Drug-Eluting Stents Heavily Used Off Label

Off-label applications with the fastest growth were ST-segment elevation MI and in-stent restenosis.

BY BRUCE JANCIN
Denver Bureau

NEW ORLEANS — More than a third of the drug-eluting stents placed in the first 9 months following marketing approval of the Cypher stent were for off-label indications, according to data from the American College of Cardiology—National Cardiovascular Data Registry.

The use of drug-eluting stents rose rapidly during this period, and growth in the off-label uses kept pace with the increase for the approved indication, Sunil V. Rao, M.D., reported at the annual scientific sessions of the American Heart Association.

Dr. Rao presented a unique picture of the clinical adoption of a major new medical technology as reflected in a large national registry experience. The American College of Cardiology—National Cardiovascular Data Registry (ACC-NCDR) is an ACC-initiated quality improvement project that to date includes more than 2 million admissions and 800,000 percutaneous coronary interventions (PCIs) at 528 participating U.S. sites.

The registry data are reassuring in that off-label use of drug-eluting stents was limited to a minority of cases. As of February 2004, 25.5% of the devices were used off label. Physicians appear to be very aware of the risks and benefits of these devices.

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Abciximab During Elective PCI Gave Diabetics No Benefit

BY MITCHEL L. ZOLER
Philadelphia Bureau

NEW ORLEANS — Treatment with abciximab failed to improve the outcomes of patients with diabetes who underwent elective percutaneous coronary interventions in a randomized study with 701 patients.

All patients in the study received a loading dose of 600 mg of the antiplatelet drug clopidogrel at least 2 hours before their percutaneous coronary intervention (PCI), which suggested that clopidogrel treatment “may obviate the need for abciximab during elective PCI in patients at low to intermediate risk,” Julinda Mehilli, M.D., reported at the annual scientific sessions of the American Heart Association.

But the results from this German study, which was not sponsored by a pharmaceutical company, cannot be considered the last word on using a glycoprotein IIb/IIIa platelet inhibitor in patients with diabetes undergoing PCI, said some experts at the meeting.

Dr. Bates was also skeptical of his group’s findings and was concerned about the study’s small size. “It’s a 100-patient study,” he said. “I think we need more studies. I would be more comforted if we had a little bit bigger study.”

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