Drug-Coated Balloon Cuts Restenosis

BY MITCHEL L. ZOLER
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CHICAGO — A coronary-angioplasty balloon coated with paclitaxel produced substantially better outcomes than a bare balloon during 1 year of follow-up in a pair of randomized studies with a total of about 100 patients.

This initial clinical experience showed that inhibition of restenosis "does not require stenting or sustained drug release," Dr. Bruno Scheller said at the annual scientific sessions of the American Heart Association.

"This is a promising technology that appears to be simple, quick, and inexpensive," but it needs testing in many more patients and at multiple centers, said Dr. Debabrata Mukherjee, associate director of the cardiac catheterization laboratory at the University of Kentucky in Lexington.

The Treatment of In-Stent Restenosis by Paclitaxel-Coated Balloon Catheters (PACCOCATH ISR) I and II studies both used balloon catheters coated with 3 mcg paclitaxel/mm^2 that were made by Bavaria Medizin Technologie, a German company that funded the research. The angioplasty catheter without the drug is marketed by the company as Orbus X.

All patients had a restenotic lesion in a stented coronary artery and stable or unstable angina or an abnormal functional study. Lesions lengths had to be less than 30 mm. The patients' average age was 66.

Repeat angiographies after 6 months were available for 96 patients (89%) and showed an average in-segment, late luminal loss of 0.11 mm in the arteries treated with a drug-coated balloon and 0.84 mm in the control arteries, a statistically significant difference in the study's primary end point, reported Dr. Scheller, a cardiologist at the Saarland University Hospital in Homburg/Saar, Germany.

The binary restenosis rate was 6% in patients treated with paclitaxel, and 49% in those who had no drug treatment, also a significant difference. After 6 months the overall rate of major adverse cardiac events was 9% in the drug-treated patients and 39% in the control arm, mostly driven by a large difference in the rate of target lesion revascularization. After 12 months, the adverse cardiac event rate was 10% in the paclitaxel-treated patients and 40% in angioplasty-alone patients. After 18 months' follow-up, the adverse event rates were 10% with paclitaxel and 45% without.

Results for the 52 patients enrolled in PACCAOCATH ISR I were published shortly after Dr. Scheller's report at the meeting (N. Engl. J. Med. 2006;355:2113-24). Results for the combined study group of 108 patients were reported only at the meeting. Study II included patients with more complex lesions than in study I.

The paclitaxel-coated balloon catheter will soon be tested on de novo stenoses in small-diameter coronary arteries, at bifurcations, in tortuous coronaries, and in peripheral arteries, Dr. Scheller said. ■

C5 Complement Inhibitor Flops in Large MI Trial

BY BRUCE JANCIN
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CHICAGO — The investigational C5 complement inhibitor pexelizumab had no effect on mortality or morbidity in a massive clinical trial involving primary percutaneous coronary intervention for ST-elevation MI, Dr. Paul W. Armstrong said at the annual scientific sessions of the American Heart Association.

Based on the negative results of the 5,745-patient Assessment of Pexelizumab in Acute Myocardial Infarction (APEX AMI) trial, pexelizumab now joins the lengthy list of once-promising anti-inflammatory therapies that ultimately failed to prevent myocardial cell damage due to reperfusion therapy, added Dr. Armstrong, professor of medicine at the University of Alberta, Edmonton, and chairman of APEX AMI.

The repeated failed trials have caused some observers to question the whole strategy of trying to improve MI outcomes by impeding the early inflammatory process involved in reperfusion injury.

APEX AMI was a double-blind, placebo-controlled study involving close to 6,000 patients with an anterior or high-risk inferior MI who presented within 6 hours of symptom onset to nearly 300 participating centers in 17 countries. All underwent primary PCI; 36% required transfer to do so, further boosting the overall risk status. Patients got placebo or a bolus of pexelizumab followed by a 24-hour infusion.

The primary end point was 30-day all-