Diagnostic test shows potential to noninvasively identify significant coronary artery disease

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Among patients with suspected or known coronary artery disease, use of a method that applies computational fluid dynamics to derive certain data from computed tomographic (CT) angiography demonstrated improved diagnostic accuracy vs. CT angiography alone for the diagnosis of ischemia, according to a study being published online by *JAMA*. The study is being released early to coincide with its presentation at the European Society of Cardiology Congress.

"Coronary computed tomographic angiography is a noninvasive anatomic test for diagnosis of coronary stenosis [narrowing of a blood vessel] that does not determine whether a stenosis causes ischemia [inadequate blood supply]. In contrast, fractional flow reserve (FFR) is a physiologic measure of coronary stenosis expressing the amount of coronary flow still attainable despite the presence of a stenosis, but it requires an invasive procedure. Noninvasive FFR computed from CT (FFRCT) is a novel method for determining the physiologic significance of coronary artery disease (CAD), but its ability to identify ischemia has not been adequately examined to date," according to background information in the article.

James K. Min, M.D., of the Cedars-Sinai Heart Institute, Los Angeles, and colleagues conducted a study to evaluate the performance of noninvasive FFRCT compared with an invasive FFR reference standard for diagnosis of ischemia. The study included 252 patients with

suspected or known CAD from 17 centers in 5 countries who underwent CT, invasive coronary angiography (ICA), FFR, and FFRCT between October 2010 and October 2011. About 77 percent of patients had experienced angina within the last month. Ischemia was defined by certain criteria. Anatomically obstructive CAD was defined by a stenosis of 50 percent or larger on CT and ICA. Among 615 study vessels, 271 had less than 30 percent stenosis and 101 had at least 90 percent stenosis.

Among study participants, 137 (54.4 percent) had an abnormal FFR as determined by ICA. The researchers found that the diagnostic accuracy for FFRCT plus CT was 73 percent, which did not meet a prespecified primary end point for accuracy (as pre-specified based on the lower limit of a calculated 95 percent confidence interval). By comparison, diagnostic accuracy of CT alone for detecting coronary lesions with stenosis of 50 percent or greater, was 64 percent. When comparing FFRCT alone with CT alone for detecting these lesions, FFRCT demonstrated superior discrimination.

"On a per-patient basis, diagnostic accuracy, sensitivity, specificity, positive predictive value, and negative predictive value of FFRCT plus CT were 73 percent, 90 percent, 54 percent, 67 percent, and 84 percent, respectively," the authors write. They note that the sensitivity and negative predictive value of FFRCT were high, indicating a low rate of false-negative studies. "These diagnostic features of FFRCT may encourage a greater sense of diagnostic certainty that patients who undergo CT who have ischemia are not overlooked, such that clinicians may be confident in not proceeding to invasive angiography in patients with stenoses on CT when FFRCT results are normal."

"Taken together, these study results suggest the potential of FFRCT as a promising noninvasive method for identification of individuals with ischemia."

In an accompanying editorial, Manesh R. Patel, M.D., of Duke University Medical Center, Durham, N.C., writes that future studies with the FFRCT technology "should be aimed at diagnostic strategies involving patients with varying pretest risks, thereby providing information on the incremental benefit from the test."

"Additionally, important comparison technologies beyond invasive angiography are needed, although improved access techniques and safety of invasive FFR may make it a plausible comparator. In addition to diagnostic performance, other outcomes of interest such as resource utilization and clinical outcomes should be captured. Finally, future studies will need to have local sites rather than core laboratories perform, analyze, and interpret the images to provide a sense of real-world function. It is with these types of continued rigorous studies that noninvasive technologies such as FFRCT plus CT may move the clinical community closer to the holy grail of a high-quality combined anatomic and functional test for detection of CAD that improves efficiency and patient outcomes."

More information:
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