



AMERICAN
COLLEGE of
CARDIOLOGY



Embargoed for Release:
Saturday, March 28, 2009
7:30 a.m. EDT

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“REAL-WORLD” STUDY FINDS DRUG-ELUTING STENTS SAFE, EFFECTIVE

Largest-Ever Registry Provides Answers for Wide Range of Patients

Orlando, FL – The largest-ever study to evaluate stenting in “real-world” patients has confirmed that drug-eluting stents are better than bare-metal stents at protecting patients against serious cardiovascular illness, and are equally safe, according to research presented during the i2 Summit at the American College of Cardiology’s 58th annual scientific session.

The study found that during three years of follow-up, drug-eluting stents significantly reduced the risk of heart attack, death and additional heart procedures when compared to bare-metal stents, while provoking no increased risk of stroke or major bleeding.

“Some previous studies have suggested that drug-eluting stents are associated with an excess long-term death rate, whereas others have not,” said Pamela S. Douglas, M.D., Geller professor of medicine at Duke University. “The biggest take home message of our study is: Drug-eluting stents are safe.”

Stents are tiny metal tubes with an expandable, mesh-like design. They are placed in a diseased coronary artery to prop it open after it has been widened through inflation of a small balloon. Drug-eluting stents slowly release a medicated coating that prevents excessive tissue growth from the inner wall of the artery, which could clog the stent and block blood flow to the heart.

Several randomized controlled trials have shown that drug-eluting stents are better than bare-metal stents at keeping the coronary artery from constricting with scar tissue, but their findings on long-term safety have been inconsistent. Equally important, randomized controlled trials are very selective about the types of patients they enroll.

“Few patients who currently require stenting would be considered eligible for a randomized controlled trial – only about 20 percent in our population,” Douglas said. “Real-world data are required to assess stent safety and performance in the other 80 percent.”

For the study, Dr. Douglas and her colleagues analyzed data from the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) on patients over the age of 65 who had a stenting procedure performed from 2004 to 2006. Of these, 217,675 were treated with drug-eluting stents and 45,025 were treated with bare-metal stents. Follow-up information for each patient was obtained from Medicare claims data. The combination of these two data sets created a novel and powerful resource for assessment of post-marketing stent performance in a community setting.

Researchers adjusted the data for 102 patient characteristics such as sex, age and co-existing medical conditions. They found that patients who received drug-eluting stents had significantly lower rates of death (hazard ratio [HR], 0.75), nonfatal heart attack (HR, 0.76) and repeat heart procedures (HR, 0.91) when compared to patients who received bare-metal stents. In addition, there were essentially no differences in rates of stroke (HR, 0.96) or major bleeding (HR 0.91).

The investigators were not able to directly assess rates of stent thrombosis. However, data that Douglas characterized as "suggestive" showed that after one year, the type of heart attack (known as STEMI) that is associated with stent thrombosis was no more common with drug-eluting stents than bare-metal stents. In addition, the long-term hazard ratio favored drug-eluting stents for both STEMI and non-STEMI heart attacks.

This study will be simultaneously published in the *Journal of the American College of Cardiology*.

The study was funded by the Cardiovascular Consortium of the Agency for Healthcare Research and Quality (AHRQ), a federal agency in the Department of Health and Human Services, with additional support from ACC-NCDR.

"Today's findings provide important new evidence for decision-making by heart disease patients and their physicians," said AHRQ Director Carolyn M. Clancy, M.D. "These findings should help resolve many lingering questions regarding the safety of drug-eluting stents in recent years."

Dr. Douglas will present the study "Outcomes Following Coronary Stenting in a Linked NCDR and CMS Database: A National Study of Long Term, Real-World Outcomes of Bare-Metal and Drug Eluting Stents" on Saturday, March 28 at 9:30 a.m. in the Valencia Ballroom

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The American 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.