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New tool could prevent needless stents and save money, cardiologist says

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Doctors may be implanting too many artery-opening stents and could improve patient outcomes — and ultimately save lives — if they did more in-depth measurements of blood flow in the vessels to the heart. That's the finding of a study, to be published Jan. 15 in the *New England Journal of Medicine*, that evaluated the benefits of a new diagnostic tool to measure blood flow and determine whether stenting was the best option.

"Not only were the outcomes better, the cost was less," said William Fearon, MD, co-principal investigator of the multicenter international study called FAME and assistant professor of cardiovascular medicine at the Stanford University School of Medicine. "Now there's scientific support for cardiologists to apply this new technique." Nico Pijls, MD, PhD, professor of cardiology at Catharina Hospital in The Netherlands, was the other co-principal investigator.

The study suggests that doctors should go one step beyond the traditional method of relying solely on X-rays from a coronary angiogram to determine which arteries should be stented for patients with coronary artery disease. In many cases, cardiologists will routinely prop open with a stent any arteries that look significantly narrowed on the angiogram, said Fearon. "The problem is you can't always tell from the angiogram whether this is absolutely necessary."

By using a method called "fractional flow reserve," or FFR, which involves inserting a coronary pressure guidewire into the artery, doctors

can measure whether blood flow is actually reduced to a dangerous level beyond any apparent narrowing. In certain cases, medication may be a better option to stenting.

"This is a critically important finding because it uses the determination of blood flow rather than an angiogram alone," said Morton Kern, MD, associate chief of cardiology at the University of California-Irvine, who was not involved in the study. "With unnecessary stents, there's a risk of complications. Patients run the risk of clots forming, of heart attacks at a later time, of repeated surgeries."

More than 1.2 million of the procedures to unclog the arteries and implant stents, called angioplasty, are performed each year in the United States, according to the American Heart Association. Narrowing of the arteries caused by buildup of atherosclerotic plaque is common. About 40 percent of Americans over the age of 60 has one or more narrowings in their coronary arteries. But most of these aren't significant enough to limit oxygen supply to the heart and can be treated with statins or aspirin. Significant narrowings can cause chest pain and an increased risk of heart attack or death.

Recent controversy over the use of drug-coated stents and the possible advantages of medical therapy over stenting make the results of the new study particularly timely, Fearon said.

The study was funded by Radi Medical Systems Inc. based in Sweden, one of two companies that make the pressure wires used in the study to measure blood flow inside arteries. Radi was recently acquired by U.S.-based St. Jude Medical. It included about 1,000 patients in the United States and Europe. Twenty hospitals participated in the study, six from the United States including 115 patients from Stanford University Medical Center and the Veterans Affairs Palo Alto Health Care System.

Patients included in the study either suffered from chest pains or were recovering from mild heart attacks. All patients had multiple coronary arteries with narrowings.

About half the patients were treated with the traditional method of using an angiogram to decide which narrowings to stent. With an angiogram, a catheter is used to inject dye into the arteries, then X-rays are taken which doctors examine looking for narrowed arteries. Any arteries that look significantly narrowed are then propped open with a stent.

The other half of the patients underwent the angiogram with the additional pressure wire technique. To measure blood flow beyond the areas in the arteries that appear narrowed, the pressure wire was threaded through the same catheter used for the angiogram.

"The pressure wire is a thin wire with a sensor near the tip that can measure the pressure of blood flow," Fearon explained. "If the narrowing is truly significant it will cause a drop in blood pressure beyond the narrowing. If the pressure was 80 percent or less than the pressure in front of the narrowing (an FFR value of .80 or less), a stent was implanted."

Researchers found that patients who received the additional blood flow test received one-third fewer stents than the group examined only with an angiogram. Those patients received 2.7 stents on average. The other half, who had their blood flow measured in each artery, received only 1.9 stents on average.

After one year, follow-up statistics showed that within the traditional group, 18.4 percent of the patients had died, suffered a heart attack or needed a bypass surgery or repeat stent procedure, compared with 13.2 percent among those who received the additional pressure wire test.

"We are most excited about the 30-40 percent decrease in cardiac events, including death, heart attack and the need for repeat stenting or bypass surgery," Fearon said.
Pijls agreed, "The improvement was so striking it can hardly be ignored."

In addition, the new procedure didn't require any extra procedural time and resulted in decreased medical costs. "Each stent on average costs roughly $2,000," Fearon said. "The pressure wire test runs an additional $700." Using fewer stents also results in using a decreased amount of contrast dye that can cause kidney failure.

"The take-home message is that the wire is able to give you more information about whether a coronary narrowing is truly causing abnormal blood flow to the heart," Fearon said. "Some narrowings that might look bad would respond just as well to medication, while others that appear innocent may benefit from stenting. By measuring FFR, one is better able to make this distinction and improve the patient's outcome, while also saving health-care dollars."

Source: Stanford University Medical Center