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**ISO-OSMOLAR X-RAY DYE FALTERS IN PCI STUDY**

*Hydration, low-osmolar contrast appear as effective  
in preventing kidney injury*

**CHICAGO, Ill. (April 1, 2008)** — A new study has found that an x-ray dye intended to reduce stress on the kidneys did not prevent renal injury during percutaneous coronary intervention (PCI) in patients who already had compromised kidney function. In addition, it made no difference in the need for dialysis or in the length of hospital stay, according to the Contrast Media and Nephrotoxicity Following Coronary Revascularization by Angioplasty (CONTRAST) study.

The CONTRAST study is 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).

Some earlier studies have shown that iodixanol (Visipaque) reduces the risk of kidney damage when moderate doses of x-ray dye, or contrast medium, are used, mainly during diagnostic angiography. This is the first randomized trial to look exclusively at PCI, which involves far higher doses of contrast medium.

Heart disease is a serious health problem for patients with chronic renal failure—and places them in a special bind. Depending on the severity of kidney dysfunction, the risk of suffering a heart attack or another type of cardiovascular event is estimated to be as much as four-fold higher than in patients without chronic renal failure.

“Patients with chronic renal insufficiency have a high need of coronary procedures; however, these procedures involve the use of contrast medium, which may lead to contrast-induced nephropathy, or further kidney damage,” said Rainer Wessely, MD, PhD, an associate professor of medicine at Deutsches Herzzentrum, Technische Universitaet, Munich, Germany. “In addition, since chronic renal failure is associated with a higher incidence of diffuse and complex coronary artery disease, invasive procedures often require the use of elevated contrast volumes.”

In fact, although the risk of contrast-induced nephropathy (CIN) in patients with normal kidney function is very low (far below 1 percent), it is as high as 20 percent to 30 percent in patients with chronic kidney disease. Iodixanol, a contrast agent that has approximately the same osmolality as blood, was designed to reduce the stress on the kidneys and significantly cut the risk of CIN when compared to contrast medium with a higher osmolality.

For the study, Dr. Wessely and his colleagues recruited 324 patients with at least mild renal insufficiency (serum creatinine  $\geq 1.5$  mg/dL or an estimated glomerular filtration rate  $< 60$  mL/min/1.73m<sup>2</sup>) who needed PCI for coronary artery disease. Patients were randomly assigned to receive either iso-osmolar iodixanol (290 mOsm/L) or low-osmolar iomeprol (618 mOsm/L) contrast medium during PCI. All patients received intravenous hydration with a saline solution both before and after the procedure.

Researchers found that the proportion of patients who developed CIN was similar in the two groups (22.2 percent in the iodixanol group vs. 27.7 percent in the iomeprol group,  $p=0.25$ ). Rates of severe CIN were not significantly different (6.2 percent vs. 3.7 percent, respectively,  $p=0.30$ ). The need for dialysis was low in both groups (1.9 percent vs. 0.6 percent,  $p=0.31$ ). Patients remained in the hospital an average of 6.3 days and 6.5 days, respectively ( $p=0.59$ ).

Clinical outcomes were similar as well. After 90 days of follow-up, there was no significant difference in individual and combined rates of heart attack, death and repeat coronary procedure.

*Dr. Wessely will present the results of the "The Contrast Media and Nephrotoxicity Following Coronary Revascularization by Angioplasty" (CONTRAST) study on Tuesday, April 1 at 11:45 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.