



AMERICAN
COLLEGE of
CARDIOLOGY



58th Annual Scientific Session
MARCH 29 – 31 • ORLANDO

Embargoed for Release:
Monday, March 30, 2009
9:15 a.m. EDT

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

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

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

EARLY vs. DELAYED PROVISIONAL UTILIZATION OF ANTI-PLATELET DRUG

Insignificant Advantage to Early Eptifibatide Use in High-Risk Patients

Orlando, FL – In patients with high risk of heart attack, early utilization of eptifibatide is not superior to delayed, provisional use of eptifibatide during percutaneous coronary intervention (PCI), according to research presented today at the American College of Cardiology's 58th annual scientific session. ACC.09 is the premier cardiovascular medical meeting, connecting cardiologists and cardiovascular specialists to the latest and most innovative findings in cardiovascular science.

The EARLY ACS study (Early Glycoprotein IIb/IIIa Inhibition in Non-ST-Segment Elevation Acute Coronary Syndromes) aimed to clarify the best strategy for eptifibatide use, an antiplatelet drug therapy successfully implemented in clinical practice for 10 years. Two common strategies of eptifibatide utilization were examined in patients with high-risk of heart attack: early intravenous injection upon immediate arrival at the hospital, and delayed, provisional injection during PCI.

“The drivers for our study are the gaps that exist in the practice guidelines for when and how best to use eptifibatide, an already tested and proven treatment, in the context of other modern therapies that have evolved since the drug was first introduced,” said L. Kristin Newby, M.D., MHS, associate professor of medicine at Duke University Medical Center, Durham, N.C. “Guidelines in North America and Europe vary in their recommendations regarding early use vs. delayed provisional treatment with eptifibatide and drugs like it. Individual hospitals and individual clinicians in all regions apply these recommendations differently.”

EARLY ACS was a randomized, double-blind, controlled study of early eptifibatide vs. provisional eptifibatide during PCI with standard background antithrombin therapy. A total of 9492 patients were enrolled, all of whom were scheduled to undergo an invasive strategy 12 to 96 hours after starting the study drug.

– more –

The primary efficacy endpoint for EARLY ACS was composite all-cause death, myocardial infarction, recurrent ischemia requiring urgent revascularization or thrombotic bailout during the first 96 hours. The secondary endpoint was death or myocardial infarction through 30 days. Safety endpoints included bleeding, transfusions, stroke and serious adverse events.

At its final enrollment, EARLY ACS had a 98 percent power to detect a 22.5 percent reduction in the 96-hour primary composite with early eptifibatide vs. delayed, provisional eptifibatide and 81 percent power for a 15 percent reduction in 30-day death or myocardial infarction.

“We set out to determine what is the better strategy when it comes to the treatment of these high-risk patients,” said Robert P. Giugliano, M.D. assistant professor of medicine at the Brigham and Women’s Hospital, Harvard, M.A. “Many hospitals in the United States routinely start a course of injectable eptifibatide early when a patient arrives at the hospital. However, there are other physicians who prefer to employ a ‘wait and see’ approach with the drug until after catheterization. Prior to this study, it was not clear which strategy was better. And, according to current practice guidelines, either strategy would be supported.”

For neither efficacy endpoint was the strategy of early eptifibatide use in all high-risk patients better than the delayed, provisional use of eptifibatide prior to PCI. Furthermore, early eptifibatide initiation was associated with more bleeding.

“Our study, although not the final word regarding eptifibatide, has helped shed a light on how to best use eptifibatide among high-risk patients,” Newby said. “In general, physicians can feel comfortable with a strategy of delayed, provisional administration after a decision to proceed to PCI is made.” As far as patients are concerned, the primary results from EARLY ACS are the key message – an early routine strategy of eptifibatide is not superior to a delayed provisional strategy.”

Drs. Newby and Giugliano will present the study “Early Glycoprotein IIb/IIIa Inhibition in Non-ST-Segment Elevation Acute Coronary Syndromes: EARLY ACS” on Monday, March 30, at 10:30 a.m. in Hall A2.

###

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. ACC.09 is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.