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## Analysis: Stents' heart value in doubt

By ED SUSMAN  
UPI Correspondent

NEW ORLEANS, March 26 (UPI) -- Doctors said Monday that angioplasty plus stenting -- a common, expensive heart procedure -- plus the best medical treatment failed to reduce the risk of death or heart attacks, when compared to optimal medical treatment alone.

In the blockbuster COURAGE Trial, doctors at the 56th annual scientific sessions of the American College of Cardiology said that the \$38,000 angioplasty-plus-stent heart surgery -- now done a million times a year in the United States with the goal of freeing patients from chest pain -- did not, in the long run, even result in less pain.

"There are hundreds of thousands of Americans who are currently getting stents placed who do not need it as initial therapy," Dr. Raymond Gibbons, professor of medicine at the Mayo Medical School in Rochester, Minn., and president of the American Heart Association, told United Press International.

Thomas Ryan, senior consultant and emeritus chief of cardiology at Boston University, agreed.

"This study shows that, if you treat people vigorously and coach them and they get their blood pressure under control, patients can do just as well on medical therapy," he told UPI. But, he cautioned, "They can't just take a pill. This is hard work. They have to get out and exercise. They have to get maximum doses of lipid lowering drugs," he said.

Originally scheduled for simultaneous release at the ACC meeting and in the New England Journal of Medicine on Tuesday, the organizations reported the findings Monday after major portions of the report were leaked and were published online in various publications.

"Our findings parallel those reported in recent trials," said William Boden, chief of cardiology at Buffalo General and Millard Fillmore Hospitals. "In the aggregate, these studies, including our own, include outcome data on more than 5,000 patients and show that percutaneous coronary intervention -- angioplasty plus stenting -- has no effect in reducing major cardiovascular events."

Mayo's Gibbons said that the procedure does relieve pain in patients with angina, or chest pain, and still is the treatment of choice in people who have uncontrolled angina, a condition marked by pain even when at rest that is not well-controlled by use of drugs such as nitroglycerine.

Angioplasty with stent implantation is also recommended to open up coronary arteries in people in the throes of an acute heart attack. Such procedures can be lifesaving in these patients, he said.

In the COURAGE study, Boden, also professor of medicine and public health at the University at Buffalo School of Medicine and Biomedical Sciences, and colleagues across the United States and Canada recruited 2,287 patients who had evidence of heart disease.

Between 1999 and 2004, the researchers randomly assigned 1,149 patients to undergo angioplasty-plus-stent and to receive optimal medical therapy and 1,138 to receive optimal medical therapy alone.

The primary outcome of the study was the composite of death from any cause and nonfatal heart attacks. There were 211 such cases in the patients who received angioplasty and 202 patients in the medical-therapy-only patients. After about 4.6 years, about 19 percent of the patients who received angioplasty as an initial treatment experienced that primary outcome, compared with 18.5 percent of the medical treatment group -- a difference that did not reach statistical significance.

Similarly, regarding rates of heart attack, stroke or death -- the trial's secondary endpoint -- patients who got drugs and stents experienced these events at a rate of 20 percent, versus 19.5 percent in the drugs-alone group.

Boden, speaking at a press briefing Monday, said that one of the surprising findings of the study was that by five years, there was little difference between the groups among patients who were angina-free -- 74 percent of those having angioplasty and 72 percent of those following medical therapy.

"We set this study up with a hypothesis that angioplasty plus medical treatment would prove superior than just medical therapy alone," he said. "We wanted to give stenting the best chance to prove it had more benefits."

In angioplasty, doctors make a small incision in a patient's leg, allowing access to the main artery in the leg. Into that artery a balloon-tipped catheter is inserted. Using X-ray guidance, the catheter is advanced through the arterial system until it reaches the coronary arteries. When these arteries become blocked they can cause chest pain or heart attacks. The catheter is positioned at the point of coronary artery blockage and the balloon is inflated, crushing the blockage against the walls of the artery and opening the blood vessel.

To make sure blood keeps flowing, doctors then implant tiny mesh coils known as stents to act as scaffolding that props open the blood vessel.

Despite Monday's news, doctors were quick to note that stents still have a place in cardiac care.

"We shouldn't lose sight of the fact that revascularization -- angioplasty -- can be beneficial in acute situations," said Sidney Smith, professor of medicine at the University of North Carolina. "However, the foundation for all our work should be comprehensive medical therapy. If you get patients to take their medicine and treat to prescribed levels, patients can have benefits."

Jim Dove of Springfield, Ill., president-elect of the ACC, promised that the organization will consider

sanctions against those individuals who were responsible for breaking the embargo on release of the study.

Steve Nissen, director of cardiovascular medicine at the Cleveland Clinic, and current ACC president, told UPI, "We are discussing sanctions. We will do what we think is right, but we will not do it rashly. We consider the embargo process an important part of the integrity of our studies."

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