Use of Drug-Eluting Stents Drops Over Past Year

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Interventional cardiology is feeling its way toward a new consensus on when to use drug-eluting coronary stents, or coronary stents of any type, be they drug eluting or bare metal.

Fueled by concern about an increased risk of thrombosis in patients who receive drug-eluting stents (DES), compared with the bare-metal variety, cardiologists agree that DES should not be placed in patients who are not sure to stay on dual antiplatelet therapy with aspirin and clopidogrel (Plavix) without interruption for at least 1 year.

Adding to the flux was a landmark report last March at the annual meeting of the American College of Cardiology on the safety of deferring coronary stenting in selected patients with stable coronary disease. Results from the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial (N. Engl. J. Med. 2007;356:1503-16) may have contributed to a small drop in stent use overall.

Other shifts in use of DES have also been occurring but are harder to pin down. Off-label use of DES in complicated patients has drawn increased scrutiny in recent months because their risk of thrombosis is higher than the risk in patients for whom DES have labeled approval. But cardiologists are quick to add that complicated patients are the ones who stand to gain the most from the reduced incidence of restenosis with DES.

Aside from avoiding placement of DES when dual antiplatelet therapy can't be assured, "the only consensus is that everyone has become much more deeply thoughtful" about using them, said Dr. Mitchell W. Krucoff, a cardiologist and professor of medicine at Duke University, Durham, N.C. DES use is no longer the "runaway train" it was a couple of years ago, when virtually all coronary stents placed in U.S. patients were drug-eluting stents.

"I've been a little more thoughtful about which stent I use," agreed Dr. Eric R. Bates, a cardiologist and professor of medicine at the University of Michigan, Ann Arbor. "In the past, I was just using DES in everybody."

"It's a pullback from what was probably too much [DES use] to what's probably right," said Dr. Deepak L. Bhatt, a cardiologist at the Cleveland Clinic.

The drop is documented in recent statistics on DES use.

This past June, DES were used for about 71% of all patients receiving a coronary stent, according to data collected in 75 representative hospitals throughout the United States by Goodroe Healthcare Solutions LLC. A year earlier, in July 2006, about 86% of all coronary stenting at the same hospitals used DES.

Expressed a different way, Goodroe found that last January about 72% of all coronary intervention procedures used a DES, about 22% used bare-metal stents (BMS), and about 6% involved balloon angioplasty only with no stent. Five months later, in June, DES use had dropped to 66% of all coronary procedures, with BMS use rising to 26% and balloon angioplasty up to 8%. (See box.)

DES manufacturers report a similar picture. In July, Johnson & Johnson, which markets the sirolimus-eluting coronary stent (Cypher), and Boston Scientific Corp., which sells the paclitaxel-eluting stent (Taxus), both reported that U.S. sales of these stents during April-June 2007 were down by about 40%, compared with the same quarter in 2006.

For stable patients, 'why not try medical therapy first before whisking them to the cath lab?'

DR. BHATT

An informal survey of a handful of cardiologists showed the clinical side of the story. At Piedmont Hospital in Atlanta, the use of DES has shifted from "close to 90%" of patients receiving coronary stents a few years ago to "about 70%-75%," said Dr. Spencer B. King III, chairman of interventional cardiology at the hospital. At Duke, DES use dropped from about 85% of all coronary stents a year or so ago to about 75%, Dr. Krucoff said in an interview. Dr. Bhatt estimated the change in use at the Cleveland Clinic to be about 10%-15% less than a year ago.

Which patients were receiving DES last year but are now getting BMS instead?

One clear answer: those who can't be relied on to take aspirin and clopidogrel for at least 1 year, the length of treatment that's now recommended to prevent stent thrombosis and the death or MI that could result from a clot forming in a stented artery. A patient's ability to stay on the regimen might be suspect because of a history of poor compliance; anticipated difficulty in affording expensive clopidogrel (about $4 a day); a history of bleeding problems, such as a chronic ulcer; an existing warfarin regimen because of atrial fibrillation; or pending surgery that might mean stopping one or both drugs for a few days. Patients undergoing stenting for an acute myocardial infarction also usually get BMS because their ability to stick with long-term antiplatelet therapy is uncertain as they receive emergency treatment.

About three-quarters of the drop in DES use at Duke has been in patients who face a problem with long-term aspirin and clopidogrel dosing, Dr. Krucoff said.

The other, smaller part of the DES decline has been in patients who are now seen as more likely to benefit from a BMS instead of a DES. Although some rough definitions of the patients who fall into this category are emerging, cardiologists stress that the choice between a drug-eluting or bare-metal stent is individualized, and involves a discussion with each patient about the risks and benefits.

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Bare-metal stents are now used in those who can't be relied on to take aspirin and clopidogrel for at least 1 year.

"We are using BMS more than DES in patients at low risk of restenosis—for example, in patients without diabetes [and/or] with larger vessels—and in short lesions. We tend to reserve DES for patients with a moderate or high risk of restenosis," said Dr. Peter B. Berger, a cardiologist and associate chief research officer at the Geisinger Medical Center, Danville, Pa.

Dr. Krucoff says that he and his associates now use BMS in vein grafts and in patients with acute ST-elevation myocardial infarction. These are the vessels and lesions with "a histology that's known to be associated with blood clots and where I worry more about endothelial healing," he said.

Another side of changing stent use has been a modest but discernible decline in total stent use over the past year. The data collected at 75 U.S. hospitals by Goodroe Healthcare Solutions showed that during the first 6 months of 2007, overall use of coronary stents fell by about 8%. This is corroborated by about an 11% fall in sales of all coronary stents, both DES and BMS, reported by manufacturers, said Joane Goodroe in an interview. "This is the first time we've ever seen an overall decrease in interventional cases." Data from the surveyed hospitals failed to show any change in the rate of coronary artery bypass grafting during this period, added Ms. Goodroe, president of the company.

The downturn in stenting may have been spurred in part by the COURAGE results, which showed that certain patients with stable coronary disease can safely be initially managed with medical treatment only, deferring stenting until the patient or physician decides it's unavoidable. But some cardiologists were skeptical that the results from a single study—even one that had as much media attention as COURAGE—could change practice so quickly. They see a slight reduction in stenting as part of a management trend that began well before last March.

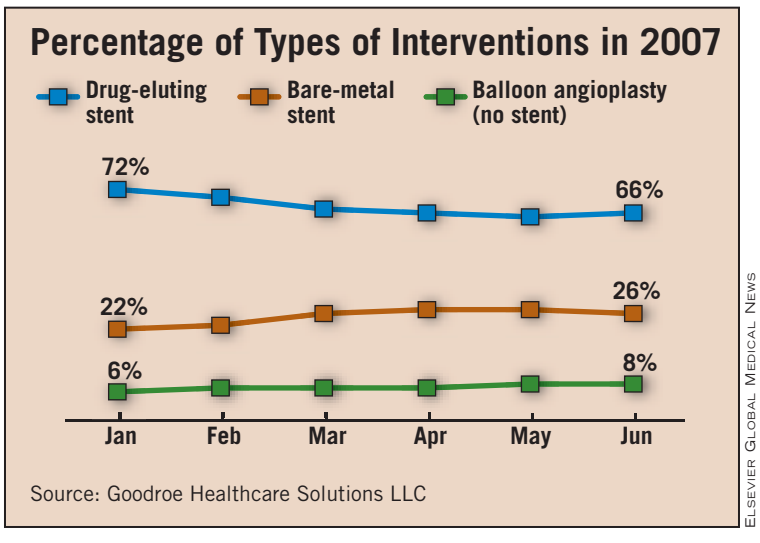
"I think what we're seeing is much more risk factor reduction and use of statins," said Dr. Neal S. Kleiman, director of the cardiac catheterization laboratory at the Methodist DeBakey Heart Center, Houston. "Physicians used to put patients on trivial doses of statins. Now everyone is on 40 mg or 80 mg of atorvastatin [Lipitor]. I think it will take awhile for the effect of COURAGE to percolate down," he said in an interview.

"COURAGE addressed a very circumscribed group of patients. [The investigators] screened about 35,000 patients to find about 3,000 eligible patients" with stable coronary disease who had also undergone an angiogram, Dr. King noted. The randomized group was also limited to patients who were rated by their physicians as having the equipoise for immediate treatment with either stenting or medical therapy only. About a third of the patients in the medical arm eventually had stenting during about 4 years of follow-up. "If physicians practiced using the COURAGE strategy, it should reduce stenting, but by just a little bit," Dr. King said.

"COURAGE hasn't changed how I decide to put in stents, but it's changed a lot of the conversations I have with patients because of the media hype. Patients say, 'Doc, you're not going to put one of those stents in me, are you?' " Dr. Krucoff said.

"COURAGE caused a perfect storm of media attention, because the results came along when concerns about DES were almost peaking," Dr. Bhatt said. "The combination may have contributed to reduced stent use nationwide. Everyone sees stent use down from a year ago.

"Most patients at academic centers were already being treated in COURAGE fashion, but it might be different in private practice," Dr. Bhatt continued. "The COURAGE results and concerns about thrombosis may influence referring cardiologists and primary care physicians. They may now think twice about stable patients: Why not try medical therapy first before whisking them to the cath lab?" ■



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