



INNOVATION IN INTERVENTION

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NEW BIOABSORBABLE DRUG-ELUTING STENT SHOWS EXCELLENT SAFETY AND PERFORMANCE

NEW ORLEANS, LA (March 24, 2007) — The use of slow-release drugs in stents (drug-eluting stents, or DES) has dramatically reduced restenosis rates after percutaneous coronary intervention (PCI) compared to early bare-metal stent implant rates. However, these permanent metal devices may impair coronary imaging with MRI (magnetic resonance imaging) or CT (computed tomography), predispose patients to late stent thrombosis, prevent positive remodeling and potentially hinder surgical revascularization.

A study presented today at the American College of Cardiology's *Innovation in Intervention: i2 Summit* assesses the safety and overall performance of a new bioabsorbable stent that, if effective, could eliminate several of the problems associated with metallic stents. *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.

In this study, known as the ABSORB Trial, researchers from the Erasmus Medical Center in the Netherlands evaluated the Bioabsorbable Everolimus-Eluting Coronary Stent System (BVS EECSS). The BVS stent has a bioabsorbable structure

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made of polylactic acid – a biodegradable polyester derived from lactic acid – and a coating that controls the release of the drug everolimus – an immunosuppressant to prevent rejection. While metallic drug-eluting stents reside permanently in the treated artery, the BVS stent is designed to be fully absorbed and slowly metabolized by the artery, leaving a healed natural vessel behind.

Researchers enrolled 30 patients at four clinical sites in Europe and New Zealand in the ABSORB Trial. Each patient had one coronary artery lesion and was treated with the BVS stent. Researchers evaluated device success (efficacy), procedural success (ease of deployment and safety), major adverse cardiac events (MACE) and stent thrombosis at 30 and 180 days.

At 30 days, device and procedural success was extremely high – 93.5 and 100 percent respectively – and no patients experienced MACE or stent thrombosis. At 180 days rates of MACE continued to be low at 3.3 percent (one patient with a non-Q wave myocardial infarction) and there were no cases of stent thromboses.

“Early results at one and six months indicate that the BVS stent is safe, effective and easy to deploy,” said Patrick Serruys, M.D., of the Erasmus Medical Center and lead author of the study. “We will continue to follow these patients to determine the long-term safety and performance of the stent, and if it eliminates any of the issues associated with metal stents.”

Dr. Serruys will present this study on Saturday, March 24, at 11:00 am 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 treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.