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Posted on Sun, Mar. 06, 2005

Drug-coated stents transform heart care

MARILYNN MARCHIONE
Associated Press

ORLANDO, Fla. - A new generation of tiny, drug-coated metal scaffolds that prop open arteries has transformed heart care in just a few years and is allowing a growing number of people to avoid having bypass surgery.

The devices, called drug-coated stents, slowly release medication that prevents vessels from relogging after procedures to open them up.

At an American College of Cardiology conference on Sunday, doctors reported that both brands sold today are equally great at keeping blood flowing smoothly, although one might be better for diabetics. Both were vastly better than the plain old metal ones that were standard just a few years ago.

Benefits apparently last for years, and even very big blockages in very small vessels can be fixed this way. The devices work so well that when an older stent clogs, it's better to put a new drug-coated one inside it than to treat the problem with radiation as has been done in the past, one study found.

Competitors also are being developed that could help cut the price of these devices. One novel type even dissolves in the body once its job is done.

"It's looking very good," Dr. Gerald Fletcher, a Mayo Clinic cardiologist, said of the evidence for drug-coated stents. "The benefit is going to be substantial in the long term."

Clogged arteries can cause a heart attack. One solution is open-heart bypass surgery, in which blood vessels from elsewhere in the body are used to create detours around blockages.

A less drastic treatment is angioplasty, in which a tiny balloon is snaked through blood vessels to blockages and inflated to flatten them. Nearly a million of these are done each year in the United States, and in most cases, a stent is placed to keep the artery from squeezing shut again.

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But even these reclogged about one-fourth of the time until drug-coated ones came along and cut the rate to around 5 percent. The first, Cypher, made by Cordis Corp., a Johnson & Johnson company, went on sale in Europe in 2002 and in the United States a year later. Boston Scientific Corp.'s Taxus stent was approved last year.

They use radically different drugs, and it hasn't been known which is better. On Sunday, results of the first large comparison study showed them to be comparable.

It involved 1,353 patients in Europe, Latin America and Asia. Rates of heart attacks, strokes and repeat procedures were similar with both stents, reported Dr. Marie-Claude Morice of Institut Cardiovasculaire Paris Sud in France.

Cordis, which sponsored the study, claimed Cypher was safer because more blood clots occurred with Taxus, but Morice said the study wasn't big enough or designed to answer that question.

"No firm conclusions should be drawn" about safety, agreed Dr. Eberhard Grube, who helped do the study.

But another one led by doctors with no ties to Cordis showed Cypher clearly outperformed Taxus in 250 diabetics, whose arteries are more prone to relogging. Problems were two to three times more frequent among those who got Taxus stents.

"These results would push us to select the Cypher stent for diabetic patients," said Dr. Adnan Kastrati of Deutsches Herzzentrum, a medical center in Munich, Germany.

Other research confirmed the effectiveness of both stents two and three years after treatment. Nearly nine out of 10 stents used in the United States now are drug-coated, and two out of three are Taxus stents.

Meanwhile, Medtronic Inc. reported that its experimental drug-coated stent, Endeavor, outperformed plain metal stents in tests on 1,197 patients. The company hopes to sell it in Europe soon and to seek U.S. approval later this year.

Finally, the first human tests of Biometrik's experimental dissolving stent were reported. Five people received the device last July, and "absorption seems to occur within the first four weeks as planned," said Dr. Raimund Erbel of University Clinic in Essen, Germany.

Competition should make drug-coated stents more affordable, said Dr. Samin Sharma, co-director of the Cardiovascular Institute at Mount Sinai Medical Center in New York. They used to cost more than \$3,000, sell for around \$2,300 now, and could drop to less than \$2,000, he said.

Also at the conference, doctors from the University of Wisconsin-Madison said they were evaluating a cholesterol skin test's ability to predict heart disease risk in people with no symptoms. Blood tests and ultrasound exams to look for blockages are the current gold standard, but the skin test could give doctors a way to identify people who are at risk during routine physicals if further research verifies its accuracy and usefulness.

In a pilot study on 81 people, those with the highest scores also had ultrasound results suggesting they were at risk of heart disease, Dr. James Stein reported.

"This looks interesting," said Fletcher, who had no role in the research. "The blood test is probably more accurate, but the more we can do to screen the American public, the better."

The test, sold by McNeil Consumer Healthcare, costs about \$25 and gives results in five minutes.

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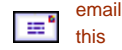
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