# Rx, Lifestyle Changes Rival Angioplasty Post MI

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CHICAGO — Routine late coronary intervention to open a persistently occluded infarct-related artery in stable patients is no longer appropriate in light of the findings of the 2,166-patient Occluded Artery Trial, said Dr. Judith S. Hochman at the annual scientific sessions of the American Heart Association.

"These results support routine use of aggressive secondary prevention—medical therapy and lifestyle changes, without revascularization—as the preferred treatment for OAT [Occluded Artery Trial]-eligible patients.

"The trial results should lead to lower rates of unnecessary coronary interventions in this specific group of stable patients and to substantial health care cost savings," added Dr. Hochman, OAT study chair and the Harold Snyder Family Professor and clinical chief of cardiology and director of the Cardiovascular Clinical Research Center at New York University.

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**DR. HOCHMAN**

She estimated that roughly 50,000 fewer U.S. patients per year will undergo percutaneous intervention (PCI) as a result of the altered treatment landscape sown by OAT, a trial sponsored by the National Heart, Lung, and Blood Institute.

Roughly one-third of MI patients don't receive acute reperfusion therapy, most often because they present too late. The practice of many cardiologists—to a greater extent in North America than in Europe—has been to look for an occluded infarct-related artery in such patients and, if they find it, to open it in expectation of improved outcomes.

It's a logical practice driven by what's known as the late open artery hypothesis. But it had never been subjected to a randomized trial prior to OAT, which showed convincingly that it's without benefit.

Moreover, there was a disturbing albeit nonsignificant trend for more nonfatal recurrent MIs in the late-PCI group.

OAT was a 217-site international study involving stable patients with a 100% occlusion 3-28 days post MI, when they were randomized to PCI and stenting plus optimal medical therapy, or to optimal medical therapy alone.

The primary end point was the 4-year cumulative rate of death, repeat MI, or hospitalization for class IV heart failure. This end point was reached by 17.2% in the PCI group and 15.6% with medical management, a nonsignificant difference. No subgroup benefited from late PCI, including higher-risk patients with a large anterior MI, an ejection fraction below 40%, or a left anterior descending coronary occlusion. Time from MI to randomization didn't affect outcome, either.

The nonfatal reinfarction rate was 6.9% in the PCI group and 5.0% with medical management, a trend that did not reach statistical significance, but that is "worrisome," Dr. Hochman said.

He stressed that late PCI remains clearly indicated in the highest-risk post-MI patients deliberately excluded from OAT, including those with angina at rest, severe heart failure, or triple-vessel disease.

OAT included a mechanistic substudy called the second Total Occlusion Study of CAnada (TOSCA-2) involving 332 subjects who underwent repeat angiography at 1 year. TOSCA-2 lead investigator Dr. Vladimir Dzavik reported that the 1-year infarct artery patency rate was 83% in the late PCI group, compared with 25% with medical therapy alone. There was also less left ventricular dilation in the PCI arm. Nonetheless, ejection fraction at 1 year improved by a similar amount—roughly 4%—in the two groups.

It seems likely that late PCI in stable patients has two competing effects: It reduces left ventricular enlargement, while also resulting in increased risk of MI. The net effect is no benefit, said Dr. Dzavik, the Brompton Group Professor in Interventional Cardiology at the University of Toronto.

Observers hailed OAT as a major, prac-

tice-changing study. Current AHA/American College of Cardiology guidelines on acute MI management give late PCI in patients with a blocked artery a class IIb recommendation with a C level of evidence. That means it's not an unreasonable thing to do and is supported only by expert opinion. Class IIb/level C is the weakest endorsement the guidelines panel bestows. Dr. Sidney C. Smith Jr. predicted in an interview that the guidelines committee will soon revisit that recommendation in response to the OAT trial.

"OAT looks like a very good study to me, a very carefully done study by good investigators on an important problem. The preliminary results are very persuasive," said Dr. Smith, professor of medicine and director of the Center for Cardiovascular Science and Medicine at the University of North Carolina, Chapel Hill.

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OAT discussant Dr. Robert M. Califf, noting that fewer than 500 OAT participants came from the United States, castigated many of his fellow American cardiologists for failing to keep an open mind in the face of scientific uncertainty, particularly when, as in this case, the stance suited their economic self-interest. Many of the nation's top medical centers declined to participate in the randomized trial on the grounds that their cardiologists felt they couldn't ethically leave an infarct-related artery closed. They already "knew" it was wrong despite an absence of quality evidence.

It's enough to make one ask whether a spirit of scientific inquiry—the ability to admit uncertainty—ought to be adopted as a health care quality performance measure, added Dr. Califf, professor of medicine and vice chancellor for clinical research at Duke University, Durham, N.C.

Simultaneously with Dr. Hochman's presentation at the meeting, the OAT results were published online (N. Engl. J. Med. 2006 Dec. 7 (Epub doi:10.1056/NEJMoa066139]). ■