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REGISTRY UNVEILS “REAL-WORLD” DATA ON NOVEL EXCEL STENT
At one year, stent with biodegradable polymer reports good clinical outcomes

CHICAGO, Ill. (March 31, 2008) — “Real-world” use of a novel drug-eluting stent coated with a biodegradable polymer is associated with good clinical outcomes, according to one-year data from a large international registry. Results of the CREATE study, which focused on the sirolimus-eluting Excel stent, 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).

For the study, Yaling Han, MD, Shenyang Northern Hospital, Shenyang, China, and colleagues recruited a total of 2,077 patients from 59 medical centers in four countries. All had stenting with the Excel stent, a novel device with a biodegradable polymer coating. Of these, 369 (17.8 percent) underwent primary stenting within 24 hours of having a heart attack.

After stenting, all patients were prescribed both clopidogrel and aspirin for six months to inhibit the action of platelets in the blood. Anti-platelet medications prevent the development of unwanted blood clots within the stent, or stent thrombosis, a serious complication that can cause heart attack or even death. On average, patients continued to take clopidogrel for 199 days.

Twelve-month follow-up data were available for 2,060 patients (99.2 percent). After 12 months, the overall rate of major cardiovascular complications was 2.77 percent, including cardiac death in 23 patients (1.12 percent), heart attack in 8 patients (0.39 percent), and repeat coronary procedure in 32 patients (1.55 percent). Death from any cause occurred in 34 patients (1.64 percent), including 11 noncardiac deaths. Overall, thrombotic complications occurred in 16 patients (0.78 percent), including six definite cases, five probable cases and five possible cases. Of these, three thrombotic complications (0.15 percent) occurred after discontinuation of clopidogrel.

The researchers concluded that the Excel stent is associated with a low incidence of cardiovascular complications, and that six months of dual-antiplatelet therapy appears to be feasible and safe.

Dr. Han will present the results of the study on Monday, March 31 at 8:00 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.