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Heart Attack Study Casts Doubt On Routine Use of Angioplasty

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Propping open clogged arteries with a tiny wire-mesh tube called a stent is no better at reducing the risk of heart attack or death in patients with stable heart disease than treatment with medications, according to a large new study that challenges routine use of a procedure that rapidly became standard medical practice.

The study of more than 2,000 patients found that those who underwent the expensive procedure, known as angioplasty, in non-emergency situations were no less likely to suffer a heart attack or die than those who took only aspirin and other medicines to lower blood pressure and cholesterol and prevent clots, along with adopting lifestyle changes.

The study is the first large, well-designed comparison of angioplasty to non-surgical care for patients who are not having a heart attack or in imminent danger of having one. The procedure, often done to relieve chest pain and to reduce the risk of having or dying from a heart attack, has become one of the most common medical procedures in the United States.

"The data are compelling," said William E. Boden of the University of Buffalo School of Medicine, whose findings were published yesterday by the *New England Journal of Medicine* to coincide with a presentation at a meeting of the American College of Cardiology in New Orleans. "We do too many of these procedures."

Several experts said they expect the findings will prompt a major shift in how doctors treat thousands of patients suffering from heart disease -- the nation's leading cause of death.

"These findings are pretty explosive," said Steven E. Nissen, president of the American College of Cardiology. "I think this is going to shake things up pretty significantly."

The findings underscore the danger of rushing to adopt a procedure before careful studies have been conducted to fully determine its benefits, Boden and others said.

"There was just this intuitive belief that it would be beneficial," Boden said. "But no one had ever done a proper randomized trial to see whether it actually improved outcomes. In the meantime, a whole industry has been created around this."

The researchers and others stressed that angioplasty clearly benefits patients who are in the throes of a heart attack or are at very high risk for one. But the findings indicate that for a patient whose condition is stable, medical therapy is just as effective at reducing the major risks. Such patients constitute at least one-third of those undergoing the 1.2 million angioplasties performed each year, and perhaps as much as 85 percent.

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Some cardiologists who specialize in the procedures, however, argued that the study did not focus on the sickest patients who are most likely to benefit, and that the main purpose of angioplasty in many is to alleviate chest pain, not to prevent heart attacks.

"I don't think this is going to cause any huge paradigm shift," said Gregory J. Dehmer, president of the Society for Cardiovascular Angiography and Interventions. "This study was limited to a fairly select group of patients with very stable symptoms."

But Boden said that the study did include patients with moderate to severe heart disease and that many such patients undergo the procedure in the belief it will protect them against heart attacks.

In the procedure, doctors thread a tiny balloon into clogged arteries, inflate the balloon to clear the blockage, and insert a stent -- a tiny wire lattice strut that props the artery open. The procedure costs about \$50,000 and is considered safe, though it does carry some risks.

The findings come on the heels of questions about the safety of new stents coated with drugs to keep arteries from reclosing. Those concerns had led doctors to curtail their use of the newer devices, and the new findings are expected to have a similar effect on angioplasty overall.

"There was an overexuberance," said William O'Neill, a prominent cardiologist at the University of Miami. "I think we're getting a midcourse correction."

The findings could also help fuel a resurgence of bypass surgery, which has become far less common with the rise of angioplasty.

"There was this sense that angioplasty would produce the same result as bypass surgery," Nissen said. "I think this will cause a tilt toward more patients with stable conditions choosing medical therapy and more people who have more severe disease getting bypass surgery, which both relieves symptoms and reduces the risk for heart attack and death."

The new study, which was funded mostly by the Department of Veterans Affairs, involved 2,287 patients at 50 centers in the United States and Canada who had chest pain or other symptoms because one or more major arteries supplying blood to the heart had clogged. Half the patients received standard medical treatment involving medication and lifestyle changes such as quitting smoking, eating better and exercising. The other half received the same treatment plus angioplasty.

After about five years, the number of patients who experienced a heart attack, were hospitalized or died because of their heart problems was virtually identical in the two groups, the researchers found.

"There was no significant difference," Boden said. "The data are clear."

Although about one-third of patients who initially got medical treatment later turned to angioplasty, the findings show how much medical treatment of heart disease has improved, Boden said.

"The paradigm for the last 20 years for patients like this been: 'Mr. Jones, you need a procedure.' End of discussion," Boden said. "I hope this will make people realize that patients have more options. They can safely choose to try medical therapy first."

Although study patients receiving angioplasty were somewhat more likely to be free of chest pain, known as angina, even that benefit was marginal, Boden said. After nearly five years, 74 percent of

those patients were free of chest pain, compared with 72 percent of those who had medical treatment alone.

"One of the unexpected findings is that it's amazing how remarkably good medical therapy was for relieving angina," Boden said.

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