDT in the Grand Ballroom, S100.

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About SCAI

Headquartered in Washington, DC, the Society for Cardiovascular Angiography and Interventions is a 4,000-member professional organization representing invasive and interventional cardiologists in over 60 nations. SCAI's mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education and representation, and advancement of quality standards to enhance patient care. SCAI's annual meeting has become the leading venue for education, discussion, and debate about the latest developments in this dynamic medical specialty.

About ACC

The American College of Cardiology is leading the way to optimal cardiovascular care and disease prevention. The College is a 34,000-member nonprofit medical society and bestows the credential Fellow of the American College of Cardiology upon physicians who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care.