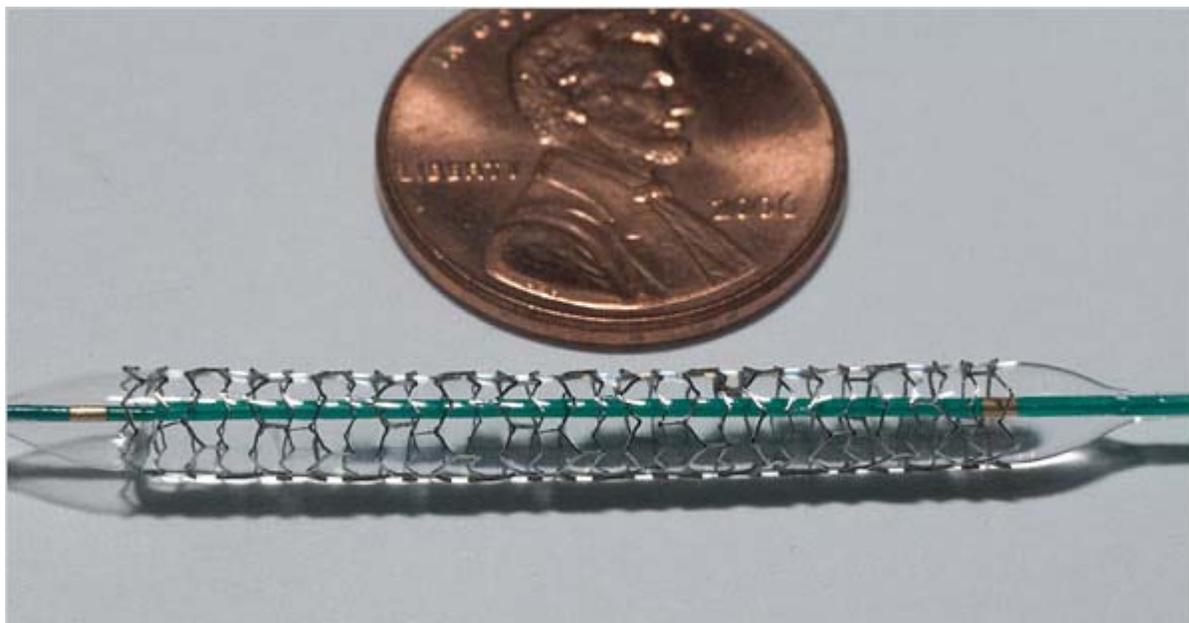


In Trial, Drugs Equal Benefits of Artery Stents

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A Taxus Express II stent by Boston Scientific on display beside a penny at the American College of Cardiology Conference in New Orleans.

By [BARNABY J. FEDER](#)
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NEW ORLEANS, March 26 — Many heart patients routinely implanted with [stents](#) to open arteries gain no lasting benefit compared with those treated just with drugs, researchers reported Monday.

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The researchers said patients with stents to prop open coronary blood vessels in addition to being treated with statins and other heart drugs in a five-year trial had better blood flow to the heart than patients treated only with drugs.

But they did not live longer or suffer fewer heart attacks, a finding that confirmed the

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results of smaller studies.

The researchers also found that the stents were highly successful at improving blood flow and relieving symptoms, including chest pain and shortness of breath, but that the advantage disappeared over time.

“When I saw the results, I was incredulous,” said Dr. William E. Boden, a cardiologist at the University at Buffalo School of Medicine and Biomedical Sciences, lead author of a report on the study published online on Monday by The [New England Journal of Medicine](#).

The use of stents, which has boomed in the United States in the last 10 years, has come under question. One study showed that stents could save lives when implanted during or shortly after a heart attack but that 50,000 Americans a year had the procedure too long afterward to benefit.

The new study was the first large trial to look at a far larger group who had symptoms of clogged arteries and were in no immediate danger. The nearly 2,300 patients in the trial all had a relatively stable form of coronary artery disease that generally progresses slowly.

A majority of Americans who receive stents are in this category, Dr. Boden said. They suffer pain or breathlessness when they try to exercise or are under stress because their heart is not receiving enough oxygen, although that condition sometimes shows up just in clinical stress tests.

But they are not believed to be in immediate danger of heart attacks or hospitalization, even though accumulating plaque has narrowed coronary arteries 70 percent or more.

In the new trial, a surprising finding was that after five years more than 7 of 10 patients in both groups were free of [angina](#) pains, the common symptom of restricted blood flow to the heart muscle, said the researchers, who reported their results at a meeting here of the American College of Cardiology.

Previously, doctors had assumed that stents performed much better than drugs at relieving symptoms over the long run. “It’s very intuitive that fixing the narrowing with a stent will yield important long-term benefits, but it didn’t,” said Dr. Steven E. Nissen, president of the cardiology group.

Dr. Nissen, who termed the new study a blockbuster, said it sent a clear message that

doctors and patients should feel secure about relying on modern drugs as a “very safe, reasonable and cost-effective strategy” for treating coronary artery disease. The findings raised new questions about the role of [angioplasty](#) and stenting, which has been used in six million patients around the world since the mid-'90s and is especially popular in the United States.

Close to one million Americans a year receive stent implants after angioplasty to create pathways through severe blockages in coronary arteries by inflating tiny balloons in them.

Angioplasty quickly became popular in the '80s as a less invasive approach for coronary blockages than open heart surgery to construct bypasses around them. Stents improved the procedure by combating the tendency of many vessels to reclose quickly after angioplasty.

Studies have shown that angioplasty and stenting can save lives when used in heart attacks. The procedure is also recommended for many patients whose symptoms of poor blood flow to the heart are not relieved by rest or drugs.

For such patients, the debate is not whether to use stents in addition to drugs but whether stents are used in too many seriously ill patients who might live longer with bypass surgery.

Angioplasty with stenting generally costs \$25,000 and up. The latest drug-coated stents cost \$2,200 apiece and are especially effective at preserving the channel created by angioplasty.

Stents generate nearly \$3 billion a year in sales in the United States for Boston Scientific and Johnson & Johnson, the two companies that dominate the market.

In a statement issued after the results became public, Dr. David E. Kandzari, chief medical officer of the Cordis Cardiology business at Johnson & Johnson, said that modern drugs slowed the progression of coronary artery disease, but that stenting was superior at relieving symptoms, so both should be available. His counterpart at Boston Scientific, Dr. Donald S. Baim, said what was apparently the loss of the symptom relief advantage of stents over time in the study might have occurred because the trial ended in 2004, just as the drug-coated stents were introduced. Just 3 percent of the patients received them.

Dr. Baim also said it was important to note that nearly one-third of the group that started on drug treatment ended up receiving stents or having bypass surgery because their

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symptoms worsened. He said most of them would have been free of angina symptoms after five years because of stents but would have still been counted in the drug group.

Shares in the two companies' stock began falling even before the official announcement. Boston Scientific, which is far more reliant on the stent business than Johnson & Johnson, fell to \$14.22, down from \$15.22, to its lowest point in the last year. It drifted lower in after-hours trading.

Sales of the drug-coated stents have been falling in the United States since last spring because of studies that showed that potentially deadly clots formed in a small percentage of patients long after the stents had been implanted. The clots were thought to occur in a handful of every 1,000 patients, but no one knows how long the risk continues.

Recipients of drug-coated stents are now told by most doctors to take anticlotting drugs indefinitely. Doctors are switching some patients to older bare metal stents that do not seem to have the same late-clotting risk. The disadvantage of that stent is that the arteries relog twice as often, exposing patients to repeat procedures.

The new clinical study adds questions about the effectiveness of stenting to the safety debate, at least in the patients studied in the trial, named Courage, for Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation. Guidelines from the [American Heart Association](#) and the American College of Cardiology have since 2002 called for using angioplasty and stenting or bypass surgery only after extensive efforts to treat such patients' symptoms with drugs.

But cardiologists say patients and doctors increasingly ignore the guidelines, choosing the quicker and initially reliable relief of stenting.

"There will be a lot of analysis and dissection of the study," said Dr. Boden of the University at Buffalo. "But that doesn't necessarily mean we will do far fewer angioplasties."

Examples of how the results might be questioned emerged even before the data. Dr. Kandzari of Cordis noted that the nearly 2,300 patients in the trial were largely from veterans' hospitals in the United States and Canada. Those patients receive many medicines free and are more likely to take them as prescribed.

The trial was supported financially by eight major drug companies in addition to the United States and Canadian governments.

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