



**INNOVATION IN INTERVENTION**  
American College of Cardiology in co-sponsorship with SCAI

EMBARGOED FOR RELEASE  
Monday, March 26, 1:30 PM CDT

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## **STUDIES HIGHLIGHT ADVANCES IN DIAGNOSIS, MEDICAL THERAPY AND CORONARY INTERVENTION**

**NEW ORLEANS, La. (March 27, 2007)** — Three studies being presented today at the American College of Cardiology's *Innovation in Intervention: i2 Summit 2007* in New Orleans, La., highlight the breadth of research propelling advances in clinical cardiology. *Innovation in Intervention: i2 Summit* is an annual meeting for practicing cardiovascular interventionalists sponsored by the American College of Cardiology in partnership with the Society for Cardiovascular Angiography and Interventions.

One study explores the best medical and interventional treatment for patients with acute coronary syndromes, the second demonstrates the long-lasting promise of non-surgical approaches to the repair of heart valves, and the third highlights a new drug-exercise combination that, when used in nuclear scanning of the heart, not only improves image quality but also wins the approval of patients by reducing side effects.

### A Prospective, Randomized Trial of Bivalirudin in Acute Coronary Syndromes: Final One-Year Results from the ACUITY Trial (Presentation Number 2414-5)

Use a synthetic version of an anticlotting compound found in the saliva of the medicinal leech results in similar long-term survival but reduces serious bleeding when compared to more complicated existing medical therapy for patients with acute coronary syndromes. The one-year results of the Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) trial suggest that bivalirudin may become an increasingly common therapeutic choice.

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“Given these outcomes, I would expect a further shift toward bivalirudin, based on the reduction in bleeding as well as a reduction in costs and the simplicity of the regimen,” said Dr. Gregg Stone, a professor of medicine at Columbia University Medical Center and chairman of The Cardiovascular Research Foundation, New York City.

Acute coronary syndrome is an umbrella diagnosis that encompasses both unstable chest pain and a type of heart attack known as non-ST elevation myocardial infarction (NSTEMI). Today, drug therapy typically consists of aspirin, clopidogrel, heparin, and glycoprotein IIb/IIIa inhibitors (GPI), each of which interferes at a specific point in the complex events that result in a blood clot in the coronary artery. Patients also typically have angiography within a few days to determine whether further invasive treatment with either angioplasty or bypass surgery is needed to restore full blood flow to the heart.

The ACUITY trial recruited 13,819 patients with moderate-to-high-risk acute coronary syndromes from 450 medical centers in 17 countries, randomly assigning them to one of three treatments: heparin (conventional, unfractionated heparin or a low-molecular-weight alternative, enoxaparin) plus GPI; bivalirudin plus GPI; or bivalirudin alone. A total of 7,789 patients had a catheter procedure in addition to medical therapy, with approximately 60 percent receiving a drug-eluting stent and 37 percent, a bare metal stent.

At one year, death occurred in 4.4 percent of patients treated with heparin plus GPI, 4.2 percent of patients treated with bivalirudin plus GPI, and 3.8 percent of patients treated with bivalirudin alone, differences that were not statistically significant. The trend toward a reduced late death rate among patients treated with bivalirudin alone could be attributed to a reduction in major bleeding at 30 days, which was shown to affect late mortality. At one year, the three groups of patients had nearly identical combined rates of death, heart attack, or unplanned procedures to relieve ischemia, a shortfall of blood and oxygen to the heart muscle (16.3 percent vs. 16.5 percent vs. 16.4 percent, respectively).

“These results, in concert with the 30-day data previously published from ACUITY, demonstrate that bivalirudin alone results in similar rates of long-term survival and freedom from adverse ischemic events as more complicated and expensive medical regimens, and reduces major bleeding, minor bleeding, and the need for blood transfusions while simplifying care in high-risk patients with acute coronary syndromes,” said Dr. Stone.

In the 7,158 patients who were treated with stents, the ACUITY investigators also evaluated the risk of blood clotting, or thrombosis, in or near the stent—a complication that can cause heart attack and even

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death, and has been shown in some studies to be more common with drug-eluting stents. The results of the ACUITY trial showed that, at one year, stent thrombosis occurred in 2.2 percent of patients. A similar rate of stent thrombosis was noted in the 4,630 patients treated with one or more drug-eluting stents (2.2 percent) and the 2,528 patients treated with only bare metal stents (2.3 percent). The rate of stent thrombosis was similar with the three anticlotting regimens tested in the ACUITY trial.

"The incidence of stent thrombosis is a critically relevant topic today, especially in high-risk patients with acute coronary syndromes," said Dr. Stone. "These data, carefully collected and adjudicated by a committee blinded to stent type, provide reassuring evidence that long-term stent thrombosis rates are not higher with drug-eluting stents when compared to bare metal stents," Dr. Stone said.

*Dr. Stone will present the one-year results of the ACUITY trial at a Late Breaking Clinical Trials session on Monday, March 26, at 2 p.m.*

#### Significant Reduction in Mitral Regurgitation Twelve Months Following Percutaneous Mitral Valve Repair: Initial Experience With the MitraClip Device (Presentation Number: 2414-3)

A catheter-mounted device that acts like a clothespin to clip together the flaps of a leaky heart valve is offering patients with moderate-to-severe mitral regurgitation a long-lasting alternative to open-chest surgery. One-year results from the first phase of the Endovascular Valve Edge-to-Edge REpair Studies (EVEREST I) confirm earlier findings that after successful treatment with the MitraClip, a substantial majority of patients continue to experience only mild leakage, or regurgitation, through the mitral valve separating the left atrium (the upper chamber of the heart) from the left ventricle (the lower chamber). Several patients have also been followed-up for three years, with similarly long-lasting benefits.

"We earlier established that we could reduce mitral regurgitation with the MitraClip, and now we've established the durability of the result," said Dr. Ted Feldman, director of the cardiac catheterization laboratory for Evanston Northwestern Healthcare, Evanston, IL. "A large number of patients have had a good enough result that they've been able to delay or completely avoid surgery."

Mounted on the end of a catheter, the MitraClip is threaded through the femoral vein in the groin and into the right atrium. A needle puncture in the wall separating the upper chambers of the heart enables the catheter to pass into the left atrium, where the clip is opened up like a clothespin. It is then passed through the mitral valve into the left ventricle. When the heart contracts, the flaps of the mitral valve fall into the clip,

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which is then closed, pinning the edges of the valve flaps together at their centers. The result is a bow-tie-shaped opening that permits blood flow from the left atrium to the left ventricle during relaxation of the heart, and enables the valve flaps to close more effectively during contraction, rather than allowing leakage of blood backward into the left atrium.

The EVEREST I study, which was conducted to evaluate the safety and feasibility of the MitraClip, recruited 55 patients with moderate-to-severe mitral regurgitation and symptoms such as fatigue and shortness of breath with exercise. Of these, 49 (89 %) received a MitraClip and 42 (76 %) returned home from the hospital with only mild or moderate regurgitation. After one year, 75 percent of patients had avoided surgery and 80 percent of those who had echocardiography to evaluate valve function still had only mild-to-moderate mitral regurgitation, or none at all.

"This is the beginning of a real revolution in valve therapy," Dr. Feldman said. "The EVEREST II study will take the next step, randomly assigning patients to MitraClip therapy or surgery."

*Dr. Feldman will present this study on Monday, March 26, at 1:30 p.m. in La Nouvelle Orleans C.*

A Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Trial of the Safety and Effect on Image Quality and Detection of Perfusion Defects in Patients Undergoing Regadenoson Submaximal Exercise Myocardial Perfusion Imaging Versus Adenosine Supine Myocardial Perfusion Imaging (The RegEx Trial) (Presentation Number: 2414-4)

Regadenoson, an investigational drug being tested in nuclear scans of the heart, appears to be safer, better tolerated and better able to deliver high-quality images than a widely used, commercially available alternative. Researchers in the RegEx study are also evaluating whether incorporating mild exercise into the scan protocol further boosts image quality.

"In nuclear cardiology, images are everything," said Dr. Gregory Thomas, a clinical associate professor of medicine at the University of California Irvine and director of nuclear cardiology at Mission Internal Medical Group, Mission Viejo, CA. "Exercise improves blood flow to the heart instead of the gut, resulting in better images."

Using radioactive tracers and drugs that cause the arteries to dilate, nuclear scanning is able to track blood flow throughout the heart muscle, in a test known as myocardial perfusion imaging (MPI). The RegEx trial is comparing an investigational vasodilator drug, regadenoson, against a commercially available

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alternative, adenosine. Regadenoson is both easier to administer than adenosine and more targeted to the arteries of the heart, a feature that is expected to minimize side effects.

The RegEx study involved 60 patients, all of whom had an adenosine scan while lying at rest on their back. Patients were then randomly assigned in a 2:1 ratio to regadenoson plus radioactive tracer (in preparation for nuclear scanning) or to matching placebos. All patients performed mild exercise. In the end, the randomization scheme resulted in 39 patients in the regadenoson-exercise-nuclear scanning group and 21 patients in the double placebo-exercise group.

Dr. Thomas and his colleagues found that regadenoson could be safely combined with exercise. In addition, patients reported greater acceptance of and fewer side effects with the regadenoson-exercise protocol than with the standard adenosine study. A full 70 percent of patients rated the regadenoson-exercise protocol as much better or somewhat better than the resting adenosine study. In addition, when three experts evaluated side-by-side images, 26 percent said the regadenoson images were of better quality; 74 percent said image quality was similar with the two imaging protocols.

“Adenosine MPI is a very good test. And the use of regadenoson makes MPI even better,” Dr. Thomas said.

*Dr. Thomas will present this study on Monday, March 26, at 1:45 p.m. in La Nouvelle Orleans C.*

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The American College of Cardiology ([www.acc.org](http://www.acc.org)) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.07 and the i2 Summit 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.