DES Boosted Survival in Primary PCI Patients

Higher 5-year survival with drug-eluting stents shows safety in setting of myocardial infarction.

BY MITCHEL L. ZOLER

FROM THE ANNUAL MEETING OF THE AMERICAN COLLEGE OF CARDIOLOGY

NEW ORLEANS – Acute myocardial infarction patients treated with a drug-eluting coronary stent during a primary percutaneous coronary intervention had significantly better 5-year survival, compared with myocardial infarction patients who received a bare-metal stent, in a review of more than 12,000 patients treated in New Jersey during 2003-2004.

Although this analysis could not take into account selection biases that might have determined whether patients received drug-eluting or bare-metal stents, the findings in general provide reassurance about the safety of drug-eluting coronary stents for patients with an acute MI, Dr. Tudor D. Vagaonescu said at the meeting.

"These data are consistent with the idea that using drug-eluting stents in the setting of an acute MI is safe," said Dr. Vagaonescu, a cardiologist at the Robert Wood Johnson Medical School, New Brunswick, N.J.

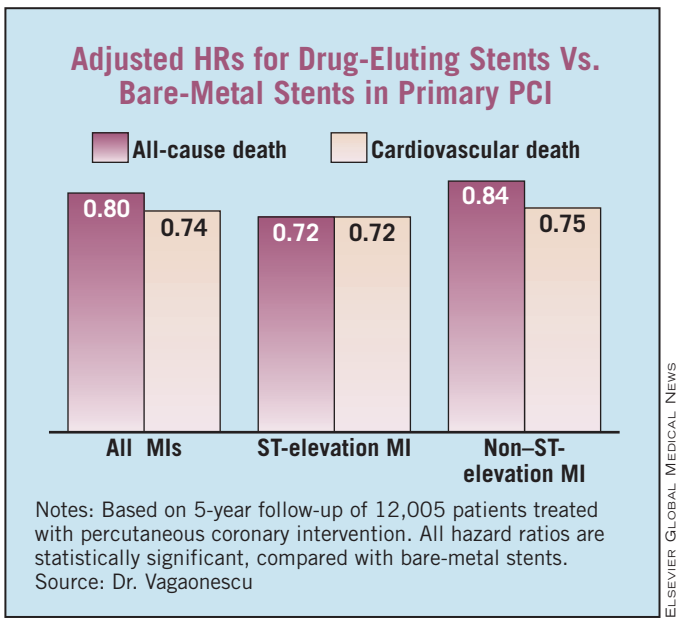
"Our data show that preventing the need for revascularization by using drug-eluting stents [DES] helped with survival, although improved survival was likely due to a combination of things, including selection bias and the type of index event," he said in an interview.

The study used data collected in the Myocardial Infarction Data Acquisition System (MIDAS) registry and included all patients who underwent primary PCI for an acute MI at a nonfederal hospital in New Jersey during 2003-2004. The group included 6,172 patients treated with one or more drug-eluting coronary stents only, and 5,833 patients treated with one or more bare-metal stents only. The analysis excluded patients who received both stent types.

Based on New Jersey death registration files, during the 5 years following stent placement, cumulative all-cause mortality in the DES recipients was 16% and was 20% in the bare-metal stent recipients, a statistically significant difference. The rate of cardiovascular death was 8% and 10% in the drug-eluting and bare-metal stent groups, respectively, also a statistically significant difference. Similar, statistically significant differences in favor of improved 5-year total survival and reduced cardiovascular deaths with DES also occurred in both the subset of patients with ST-elevation myocardial infarction and in patients with non–ST-elevation myocardial infarction, Dr. Vagaonescu reported.

He and his associates also performed multivariate analyses of mortality rates adjusted by age, sex, race, diabetes, hypertension, renal disease, anemia, cancer, cerebrovascular disease, prior MI, and treatment with a glycoprotein IIb/IIIa inhibitor. All of these multivariate analyses showed statistically significant survival advantages for the patients who received drug-eluting stents (see graph).

Another aspect of the analysis showed the dramatic shift toward use of DES for primary PCI during the period studied, which covered the time when the first sirolimus-eluting stent received Food and Drug Administration approval in April 2003, and when the first paclitaxel-eluting coronary stent received FDA approval in March 2004. In 2003, 73% of the 6,027 patients who received a single type of coronary stent for primary PCI in New Jersey received a bare-metal stent. By 2004, this pattern flipped, and 76% of the 5,978 patients who received a single type of coronary stent for primary PCI received a drug-eluting stent. Both years predated the reports in 2006 that first raised awareness of the risk for stent thrombosis in patients who received a DES, especially patients who prematurely stopped dual-antiplatelet therapy. ■



Notes: Based on 5-year follow-up of 12,005 patients treated with percutaneous coronary intervention. All hazard ratios are statistically significant, compared with bare-metal stents.
Source: Dr. Vagaonescu

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Major Finding: Acute myocardial infarction patients treated with drug-eluting coronary stents had a 16% mortality rate during 5 years of follow-up, significantly better than the 20% mortality rate in patients treated with bare-metal stents.

Data Source: Review of 12,005 New Jersey patients treated with primary percutaneous coronary intervention during 2003-2004.

Disclosures: Dr. Vagaonescu said that he had no disclosures.

VIEW ON THE NEWS

Jury Out on First-Generation DES

A major concern when using drug-eluting coronary stents to treat acute myocardial infarction is the risk of late stent thrombosis, especially with the first-generation drug-eluting stents, the sirolimus-eluting Cypher and the paclitaxel-eluting Taxus stents.

For several years, since evidence established a link between long-term dual-antiplatelet therapy and reduced stent thrombosis, the issue has been can an acute myocardial infarction patient reliably remain on dual-antiplatelet therapy for at least 1 year. This information is often difficult to know in the emergency department at the time of primary percutaneous coronary intervention.

This concern has been balanced by the very respectable performance of bare-metal stents when placed in acute myocardial infarction patients. Experience has taught us that when you have doubt about a patient's willingness or ability to remain on dual-antiplatelet therapy, there is nothing wrong with using a bare-metal stent.

What's unclear is the potential role for the second-generation drug eluting stents for primary percutaneous coronary interventions. The everolimus-eluting stents seem to have a reduced risk for late thrombosis, compared with the first-generation stents in patients without an acute myocardial infarction. We'd like to know the performance of second-generation drug-eluting stents in myocardial infarction patients, but we currently have no evidence about this.

The data presented by Dr. Vagaonescu do not provide a solid case for using first-generation drug-eluting stents in myocardial infarction patients. These data came from a retrospective review, and the patients involved were very heterogeneous. It's just a first step toward understanding, in a broad group of patients, how drug-eluting and bare-metal stents perform in myocardial infarction patients.

DAVID G. RIZK, M.D., *is an interventional cardiologist and director of the division of heart and vascular medicine at the Scottsdale (Ariz.) Healthcare Hospital. His comments were made in an interview. He said that he had no disclosures.*

FDA Expands Carotid Stent Indication to Standard-Risk Patients

BY MARY ELLEN SCHNEIDER

The Food and Drug Administration expanded the indication for the RX Acculink carotid stent, allowing it to be marketed for use in patients with carotid artery disease who do not face an increased risk of complications from surgery.

The RX Acculink stent, which is marketed by Abbott Vascular, a subsidiary of Abbott Laboratories, was originally approved by the FDA in 2004. At that time, the stent was approved for patients at high risk of complications from carotid endarterectomy.

The company sought an expanded approval based on the results of the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST), a randomized, multicenter, noninferiority study sponsored by the National Institutes of Health and funded in part by the manufacturer.

The study of more than 2,500 patients in the United States and Canada showed that at 1 year, patients who were treated with RX Acculink had a combined 30-day rate of death, stroke, and myocardial infarction, and a 31 to 365-day rate of ipsilateral stroke, of 7.1%, compared with 6.6% among those who underwent endarterectomy, a difference that met the prespecified criteria for noninferiority.

As a condition of the expanded approval, the FDA is requiring Abbott Vascular to conduct a postapproval study. The study would follow new patients treated with RX Acculink for at least 3 years to confirm the results from the CREST study.

The FDA has also asked the manufacturer to look at how patients aged 80 years and older respond to treatment and whether patients who show symptoms prior to treatment experience different outcomes than those who don't exhibit symptoms.

The FDA's action follows a recommendation from the Circulatory System Devices Panel. In January, a majority of those experts voted that the benefits of using the RX Acculink stent outweighed the risks when used in patients at standard risk for surgery. ■