



INNOVATION IN INTERVENTION

American College of Cardiology in co-sponsorship with SCAI

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VALUE OF STENT-COATING DRUGS QUESTIONED

NEW ORLEANS, La. (March 26, 2007) — Patients admitted to the hospital with acute coronary syndromes (ACS) are often treated with a catheter-based procedure known as percutaneous coronary intervention (PCI), during which a stent is inserted into an occluded or narrowed coronary artery to restore blood flow to and from the heart. Previous research has shown that rapamycin used in drug-eluting stents (DES) successfully reduces restenosis, or repetitive narrowing of the arteries. But doctors are concerned about cases of delayed reendothelialization – when the layer of flat cells lining the inside of blood vessels are restored – and endothelial dysfunction after rapamycin-eluting stent placement, which could lead to blood clots and later restenosis.

New research about possible additive drugs to help reduce in-stent restenosis was presented today at the American College of Cardiology's *Innovation in Intervention: i2 Summit in New Orleans, La.* *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. The research will also appear in the March 27 print issue of the *Journal of the American College of Cardiology*.

Past research has shown that estradiol promotes rapid reendothelialization of coronary stents in animals and can effectively moderate the release of rapamycin from the coated stent surface. Researchers hypothesized that estradiol might improve the efficacy profile of rapamycin-coated stents. A total of 500 patients undergoing PCIs in a native coronary vessel were enrolled in the ISAR-PEACE study –

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Intracoronary Stenting and Angiographic Restenosis: Promote Endothelial Cells with Estradiol. All enrolled patients were randomly assigned to receive a polymer-free, 17 β estradiolvalerat plus rapamycin-eluting stent or a polymer-free, rapamycin-eluting stent. The stent platform was the ISAR stent with a rough surface, the value of which has been established by several previous studies. A specifically designed rough surface may increase the drug-storing capacity of stents.

All patients received dual-antiplatelet therapy with ASA and clopidogrel for a minimum of six months, were scheduled for a re-angiography at 6-8 months and were contacted at 30 days and at one year for the assessment of the clinical status. Patients with ST-elevation myocardial infarction (MI), cardiogenic shock or a left main disease were excluded from the trial. The primary endpoint of the trial was in-stent late lumen loss. Secondary end points were binary angiographic restenosis, target lesion revascularization, combined incidence of death or MI and the incidence of stent thrombosis.

Researchers found no significant differences between the 17 β estradiolvalerat plus rapamycin-eluting stent group and the rapamycin-eluting stent group according to late lumen loss (0.52 mm vs. 0.51 mm), the incidence of binary angiographic restenosis (17.6% vs. 16.9%), the incidence of target lesion revascularization (14.3% vs. 13.2%), the combined incidence of death and myocardial infarction (7.9% vs. 8.0%) and the incidence of stent thrombosis (0.8% vs. 1.2%).

"The ISAR-PEACE trial represents the largest clinical experience with 17- β -estradiol-eluting stents and the first clinical trial to assess a combination of drugs such as estradiol and rapamycin in the settings of DES technology," said Julinda Mehilli, M.D., of Deutsches Herzzentrum, Munich, Germany, and lead author of the study. "The trial shows that adding estradiol to a polymer-free rapamycin-eluting stent is not associated with any measurable benefit during the first year after PCI. However, further research is needed to fully determine the role of estradiol as a drug used for stent coating."

Dr. Mehilli will present the results of the "Intracoronary Stenting and Angiographic Restenosis: Promote Endothelial Cells with Estradiol (ISAR-PEACE)" study on Monday, March 26 at 11:00 a.m. CDT in room La Nouvelle Orleans C.

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The American College of Cardiology (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 the treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.