Drug-Coated Stents: The Real Risks
Use for Complex Heart Disease May Be Riskier Than Once Thought

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May 8, 2007 - For about half of patients who've been getting them, drug-coated stents are more risky than previously thought.

Drug-coated stents don't clog up as easily as bare-metal stents. They've been tested -- and approved -- only in patients with relatively mild coronary heart disease. But doctors have been using these devices "off label" in far more complex cases.

What kind of risk does this off-label use mean for patients? Two new studies look at the issue. Both show that "off-label" or "untested" use of the drug-coated stent approximately doubled a patient's short-term risk of death, heart attack, dangerous blood clot, or reclogging of the artery.

Neal S. Kleiman, MD, director of the cardiac catheterization lab at Houston's Methodist DeBakey Heart Center, led a study of 3,323 patients at 42 different U.S. hospitals who got at least one drug-coated stent.

While still in the hospital, the off-label patients had a small (0.4%) but higher risk of developing a dangerous blood clot in their stents. A year after getting their stents, the off-label patients still had more than twice the risk of death, heart attack, or reclogging (17.5%) as the on-label patients (8.9%).

"We knew before that patients who fell into these off-label categories were at higher risk -- we just didn't know how much higher," Kleiman tells WebMD. "Now we know their risk is 2.25 to 2.5 times higher. And we know what patient characteristics confer the risk."

Charles J. Davidson, MD, director of the cardiac catheterization lab at Northwestern Memorial Hospital in Chicago, and colleagues studied 5,541 patients who got drug-coated stents at 140 U.S. hospitals.

They found a greater than twofold higher risk of death, heart attack, and stent clotting in the patients with off-label stents. But after adjusting for disease severity, the safety of drug-coated stents was similar in both the on- and off-label groups.

"We found that compared to standard [on-label] use, there was about a half a percent higher risk of death or heart attack when patients got [drug-coated] stents off label," Davidson tells WebMD. "At first glance one would be concerned this was about twice that of the standard group, but at second look, less than 1% of the off-label patients had any adverse event. The difference was related to the patient factors. The device performed just as well off-label as it did in standard indications."
Both studies appear in the May 9 issue of *The Journal of the American Medical Association*.

**Putting Stent Risk Into Perspective**

What does all this mean to the patient who is considering getting a drug-coated stent?

Robert A. Harrington, MD, professor of medicine at Duke University and director of the Duke Clinical Research Institute, is an interventional cardiologist who has studied the stent issue.

The problem, Harrington says in an editorial accompanying the new studies, is that the U.S. device-safety system is flawed. There simply isn't a reliable system for systematically following up on -- and reporting -- what happens when newly approved implanted devices are used in the real world.

So what patients should do, Harrington says, is ask their doctors about the evidence that a drug-coated stent would be effective and safe for them as individuals.

If a patient is in the "on-label" group, the evidence is good. If the patient is in the "off-label" group, there isn't a lot of evidence -- and doctors should explain why they think a drug-coated stent's benefits might outweigh its risks.

"Doctors need to say, yes, we know that when we use these devices off label, there is a higher risk," Harrington tells WebMD. "The doctor should say, 'Here is how I interpret the evidence available, and here is how it applies to your situation.' This does not mean don't use the stents outside their approved indications, but if you start to do that, you'd better have a pretty good reading on what the risks are."

All of the experts who spoke to WebMD stressed one additional point: Anyone who gets a drug-coated stent, on- or off-label, must be willing to take anticlotting medications for a year or more.