Bleeding Drops in Elective PCI With Bivalirudin

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WASHINGTON — The risk of adverse events such as major bleeding during elective coronary artery stenting is significantly lower when the procedure is performed with bivalirudin antithrombotic monotherapy than with other combinations based on unfractionated heparin, according to two Italian randomized trials.

The antithrombotic effects of bivalirudin have been shown to reduce bleeding rates after percutaneous coronary intervention (PCI), compared with unfractionated heparin (UFH) alone, but few data exist that compare bivalirudin monotherapy with UFH in combination with a glycoprotein (GP) IIb/IIIa inhibitor such as tirofiban (Aggrastat) or with the heparin-reversing drug protamine.

One of bivalirudin's advantages over UFH is its short, 25-minute half-life. Investigators in the ARNO (Antithrombotic Regimens and Outcome) trial tried to see if this advantage could be equalized by administering protamine immediately after PCI to reverse the effects of UFH.

The ARNO trial featured 850 patients who were randomized to bivalirudin (Angiomax) or UFH plus protamine. Patients in both arms had a mean age of about 69 years; 22% had diabetes.

Bivalirudin monotherapy was associated with significantly fewer in-hospital major bleeding events than was therapy with UFH and protamine (0.5% and 2.1%, respectively). At 1 month after the procedure, bivalirudin still was associated with significantly fewer major bleeding events (0.9% vs. 2.8%), Dr. David Antoniucci reported at Transcatheter Cardiovascular Therapeutic 2008.

The combined rate of MI, target vessel revascularization, and death at 1 month was significantly lower in bivalirudin-treated patients (2.8%) than in heparin-treated patients (6.4%), said Dr. Antoniucci of the cardiology division at Careggi Hospital, Florence, Italy.

The second trial presented was conducted to determine the safety of bivalirudin in diabetic patients undergoing PCI by Dr. Carlo Briguori and his coinvestigators in the interventional cardiology laboratory at Clinica Mediterranea, Naples, Italy. They randomized 335 diabetic patients with an average age of about 65 years to treatment with either bivalirudin alone or UFH plus tirofiban. Aspirin and clopidogrel (Plavix) were given before the procedure to all patients in the trial, called NAPLES (Novel Approaches for Preventing or Limiting Event Study). The severity of bleeding risk was distributed similarly in both groups of diabetic patients.

Despite having diabetes, only 13% of the patients had multivessel disease. Only 11%-19% of the patients had unstable angina. None had acute coronary syndrome with elevated biomarkers.

Bivalirudin was associated with a significantly lower rate of adverse clinical events than was UFH plus tirofiban (12% vs. 21%, respectively). The difference was due primarily to a significantly higher rate of bleeding of 8% in the combination therapy patients, compared with the 2% rate in bivalirudin-treated patients.

In both ARNO and NAPLES, patients received aspirin and clopidogrel before undergoing PCI. Bivalirudin was administered in a single 0.75-mg/kg IV bolus, followed by an infusion of 1.75 mg/kg per hour during PCI. Patients in the NAPLES trial received 70 U/kg UFH, followed by additional boluses if their activated clotting time was less than 250 seconds, whereas those in the ARNO trial initially received 100 U/kg UFH.

Both Dr. Antoniucci and Dr. Briguori reported having no financial conflicts of interest related to their studies. ■

New Carotid Stent

The Food and Drug Administration has approved the Carotid Wallstent Monorail Endoprosthesis for treatment of patients with carotid artery disease who are at high risk of surgery. The stent's closed-cell design is engineered for optimal lesion coverage. It is the leading carotid artery stent in Europe and other international markets. For more information, contact Boston Scientific Corp. by visiting www.bostonscientific.com. ■