Uses for Drug-Eluting Stents Are Rising Rapidly

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Despite their higher cost, and despite recent concerns about late thrombosis, drug-eluting stents now dominate.

In the final 3 months of 2004, drug-eluting stents were estimated to have been used for 87% of all interventional coronary procedures in the United States, Martin B. Leon, M.D., said last November at the American Heart Association's scientific sessions in New Orleans. Less than 2 years earlier, not a single drug-eluting stent had been used in the United States outside of a clinical trial. The Food and Drug Administration first approved a drug-eluting stent in April 2003.

"We have not yet identified any subsets of patients who don't benefit from receiving drug-eluting stents [by having less restenosis] compared with bare metal stents," said David J. Cohen, M.D., associate director of interventional cardiology at Beth Israel Deaconess Medical Center in Boston. "De facto practice in the United States today is to use drug-eluting stents whenever the available stent lengths and diameters fit. At Beth Israel Deaconess, most of the time when patients [who are undergoing coronary stenting] don't receive drug-eluting stents it's because the vessel is too small or too large to accommodate available stent sizes," he told this newspaper.

They are so widespread that medicolegal concerns may now drive their use even more than purely clinical factors. "When the risk of restenosis is low, operators must balance the need for drug-eluting stents with the medicolegal risk of avoiding what has become the de facto standard of care for all patients," said Herbert D. Aronow, M.D., director of the cardiac catheterization laboratories at the Veterans Affairs Medical Center in Philadelphia.

According to one study, in 2003, about a third of all sirolimus-eluting (Cypher) stents used in the United States were for off-label coronary artery indications (CARDIOLOGY NEWS, February 2005, p. 15).

As of early this year, no cardiology society had issued formal recommendations on the appropriate uses of drug-eluting stents, although these are expected soon. In the meantime, some experts have given their personal opinions.

One set of standards was laid out by Gregg W. Stone, M.D., in a talk at the AHA scientific session. "In workhorse lesions, in patients undergoing elective coronary interventions with de novo lesions up to 46 mm in length and in vessels with reference diameters of 2.5-3.75 mm without acute coronary syndrome or acute MI, in general the safety and efficacy of two drug-eluting stents, Cypher and Taxus [paclitaxel-eluting], has been proved," said Dr. Stone, an interventional cardiologist at Columbia University in New York. "Using drug-eluting stents over bare metal stents in these lesions is the appropriate thing to do."

But, he added, "we desperately need more data regarding the safety and efficacy of drug-eluting stents in unapproved and high-risk indications before their use should be considered routine. … You need to be aware of the evidence so you know what you are doing."

A step was taken this past March to better define the safety and efficacy of drug-eluting stents in more complex vessels and lesions, with reports from two studies at the annual meeting of the American College of Cardiology. A Danish study with 322 patients compared sirolimus-eluting with bare-metal stents in patients with total occlusions, lesions at bifurcations, ostial lesions, and lesions in angulated arteries. Patients who received drug-eluting stents had better angiographic and clinical outcomes. A second report involved more than 1,100 patients who were treated with either paclitaxel-eluting or bare metal stents. The results showed that the drug-eluting stents were superior in coronaries narrower than 2.25 mm and in wide arteries.

According to Dr. Stone last November, there are also grounds for using a single drug-eluting stent to treat in-stent restenosis within a bare metal stent. But he cautioned physicians to "think twice" about using drug-eluting stents outside of a study for unprotected left main disease, in-stent restenosis following failed brachytherapy, and in patients with acute myocardial infarction. There is even less evidence on using drug-eluting stents for V-stenting of a bifurcation, and it is completely unclear how cardiologists should manage restenosis within a drug-eluting stent. ■