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Contact: Amy Murphy
(202) 375-6476
amurphy@acc.org

Andrew Crosby
(901) 575-0010
acrosby@cvic.com

ACC.09 News Room:
(407) 685-5405

LACKLUSTER SHOWING FOR NOVEL STENT IN HEART ATTACK STUDY

*Researchers Call for Larger Trial to Test Unique Approach to Preventing
Restenosis, Late Stent Thrombosis*

Orlando, FL – Researchers are blaming the inadequate size of the trial for new data that did not prove the effectiveness of a novel stent designed to speed arterial healing in heart attack patients by attracting the body's own circulating stem cells to create a protective layer over the implanted device, according to research presented during the i2 Summit the American College of Cardiology's 58th annual scientific session

In the Randomized Comparison of Genous Stent Versus Chromium-Cobalt Stent for Treatment of ST-Elevation Myocardial Infarction (GENIUS-STEMI) trial, researchers evaluated the investigational stent's ability to reduce both re-narrowing (restenosis) of the treated artery and blood clot formation on the stent (stent thrombosis). Instead, the study demonstrated increased rates of both, when compared to a third-generation bare-metal stent.

"The results have to be interpreted cautiously because this is a small, single-center study," said Pavel Cervinka, M.D., Ph.D, an associate professor and head of cardiology at Masaryk Hospital and University of J.E. Purkyne, Ústí nad Labem, Czech Republic. "However, in a head-to-head comparison, the chromium-cobalt stents were doing better than the Genous stent at six month follow-up."

For the GENIUS-STEMI study, 100 consecutive patients with a type of heart attack known as ST-elevation myocardial infarction (STEMI) were studied. Equal numbers of patients were randomly assigned to undergo stenting with the Genous EPC (endothelial progenitor cells) capture stent or a chromium-cobalt stent.

The Genous stent is designed to reduce the risk of restenosis while overcoming the tendency toward late stent thrombosis that has shadowed drug-eluting stents. Coated with an antibody, the Genous stent attracts circulating EPCs. These EPCs are naturally elevated in response to arterial

injury and have the capacity to differentiate into mature endothelial cells, like those lining the inner surface of arteries. It is hoped that this unique characteristic will accelerate the healing process, protect against blood clot formation, and minimize restenosis in stented arteries. Previous data from non-randomized studies and clinical registries have been promising.

During follow-up, researchers evaluated the patients clinically as well as with angiographic imaging and intravascular ultrasound. They found that at 30 days, the combined rate of major adverse cardiac events (MACE)—defined as heart attack, cardiovascular death, and repeat treatment of the target lesion—was comparable in the two groups. At six months, however, there was a significantly higher MACE rate among patients treated with the Genous stent when compared with those treated with the chromium-cobalt stent (24 percent vs. 10 percent; $p=0.03$). Patients treated with the Genous stent also had a statistically higher rate of repeat procedures in the originally targeted lesion (14 percent vs. 4 percent; $p=0.04$).

Intravascular ultrasound showed larger amounts of tissue overgrowth, the most common cause of restenosis, inside the Genous stent, although the difference was not statistically significant. In addition, there were three cases of late stent thrombosis in patients treated with the Genous stent (6 percent), but none in patients treated with the chromium-cobalt stent.

The researchers concluded that use of the Genous EPC capture stent in patients suffering from an acute heart attack is feasible and safe, while expressing caution over the unfavorable results compared to the chromium-cobalt stent.

“The rate of late stent thrombosis in the Genous group is worrisome,” Cervinka said. “Before generalizing these results, a large randomized trial is needed to finally address this issue.”

Dr. Cervinka will present “A Randomized Comparison of Genous Stent Versus Chromium-Cobalt stent for Treatment of ST-Elevation Myocardial Infarction” on Saturday, March 28 at 9:10 a.m. in the Valencia Ballroom.

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The American College of Cardiology’s Innovation in Intervention: i2 Summit 2009 features the latest in interventional science and is the leading forum and exposition for interventional cardiology. A platform for the world’s leading interventional cardiologists to share knowledge, discuss new ideas and discover new innovations, the i2 Summit 2009, in partnership with the Cardiovascular Research Foundation, is being held in conjunction with ACC.09, the American College of Cardiology’s 58th annual scientific meeting. The American College of Cardiology (www.acc.org) works to influence health care policy and represents the majority of board certified cardiovascular care specialists through education, research, promotion, and the development and application of standards and guidelines.