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MATRIX REGISTRY PROBES ADHERENCE TO CLOPIDOGREL AT ONE YEAR
Study digs into reasons, consequences for stopping anti-clotting medication early

CHICAGO, Ill. (March 31, 2008) — A large community-based registry of patients treated with drug-eluting stents is providing important insight into how long patients with complex coronary artery disease typically stick to their doctors' orders to take clopidogrel, a drug that prevents unwanted blood clots; why they stop taking the drug; and the long-term consequences of that decision.

The new data from the MATRIX Registry, a large proportion of which represents "off-label" use of sirolimus-eluting stents, will be 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).

Long-term clopidogrel therapy appears to be a critical factor in avoiding late stent thrombosis, an uncommon but serious complication that occurs when a blood clot blocks the stent. Such clots can form a year or more after stenting and can cause a heart attack or even death.

The MATRIX Registry is particularly valuable because it provides a "real-world" view of a wide variety of patients, many of whom do not fit the strict profiles used in clinical trials leading to device approval by the Food and Drug Administration. Treatment of such patients with drug-eluting stents is considered "off-label," but is both common in clinical practice and legal.

George Dangas, MD, PhD, an associate professor of medicine at Columbia University Medical Center and program director of interventional cardiology at New York-Presbyterian Hospital, New York City, led the new analysis of the MATRIX Registry data. A total of 1,510 patients were included in the study. They had a very different profile from patients enrolled in early clinical trials. Some 33.3 percent had

previously had a heart attack, 44.4 percent had had a prior coronary intervention, 21 percent had had bypass surgery, 33.7 percent had diabetes and 27.7 percent had unstable angina.

All patients received aspirin, clopidogrel and other anti-clotting drugs during stenting. After stenting, all were prescribed aspirin 325 mg daily for one month and 81 mg indefinitely thereafter, plus clopidogrel 75 mg daily for one year, with subsequent clopidogrel prescription left up to physician discretion.

The researchers found that by six months, 10 percent of patients who were available for follow-up (133 out of 1,324) were no longer taking clopidogrel as prescribed. By one year, that number had edged up to 17.4 percent (233 out of 1,338) and by two years, to 33.2 percent (291 out of 877). However, of patients who were no longer taking clopidogrel at six months, nearly half were back on the medication at one- or two-year follow-up.

At one year, discontinuation of clopidogrel was attributed to doctor's choice in 9.9 percent of patients, bleeding in 5.2 percent, surgery in 2.1 percent, rash or allergy in 1.7 percent and cost in 0.4 percent. In 39.5 percent of patients, the reason for discontinuation was unknown; 41.2 percent of patients discontinued clopidogrel simply because the recommended one-year dosing period had come to an end.

Researchers also evaluated clinical outcomes at various time points, dividing patients into those who continued taking clopidogrel and those who stopped. Patients who stopped taking clopidogrel by one year had a significantly higher risk of death when compared to those who continued taking the medication (4.8 percent vs. 1.4 percent, respectively, $p=0.005$); however, there was no significant difference in rates of cardiac death (1.1 percent vs. 0.2 percent, $p=0.054$), noncardiac death (2.7 percent vs. 1.0 percent, $p=0.08$) and unknown death (1.0 percent vs. 0.3 percent, $p=0.16$). The need for a repeat procedure to re-treat the target lesion or to reopen the target coronary artery was lower in patients who stopped taking clopidogrel (0 percent vs. 5.5 percent, $p=0.001$, and 0.5 percent vs. 6.1 percent, $p=0.002$, respectively).

Rates of stent thrombosis in the MATRIX Registry were 0.9 percent at two years—very low, particularly given that 86 percent of patients were treated for an “off-label” indication. Investigators attributed the low thrombosis rate to the highly experienced interventional cardiologists who performed stent implantation and the use of intravascular ultrasound to ensure precise stent placement in 35 percent of patients.

Dr. Dangas will present the new data from the MATRIX Registry on Monday, March 31 at 8:30 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.