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ISAR-REACT 3 PITS BIVALIRUDIN VS. UNFRACTIONATED HEPARIN IN PCI
Will direct thrombin inhibitor excel with high-dose clopidogrel on board?

CHICAGO, Ill. (March 29, 2008) — A large randomized trial will shed light on the ideal combination of medications for preventing unwanted blood clotting during and shortly after percutaneous coronary intervention (PCI). Specifically, study investigators expect to determine whether bivalirudin, a direct inhibitor of the clotting protein thrombin, is better than unfractionated heparin, an indirect thrombin inhibitor, in patients who have also been treated with high-dose clopidogrel.

The Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment 3 (ISAR-REACT 3) study is being presented 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).

Bivalirudin has outperformed unfractionated heparin in some previous studies of PCI, but it's not clear how the two anti-clotting medications measure up when used in combination with what has become standard protocol in the cardiac catheterization laboratory: preloading with a 600-mg dose of clopidogrel, a medication that prevents clotting by inhibiting platelets.

“The distinguishing feature of our study is that a double-blind comparison of the two different anti-thrombotic regimens was performed against a backdrop of optimal oral anti-platelet loading therapy,” said Adnan Kastrati, MD, a professor of cardiology and head of the catheterization laboratory at Deutsches Herzzentrum and Technical University, Munich, Germany. “We hypothesized that in patients who were optimally pre-treated with clopidogrel, bivalirudin would continue to prove superior to unfractionated heparin, at least in terms of safety—by reducing bleeding side effects.”

Bivalirudin has several potential advantages over unfractionated heparin: It does not rely on antithrombin to achieve its effects, it has a more predictable dose–response pattern (and, therefore, does not require routine blood test monitoring) and it has a short plasma half-life, which is important if a patient develops a bleeding problem.

For the study, Dr. Kastrati and his fellow ISAR-REACT 3 investigators recruited 4,570 low-to-intermediate-risk patients who were undergoing PCI for reasons other than heart attack, randomly assigning them to receive either unfractionated heparin or bivalirudin during the procedure. All patients received 600 mg of clopidogrel at least two hours before PCI, and all patients continued to take 75 mg of clopidogrel for at least one month after balloon angioplasty or implantation of bare-metal stents, and for at least six months after implantation of drug-eluting stents. Patients continued to take aspirin indefinitely.

The study will determine whether use of bivalirudin influences rates of bleeding during the initial hospitalization or the 30-day combined rates of death, heart attack or urgent procedure to reopen the treated artery.

“This population under study is important, as it reflects the predominant group undergoing PCI, perhaps up to 70 percent,” said Dr. Kastrati. “Our results may clarify the paradigm for peri-procedural adjunctive therapy in this important group.”

Dr. Kastrati will present the results of the "Intracoronary Stenting and Antithrombotic: Regimen Rapid Early Action for Coronary Treatment 3" (ISAR-REACT 3) study on Saturday, March 29 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.