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## PAIRING MEDICAL THERAPY WITH CORONARY INTERVENTION FAILS TO REDUCE HEART DISEASE DEATHS

**NEW ORLEANS, La. (March 27, 2007)** — Percutaneous coronary interventions (PCI) involve opening partially blocked arteries to improve blood flow to the heart. These procedures are performed more than 1 million times a year. Since the introduction of PCI more than 30 years ago, there have been enormous advances in the understanding and medical treatment of coronary artery disease. While PCI is known to improve survival when done to restore blood flow in a heart attack, no study has examined the ability of PCI to improve outcomes over and above modern, optimal medical therapy (OMT) in patients with stable coronary disease.

Results of research presented today at the American College of Cardiology's 56<sup>th</sup> Annual Scientific Session showed that PCI combined with OMT was no more effective than OMT alone in preventing heart attacks and other cardiac events among patients with coronary artery disease. The study will be simultaneously published in the *New England Journal of Medicine* and will appear in the April 12 print issue. ACC.07 is the premier cardiovascular medical meeting, bringing together cardiologists and cardiovascular specialists to further breakthroughs in cardiovascular medicine.

During PCI, a doctor inserts a catheter into an artery in a patient's arm or leg and advances the catheter into the coronary arteries where a balloon is inflated to clear the blockage. Usually, a stent (small, lattice-shaped, metal tube) is implanted into an artery to help keep it open. The Clinical Outcomes Utilizing

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Revascularization and Aggressive Drug Evaluation (COURAGE) trial enrolled 2,287 patients at 50 hospitals in the United States and Canada, randomizing them to one of two study arms: PCI and OMT together or OMT alone. Enrolled patients suffered from chronic chest pain (angina pectoris) and had at least a 70 percent blockage of one or more coronary arteries.

Both groups of patients received OMT, which includes guideline-driven intensive treatment with medicines such as aspirin, statins, anti-platelets, nitrates, ACE inhibitors, beta-blockers and calcium channel blockers, as well as lifestyle programs such as smoking cessation, exercise and weight control and nutrition counseling.

A majority of the patients in the study were men (85%) and had experienced chest pain for about two years, with an average of 10 episodes per week (median three episodes per week). Most exhibited several risk factors for heart disease: 29 percent were smokers, 67 percent had hypertension, 38 percent had a prior heart attack, 71 percent had high cholesterol, 27 percent had previous PCI and 69 percent had multi-vessel coronary artery disease. Approximately half of the patients met criteria for metabolic syndrome.

Patients in the study group underwent PCI to clear the affected artery or arteries. Dr. William Boden at Buffalo General Hospital/Kaleida Health in Buffalo, New York and his collaborating investigators followed patients for two-and-a-half to seven years, with a primary endpoint of a death or a non-fatal heart attack.

Results of the study showed a similar rate of death, heart attack or stroke. There were 211 primary events in the PCI group and 202 events in the medical therapy group. The 4.6-year cumulative primary rates of death or non-fatal heart attack were 19.0 percent and 18.5 percent in the PCI and medical therapy groups, respectively.

Hospitalization rates for acute coronary syndrome were similar for both groups as well, at 12.4 percent and 11.8 percent, respectively. There was no statistically significant difference between the rates of heart attack: 13.2 percent in PCI plus OMT patients and 12.3 percent among OMT alone. The one benefit found for the PCI group was less angina compared with the medical therapy group, suggesting that while, on average, PCI does not allow patients to live longer or reduce their chances for a heart attack, it does improve their symptoms and quality of life.

“Conventional wisdom would indicate that PCI and OMT together would be superior to OMT alone. Indeed, that was our initial hypothesis,” said Dr. Boden, lead investigator of the study, which was supported

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by the Department of Veterans Affairs. “But results of the COURAGE trial demonstrate that two treatments are not always better than one. These findings, along with data from recent studies of more than 5,000 patients combined, show that PCI has no impact on reducing major cardiovascular events.”

*Dr. Boden will present this study “A Randomized Trial of Percutaneous Coronary Intervention Added to Optimal Medical Therapy in Patients With Stable Coronary Heart Disease: Results of the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) Trial” on Tuesday, March 27 at 9:10 a.m. in Hall A.*

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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.