Abciximab During PCI Seems No Aid to Diabetics

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.

One limitation is that the current study excluded patients with acute coronary syndrome, an acute myocardial infarction, or visible thrombus. "These patients have been the sweet spot for abciximab and other IIb/IIIa inhibitors," commented Gregg W. Stone, M.D., director of cardiovascular research and education at the Cardiovascular Research Foundation of Lenox Hill Hospital in New York.

Other shortcomings of the study included its enrollment of a relatively small number of insulin-dependent diabetics, and the fact that it was underpowered to prove that patients did just as well without abciximab as they did with the drug, commented Eric R. Bates, M.D., a professor of medicine at the University of Michigan, Ann Arbor.

The study was designed as a superiority trial, to prove that abciximab-treated patients fared better than those who didn't get the drug. Dr. Bates was also skeptical that physicians who now use abciximab to treat diabetic patients undergoing elective PCI would be persuaded to change their practice based on the results of a single study.

The study was done at three German hospitals from January 2001 to October 2003. Patients were enrolled if they were on active treatment with either insulin or an oral hypoglycemic agent and were scheduled to undergo an elective PCI in a native coronary vessel. The study's primary end point was the incidence of death or MI during the first 12 months following the procedure.

All patients received a loading dose of clopidogrel plus 500 mg aspirin. Following randomization, patients in the abciximab group received a 0.25-mg/kg bolus followed by a 0.125-mcg/kg per minute infusion for 12 hours, along with 70 U/kg of unfractionated heparin.

Patients in the placebo group received a placebo bolus and infusion, along with a 140-U/kg bolus of heparin. Following their procedure, all patients received a 200-mg daily aspirin dosage that was continued indefinitely. Patients also received 75 mg clopidogrel b.i.d. until discharge or for a maximum of 3 days, and then continued on 75 mg clopidogrel daily for at least 6 months. Patients received other medications as indicated.

After 1 year of follow-up, the incidence of death or MI was essentially identical in the two groups: 8.3% among the 351 patients treated with abciximab, and 8.6% among those treated with placebo, reported Dr. Mehilli of the German Heart Center in Munich.

The secondary end point of the study was the incidence of angiographic restenosis at follow-up. By this criterion, the abciximab group did better: Angiographic restenosis occurred in 28.9% of the patients in the abciximab group, compared with 37.8% of placebo patients, a statistically significant difference.

But this result is already outdated because the study was done largely before the advent of drug-eluting stents. Only 10% of the patients received drug-eluting stents; in this small subgroup, treatment with abciximab conferred no significant advantage over placebo.

The edge in restenosis conferred by abciximab "would have been a very important finding 2 years ago, but now it's too little too late," said Dr. Stone. "Drug-eluting stents are clearly the treatment of choice to reduce restenosis in patients with diabetes, and no drug has been shown to reduce restenosis when used on top of drug-eluting stents," he said. ■

Pages 16a—16b