DES Beats BMS for Saphenous Vein Graft Stenosis

BY ALICE GOODMAN

FROM THE ANNUAL MEETING OF THE AMERICAN COLLEGE OF CARDIOLOGY

NEW ORLEANS – Drug-eluting stents outperformed bare-metal stents when placed in saphenous vein graft lesions that developed post–coronary artery bypass graft, in ISAR-CABG, the largest study ever performed to compare these two types of stents in this setting.

Specifically, DES significantly reduced the rate for the combined primary end point of death, MI, and repeat revascularization procedures.

"This study shows us that we don't have to be afraid of DES in patients with these high-risk lesions, because use of DES cuts down the need for target vessel revascularization by 50% and does not increase myocardial infarction mortality and stent thrombosis formation when compared with BMS [bare-metal stents]," Dr. Julinda Mehilli, director of clinical research and data coordinating ISAR (Intracoronary Stenting and Antithrombotic Regimen) at the German Heart Center in Munich, said at the meeting.

ISAR-CABG enrolled 610 patients who underwent a first CABG with a saphenous vein graft and developed at least one stenotic lesion of at least 50% in the graft. Patients were randomized to receive either a DES or a BMS in a 1:1 ratio. In the DES group, patients were assigned 1:1:1 to three commonly used types of stents (sirolimus, paclitaxel, and biodegradable sirolimus) to mirror real-world use, Dr. Mehilli explained.

The primary end point was a composite of death, myocardial infarction, and target-vessel revascularization at 1 year of follow-up after percutaneous

coronary intervention for stent placement. Secondary end points were each of those events separately, as well as ARC (Academic Research Consortium)-definite stent thrombosis.

Both groups had comparable characteristics at baseline. Their mean age was about 71.5 years, and the age of their stents averaged 13.5 years; about 15% were female, about 72% had hypertension, about 36% had diabetes, about 7% were current smokers, about 87% had hyperlipidemia, and about 55% had a previous MI. Also, disease characteristics were similar between the two groups. About 50% of patients had diffuse disease. More than 60% had unstable angina, and 99% had multivessel disease. Lesions were evenly distributed in the saphenous vein graft. The degeneration score for saphenous vein grafts and the distribution of lesions within the graft were similar between groups, with about 40% of patients having moderate or severely degenerative grafts.

At 1 year, the primary end point was reduced by a significant 35% with DES, compared with BMS, with rates of 15.4% and 22.1%, respectively. The reduction in the DES group was driven primarily by a significant 52% reduction in target vessel revascularizations, which occurred in 7.2% of the DES patients, compared with 13.1% of the BMS recipients.

Both types of stent were comparable in safety, with a similar rate of stent thrombosis, death, or myocardial infarction, said Dr. Mehilli. The rates of all-cause death or MI were similar between the two groups, at 8.5% and 10.9% of patients in the DES and BMS groups, respectively. One patient and zero patients, respectively, experienced ARC-definite stent thrombosis.

"Although saphenous vein graft lesions remain a challenging disease subset for angioplasty, this study demonstrates that DES can be safely used to reduce adverse events in this high-risk subset of patients," Dr. Mehilli said.

She noted that, in Germany, the overwhelming majority of stents used in saphenous vein graft lesions are DES, and that the current study supports this practice.

The study was funded by the German Heart Center in Munich and by Cordis. Dr. Mehilli has received lecture fees from Abbott. ■

Keep Antiplatelet Interruptions as Brief as Possible

EXPERT ANALYSIS FROM THE ANNUAL ACADEMIC SURGICAL CONGRESS

HUNTINGTON BEACH, CALIF. – Patients with recently placed coronary stents who are on clopidogrel may need to discontinue the drug to prevent excessive bleeding during surgery, but it should be restarted as soon as possible, according to Dr. Alan Dardik.

Continuing antiplatelet therapy during the perioperative period is crucial, he noted, because "the risk of surgical bleeding, if dual-antiplatelet therapy is continued, is actually lower than the risk of coronary thrombosis due to agent withdrawal."

Antiplatelet drugs pose a considerable bleeding risk: Aspirin can increase surgical blood loss up to 20%, and dual therapy up to 50%. According to Dr. Dardik, however, although "many studies show a small increase in complications from this bleeding, particularly increased transfusions, no study has actually shown an increase in mortality."

Meanwhile, the risk of a fatal myocardial infarction is high when antiplatelet therapy is withdrawn, especially within 6 weeks of stent placement. The risk is especially high in patients with cancer, diabetes, and other hypercoagulable states, and in those with long, multiple, or overlapping stents, Dr. Dardik said.

"Keep the nontherapeutic window short, from about 3 days before the surgery to 1-2 days afterward, [and] reload [patients] at high risk for thrombosis with 300 mg of clopidogrel," Dr. Dardik said at the meeting.

Since dual-antiplatelet therapy is standard for 6 months following stent placement, patients on clopidogrel (Plavix) will almost certainly also be on aspirin. To offset the temporary loss of clopidogrel, he recommended increasing the aspirin dose, said Dr. Dardik, a vascular surgeon at Yale University, New Haven, Conn.

The best option for recently stented patients is to postpone surgery for at least 6 months – the point at which dual-antiplatelet therapy can be stopped – or even a year, when aspirin can also cease. When that's not possible, Dr. Dardik recommends performing a less invasive procedure, with easier hemostasis.

He said he has no relevant disclosures.

–M. Alexander Otto