MDCT Excels in Trial, but Critics Remain Wary

BY MITCHEL L. ZOLER
Philadelphia Bureau

ORLANDO — CT angiography remains controversial after a report on the diagnostic accuracy of multidetector CT measured in 316 patients.

Noninvasive multidetector CT (MDCT) angiography had a 91% positive predictive value and an 83% negative predictive value, compared with conventional angiography, for identifying significant coronary stenoses in the "first large, multicenter trial of the 64-slice technology" for coronary angiography, Dr. Julie M. Miller said at the annual scientific sessions of the American Heart Association.

"This represents a high degree of diagnostic accuracy" for MDCT angiography, said Dr. Miller, a cardiologist at Johns Hopkins University, Baltimore.

But Dr. Miller's report of a high correlation between noninvasive and invasive angiography was immediately followed at the podium by strong comments from the invited discussant for the study, Dr. Michael S. Lauer. After criticizing the study's clinical relevance and questioning the technique's safety, he called for a moratorium on using MDCT angiography until its value for patients was better defined.

"This is a technology with no evidence of benefit and real concern for harm," said Dr. Lauer, a cardiologist and director of the division of prevention and population science at the National Heart, Lung, and Blood Institute. His safety concern was that the radiation dose from repeated scans could pose a significant cancer risk.

Routine use of MDCT should stop until results from large-scale, randomized studies prove that "this test saves lives or prevents heart attacks with an acceptable margin of safety," Dr. Lauer said.

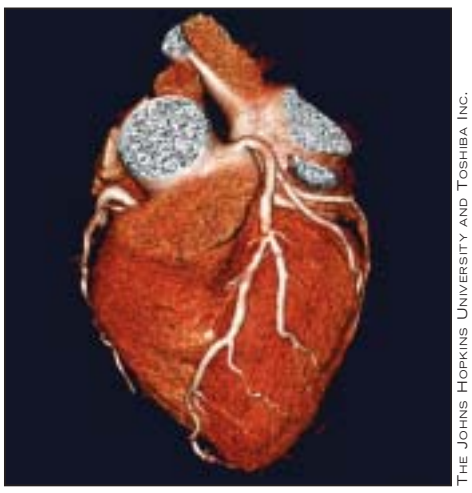
His sharp critique contrasted with the response to Dr. Miller's report from other experts. "Dr. Miller's study is important because it shows that MDCT angiography gives you coronary anatomy outside the catheterization laboratory," said Dr. Daniel Mark, a cardiologist and professor of medicine at Duke University, Durham, N.C.

In an interview after Dr. Lauer's remarks, Dr. Miller contended that his criticism mostly applied to using CT to screen people for their coronary calcium scores rather than issues of MDCT angiography.

She stressed that the study did not use MDCT for screening. A reliable, noninvasive image of coronary anatomy could help many patients avoid the cost and potential complications of catheterization, Dr. Miller said.

"Until now, there was no proof that MDCT angiography was accurate for making diagnoses. We proved that MDCT works." The next step is to compare noninvasive angiography with other noninvasive tests, she said.

On the issue of safety, the radiation dose each patient received, about 14-15 mSv, is comparable to the dose from conventional coronary angiography and less than the exposure during a nuclear perfusion scan, Dr. Miller said. The contrast volume also was similar to conventional angiography.



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MDCT has been shown to have high positive and negative predictive value.

The Coronary Evaluation Using Multidetector Spiral Computed Tomography Angiography using 64 Detectors (CORE-64) trial enrolled patients older than 40 years (median age 59 years) who had been referred for conventional, quantitative coronary angiography at nine centers in seven countries. The study used equipment made by and was sponsored by Toshiba. Dr. Miller has received research support from Toshiba.

The patients' hearts were scanned with a 64-slice MDCT device that takes images at 0.5-mm intervals. The MDCT examination first was analyzed to get each patient's calcium score, and the study continued with 316 patients who had calcium scores of less than 600.

The images obtained from these patients were then analyzed at 19 locations throughout the coronary tree. Each location was at least 1.5 mm in diameter, and stented segments were excluded. All stenoses that blocked more than 30% of a vessel were quantified, and lesions that were 50% stenotic or greater were counted as significant. Patients underwent conventional quantitative angiography within the next 30 days.

A receiver-operator curve analysis showed that 93% of the patients with significant stenoses identified by conventional angiography were also spotted using the noninvasive method, the study's primary end point, reported Dr. Miller. The patients had a 56% prevalence of having at least one coronary artery with a significant stenosis.

A second analysis compared the noninvasive and invasive methods on a per vessel basis, with 868 individual vessels evaluated. By this measure, MDCT angiography identified 91% of the individual coronary vessels with a significant stenosis, compared with catheterization angiography, and produced a positive predictive value of 82% and a negative predictive value of 89%.

"We can define which patients need revascularization," Dr. Miller observed in an interview. ■

Accuracy of Coronary CT Angiography Supported by Trial

BY PATRICE WENDLING
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CHICAGO — A second multicenter trial has shown that noninvasive CT angiography is highly accurate in assessing coronary artery disease when compared with conventional invasive angiography.

The per-vessel negative predictive value of 64-slice coronary CT angiography (CCTA) was 97% for identifying blockages greater than 50%, and 99% for blockages greater than 70%, when measured in 232 patients with typical or atypical chest pain in the Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography (ACCURACY) trial. Positive predictive values were 51% and 33%, respectively, Dr. James K. Min and his associates reported at the annual meeting of the Radiological Society of North America.

"The ACCURACY results [obtained] in a prospective, multicenter fashion definitively establish the high diagnostic accuracy and high negative predictive value of 64-detector-row CT angiography in chest pain patients with intermediate prevalence of coronary artery disease," said Dr. Min, director of the cardiac CT laboratory at New York–Presbyterian Hospital in New York City.

The findings echo those of the recent Coronary Artery Evaluation Using 64-Row Multidetector Computed Tomography Angiography (CORE-64) trial, in which CT angiography had a 91% positive predictive value and an 83% negative predictive value for identifying significant coronary artery stenoses. CORE-64 was the first large, multicenter trial of the 64-slice technology for coronary angiography, but was criticized by some attendees at the annual scientific sessions of the American Heart Association where it was presented. Concerns were raised that the radiation dose from repeated CT scans could pose a potential cancer risk. No such concerns were raised at the radiology meeting.

To reduce the amount of radiation given to patients in the ACCURACY trial, investigators used a radiation-dose reduction algorithm called EKG modulation that reduces CT angiography radiation by about 40%, Dr. Min said in an interview. The radiation dose per patient was about 10-15 millisieverts (mSv), which is about twice that of an invasive coronary angiogram and about half that of a noninvasive thallium stress test.

Since the trial began, a new algorithm called perspective axial gating has been commercially released and is reported to reduce exposure by 90%, to about 2-4 mSv. Both algorithms work by activating the CT scanner during select parts of the cardiac cycle only, Dr. Min said. For comparison, New York City residents are exposed to about 3 mSv of radiation annually through background exposure.

Neither study used CT angiography for screening. "I believe very emphatically that the data to date don't support CT angiography as a screening tool at all," Dr. Min said. "In asymptomatic patients, we don't have any data of what to do with the results, and if treatment benefits them."

CT angiography is of greatest benefit for patients without known coronary disease who have low or intermediate pretest risk. "If you have a high pretest suspicion that someone has coronary artery disease, then direct progression to invasive coronary angiography or even myocardial perfusion imaging is probably a better alternative," he said.

The ACCURACY trial was unique in that it included all coronary artery segments in its analysis and all patients irrespective of their baseline coronary calcium score. In the CORE-64 trial, stented segments were excluded, as were patients with a calcium score higher than 600. As a result, the ACCURACY findings of high diagnostic accuracy are even more impressive and representative of actual clinical usage of CCTA, Dr. Min said.

Between May 2006 and January 2007, ACCURACY investigators performed CCTA prior to conventional quantitative coronary angiography (QCA) on 232 patients who had typical or atypical chest pain and had been referred for evaluation at 16 U.S. centers. The images were obtained on a GE Healthcare LightSpeed VCT scanner, and analyzed at 15 different locations throughout the coronary tree. The investigators used equipment made by GE Healthcare, which sponsored the study. Dr. Min is on the speaker's bureau for GE Healthcare.

Three independent radiologists interpreted the CCTA images, and one independent radiologist interpreted the QCA images. No segments were excluded based on nonagreement between readers, and only one segment was debated among readers, Dr. Min said.

The patients' mean age was 57 years (range 31-82 years); 138 were male, 203 were white, and 13 were black, and their average body mass index was 31 kg/m^2 (range 16.8-50.5). Risk factors included a family history of coronary disease (169 patients), hyperlipidemia (158), hypertension (155), diabetes mellitus (47), obesity (87), smoking (127), and sedentary lifestyle (80).

QCA detected 82 blockages greater than 50% in 55 patients and 31 blockages greater than 70% in 34 patients.

For noninvasive CCTA, per-patient sensitivity was 93% and specificity was 82% for blockages greater than 50%; sensitivity was 91% and specificity was 84% for blockages greater than 70%, Dr. Min said.

Additional analyses of the ACCURACY data are being conducted, including a comparison of CT angiography to historical single-photon emission computed tomography (SPECT) imaging, cost-effectiveness versus standard of care, incremental benefit of CT angiography beyond traditional coronary calcium scoring, and interreader, interpatient, and intersegment reliability. ■