Update on Coronary Artery Calcium Imaging

Lawrence J. Hergott, MD

This update of coronary calcium imaging discusses methods of detecting and measuring coronary artery calcium and their correlation to coronary artery disease risk. The value of EBCT to traditional non-invasive cardiovascular tests is compared. A negative EBCT test makes the presence of atherosclerotic plaque, including unstable plaque, very unlikely. Negative EBCT may be consistent with low risk of a cardiovascular event over the next 2–5 years. Conversely, positive EBCT confirms the presence of a coronary plaque. The greater the amount of calcium, the greater the likelihood of occlusive disease, but there is a not a 1:1 relationship and findings may not be site specific. A high calcium score may be consistent with moderate to high risk of cardiovascular event within the next 2–5 years. Limitations and cautions concerning the general use of EBCT for screening are discussed.

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This update of coronary calcium imaging, electron beam computed tomography (EBCT), will discuss methods of measuring calcium scores, the risk associated with calcium scores and their percentile rank, and compare the value of EBCT to traditional non-invasive cardiovascular tests.

PATHOPHYSIOLOGY

The pathophysiology of coronary artery calcification is one and the same as the pathophysiology of atherosclerosis. The atherosclerotic process begins with the attachment of oxygen radicals to LDL particles circulating in the blood. These complexes are ingested by phagocytic cells (macrophages), becoming "foam cells," the first microscopically visible sign of the atherosclerotic process. Groups of foam cells form "yellow streaks" in the arterial wall, the first grossly visible sign of the atherosclerotic process. Microlcalcification begins just after fatty streaks form, very early in the pathogenesis of the atherosclerotic plaque, and as early as the second decade of life. Some ECBT scans performed in people in their 20s are already positive. Calcium phosphate is the substance deposited. Arterial calcium deposition occurs exclusively in atherosclerotic vessels; there is no calcification in arteries for any other reason. Extensively calcified lesions may or may not be stable. Generally, it is thought that soft plaques tend to rupture and cause sudden death and acute coronary syndromes.

Calcification is a chronic inflammatory process that may identify hard plaques. Extensively calcified lesions may be relatively sta-
ble; however, just downstream from the calcification, there may be a vulnerable soft plaque, which could either erode or rupture. Coronary calcification does not identify the specific lesion that may be of greatest concern. The total area of coronary calcification measured with EBCT correlates linearly with plaque area. The more extensive the calcification, the more likely a coronary event will occur, but the calcium does not concentrate exclusively at the site of severe stenosis.

Coronary calcium may not be good for identifying the site of severe coronary artery stenosis. But it is good at identifying the atherosclerotic process. In a study by Wexler et al involving all male subjects at age 25, the prevalence of coronary calcification is about 10%.

In the 1970s and 1980s, computed tomography (CT) and magnetic resonance imaging (MRI) appeared, and in the 1990s, electron beam CT and helical, or spiral CT, came into clinical use.

**IMAGING AND SCORING MODALITIES**

Conventional CT, spiral or helical CT (now called multidetector CT), or electron beam CT are the currently available technologies that can be used to detect coronary calcium. X-rays are generated by an x-ray tube (conventional and multidetector/helical CT) or electron sweep of stationary tungsten target rings (EBCT). Very good high resolution images can be acquired quickly. Images are “gated,”

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**Figure.** Coronary artery calcium prevalence, 10-year event risk and prevalence/risk ratio in asymptomatic men. From Wexler et al. Permission to reprint granted by Lippincott Williams & Wilkins.

**HISTORICAL PERSPECTIVE**

In 1912 Faber concluded that Mönckeberg’s calcific medial sclerosis does not occur in coronary arteries. The first coronary calcification described on fluoroscopy was by a German physician, R. Lenk, in 1927 in an article titled, “Rontgendiagnose der koronarsklerose in vivo.” In 1961 Blankenhorn summarized evidence that coronary artery calcium occurred only in atherosclerotic vessels.

In the 1960s, the increased resolution provided by image intensifiers allowed visualization of smaller calcified lesions. It was at that time that coronary angiography findings were also correlated with fluoroscopic findings and coronary anatomical findings. I remember reading a paper in the 1970s mentioning that there can be calcification in the coronaries that can be seen moving with the heart with cardiac cycle on the fluoroscopy before contrast injection. However, even then the paper showed that the site of the calcification did not imply that it was the obstructive site.

The history of coronary calcium includes a 1974 American Heart Journal article exploring the clinical implications of coronary artery calcification identified on angiography. They compared 500 patients, with 250 patients having normal coronary angiograms and 250 without. Coronary calcification was found in individuals with normal coronaries, with the percentage increasing with age. However, those diagnosed with arteriosclerotic heart disease on angiography had a much higher prevalence of coronary artery calcification.

In the 1970s and 1980s, computed tomography (CT) and magnetic resonance imaging (MRI) appeared, and in the 1990s, electron beam CT and helical, or spiral CT, came into clinical use.
meaning that they are timed with cardiac cycle, and acquired during late diastole (before P wave on ECG) with patients holding their breath. Patients hold their breath for about 20–30 seconds while a pass through the CT machine is completed. The area and density of calcium can then be scored by a relatively arbitrary system using the x-ray attenuation coefficient, measured in Hounsfield units (HU). Hounsfield units are a measure of radiographic density. Air has a density of $-1000$ HU, water is 0 HU, and dense cortical bone is $+1000$ HU. A density of at least 130 HU is needed for a density to be considered coronary calcification. The area, volume, or even the mass of calcium deposits can be calculated.

Of these two modalities, helical/spiral (multidetector) CT is more widely available than EBCT. As of 2 or 3 years ago, there were only 39 EBCT machines in the country, whereas every large hospital had a helical/spiral (multidetector) CT. Though multidetector CT is more widely available, radiation exposure is higher, because the image acquisition times are longer compared to EBCT.

Radiation exposure is an important consideration for evaluating screening tests. To compare radiation exposure levels: a PA and lateral chest x-ray is 10 millirems; two-view mammogram is 35 millirems; diagnostic coronary angiography is 210–230 millirems (not including an intervention); EBCT exposure is 70–100 millirems for men and 90–130 millirems for women (radiation dose is increased because of image attenuation by breast tissue); and multidetector CT is 100–150 millirems for men and 100–180 millirems for women.

Multidetector scanners are expensive, $1.5 to $3 million each, but they are multifunctional and can be used to rule out pulmonary emboli, aortic dissection, and for high resolution CT of the lung. Because multidetector CT has only been available since 2000, a great majority of the coronary calcium score data is based on EBCT machines, which have been around for 13 years longer than the multidetector CT. The literature for multidetector CT measured coronary calcium is relatively sparse, and it is difficult to convert EBCT scores to the multidetector format. If a patient had an EBCT in 1999 and has a multidetector helical CT now, “Agatston’s score” can be used to attempt to make this correlation, but it is very difficult.

Five hundred articles on electron beam CT scanning have appeared in the medical literature since 1987, but the application of this technology remains uncertain. EBCT has been most intensely promoted by those who are at least potentially biased. EBCT has been promoted and marketed to the public as a screening technique, but it has never been recommended by the American Heart Association (AHA) or American College of Cardiology (ACC) for this purpose. It has been intensely promoted, largely by people who either own or have vested interest in the success of the “machine.” There are EBCT scanners on trucks that can go to any small town or neighborhood. The technology is available and can go anywhere, but the value of the results remains uncertain.

In general, the images begin with a “cut” at the level of the aorta where the left main coronary artery originates, so the course of the coronaries can be traced in the images. See Greenland’s recent New England Journal of Medicine article3 for an example of a representative image (Figure 2 of this reference). This shows focal calcium in the LAD and in the circumflex of an individual whose calcium score was 70.

**AS A PROGNOSTIC INDICATOR**

Use of coronary artery calcification as a prognostic indicator is based on the principle that calcification occurs exclusively in atherosclerotic arteries and is absent in the normal vessel wall. Important questions that remain include: whether the detection of coronary calcium increases the likelihood of obstructive coronary heart disease beyond proven, available tests; whether knowledge of calcium score predicts or improves patient outcomes; and the specific role of coronary calcium as-
essment in patient care. The American College of Cardiology and the American Heart Association published a consensus statement in 2000 that provided guidelines for use of EBCT. A negative EBCT test makes the presence of atherosclerotic plaque, including unstable plaque, very unlikely. Although possible, the presence of soft plaque with no calcification somewhere in that vessel is unlikely. A negative EBCT is highly unlikely in the presence of significant luminal obstructive disease. Negative EBCT tests occur in the majority of patients who have normal coronary arteries, where there is no evidence of atherosclerotic plaque. Negative EBCT may be consistent with low risk of a cardiovascular event over the next 2–5 years.

Conversely, positive EBCT confirms the presence of a coronary plaque. The greater the amount of calcium, the greater the likelihood of occlusive disease, but there is a not a 1:1 relationship and findings may not be site specific. The total amount of calcium correlates best with the total amount of plaque, although the true “plaque burden” is underestimated. Generally, it is thought that calcium score identifies about 20% of the plaque, ie, most of the plaque is not actually calcified. Calcium score does not assess whether the plaque is moving into the lumen and developing into an obstructive lesion at the site. A high calcium score may be consistent with moderate to high risk of cardiovascular event within the next 2–5 years.

LIMITATIONS TO CAC ASSESSMENT

There are major limitations to coronary artery calcification (CAC) assessment. Health insurance companies do not pay for CAC, which costs the patient around $350–$500 out of pocket. As a clinician, I question where this test fits in, if insurance companies do not believe it identifies those that should be treated more aggressively. Patients often present to cardiologists after an EBCT shows a high CAC score. A treadmill myocardial perfusion study is usually performed to assess the CAC result. Thus, CAC assessment often requires additional tests, which are expensive and perhaps add risk, leading to questions concerning the incremental value over traditional risk assessment.

The prevalence of calcification in women and African-American men is lower than in Caucasian men. African-American men with either the same or worse risk profile have about 39% as much calcification as Caucasian men based on a large study conducted by the Army. If an African-American man has calcification, there is probably more plaque than would be indicated if the score was indexed against those developed for Caucasians. In women, there are two variables to consider. Coronary atherosclerosis has a 10-year lag in women compared to men, and in general, women tend to calcify less than men. The major reason why calcium scores are lower in women is because of the 10-year lag. The prevalence of CAC in women at age 60 is similar to that of men at age 50.

EBCT reproducibility is suboptimal. One study compared scoring of two EBCT scans performed the same day and showed major statistical differences in the scoring. With more defined measurement techniques, EBCT has a 15% reproducibility error, and multidetector CT has a 23% error. With multidetector CT in almost one fourth of instances, serial CAC scanning results in significantly different scores. The next time the patient is scanned, the CAC may appear to change. This has implications for serial testing.

A further limitation is that after 18 years of use, there are insufficient high quality data about EBCT for the AHA/ACC to generate practice guidelines for its use in screening for coronary calcium. There are guidelines for treadmill testing, coronary angiography, echocardiography; and many other topics that have been well studied and defined, but there are no guidelines for the use of coronary artery calcium screening from these organizations. There is a 2003 task force paper and an anticipated modification to the ACC/AHA EBCT consensus statement, but there are still
no guidelines for cardiologists and other clinicians.

The term “large randomized control trial” does not apply to any of the 500 papers that have been published about EBCT testing. Currently, there are two large perspective randomized controlled trials. One is called the Multiethnic Study of Atherosclerosis (MESA) in the United States, and there is a similar trial in Europe. Data will not be evaluated and analyzed until 2007.

In available publications, most data have been acquired from self-referred people. This population is skewed by including people who can spend $350–$500 on the test. Two patient groups seek EBCT, healthy persons who want to know their status, and persons with chest pain concerned that the cause is cardiac. Persons with new onset chest pain sometime obtain these tests before being evaluated by a cardiologist. To emphasize once again, CAC assessment has not yet been shown to improve patient outcomes, and there are no data that show CAC results alter treatment.

O’Rourke et al compared exercise testing and other test modalities including perfusion scintigraphy, exercise echocardiography, pharmacologic stress scintigraphy, dobutamine echocardiography, and EBCT.4 In Table 1 they are listed as sensitivity, specificity, and predictive accuracy, the percent of time the test correctly assigns the patient to disease if the test is abnormal and to no disease if the test is normal. Sensitivity for a standard treadmill test is 68%, specificity 77%. If perfusion scintigraphy is added to exercise testing, sensitivity increases considerably to 89%, specificity stays about the same, but the predictive accuracy increases from 73% to 89%. Exercise echocardiography has about the same statistics. Pharmacologic stress testing and dobutamine echocardiography have about the same sensitivity, specificity, and predictive accuracy. EBCT is the most sensitive (91%), but the least specific (49%) for the detection of obstructive coronary disease. The low specificity results in a predictive accuracy that is even less than a standard treadmill test. This highlights one of the major limitations of EBCT. It identifies atherosclerosis, but it does not identify obstructive disease. The benefit of EBCT is largely its negative predictive value. A score of 11 compared to 1000 seems reassuring, but a CAC score of 0 is the most predictive. Even at CAC scores between 507 and 680, the positive predictive value for cardiac events is only 14% over 4 years.4

Receiver-operator characteristic (ROC) analysis of data from several studies demonstrate that high sensitivity (true positive rate) is only achieved at a high false-positive rate. The low specificity of EBCT is a major issue.

ACC and AHA guidelines and scientific statements have discouraged the use of ambulatory monitoring, treadmill testing, stress echo, stress myocardial perfusion imaging, and EBCT as routine screening tests in asymptomatic individuals. On the other hand, the September 20, 2004, issue of TIME magazine had an article suggesting President Clinton could have avoided his bypass, if he had only had an EBCT. The TIME author refers to a study published in the medical literature7 where out of 1119 patients that had negative perfusion studies, more than half of them had high calcium scores on EBCT, suggesting (according to TIME) significant hardening of the arteries. Which test is the gold standard, myocardial perfusion treadmill test or EBCT? The TIME article suggested that high calcium score on EBCT is an indication for the performance of a coronary angiogram on the patient. Such statements lead patients to seek angiography, or question why angiography is not performed, but such advice is counter to current guidelines for coronary angiography and has nothing to do with the reality of how CAC testing should be used.

Arad and associates studied the EBCT CAC scores of 1172 asymptomatic subjects who had EBCT in response to an advertisement.8 Calcium scores ranged from 0 to over 8000, average follow-up was 3.6 years, and the endpoints of the study were death, nonfatal MI, or revascularization, including bypass surgery or angioplasty. When revascularization

<table>
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<th>Grouping</th>
<th>No. of Studies</th>
<th>Total No. of Patients</th>
<th>Sensitivity, %</th>
<th>Specificity, %</th>
<th>Predictive Accuracy, %</th>
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MI indicates myocardial infarction.

is added as an endpoint, an element of subjectivity is added. Death and myocardial infarction are easily and objectively defined, but each individual physician determines when and if a patient is treated with revascularization. There were 3 coronary deaths in these 1172 patients, but the scores of these individuals were not given. A progressive increase in events with increasing coronary artery calcium scores was shown, so the higher the score the more likely are events.

Very high CAC scores pose an extremely elevated risk for “hard” events. An observational study compared 98 asymptomatic patients with calcium scores greater than 1000, with no further testing, to a control group of symptomatic patients who had positive myocardial perfusion studies. The patients who had EBCT scans chose not to have any testing. Whether these patients were treated more aggressively or not is unknown. The study outcomes were hard events, coronary death or myocardial infarction. The event-free survival curve for the 98 patients showed a decrement up to about 27 months and then became flat, with no events from 27 to 37 months. Event-free survival rate was significantly decreased compared to controls. There were 23 myocardial infarctions and 12 deaths in the 98 patients with very high calcium score.

An article that appeared in JAMA in January 2004 evaluated the combination of coronary artery calcium score with Framingham score for risk prediction in asymptomatic participants of the South Bay Heart Watch study from California. This is a prospective observational study of 1400 asymptomatic subjects, mostly Caucasian men, with at least moderate risk followed for a median of 7 years. The endpoint was hard coronary events, either death or myocardial infarction. Diabetics were excluded from this study, important because calcium scoring has not been found to have predictive value in diabetics. The receiver operating characteristic curve for Framingham score vs coronary calcification showed that the area under the Framingham plus CAC score curve was greater than the area under the Framingham risk score-only curve. Univariate Cox regression analysis of all-cause mortality showed that coronary artery calcium score (using >300 as the cut point) was not predictive of an increased hazard of death. A Framingham risk score predictive for >20% 10-year cardiac event risk (2% per year) did predict all-cause mortality. A calcium score >300 was shown to add predic-
Table 2. Probability of a Coronary Event Within 10 Years Calculated on the Basis of the Results of Electron-Beam CT or of Exercise Electrocardiography. From Greenland and Graziano.3 Reprinted with permission. ©2003 Massachusetts Medical Society. All rights reserved

<table>
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<tr>
<th>Pretest Probability of a Coronary Event within 10 Yr</th>
<th>Probability within 10 Yr According to Results of Electron-Beam CT</th>
<th>Probability within 10 Yr According to Results of Exercise Electrocardiography</th>
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<tr>
<td>Calcium Score ≥80</td>
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<td>20.0</td>
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</table>

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tive value in a moderate risk patient (10%–20% Framingham 10-year cardiac event risk), however, 14 of 316 (4%) subjects with a calcium score of 0 had a coronary event. Therefore, a calcium score of 0 doesn’t completely exclude coronary risk.

CALCIFIED SCORING VS OTHER NON-INVASIVE TESTS

Greenland et al presented post-test 10-year coronary event probability for EBCT score ≥80, vs <80, given a range of pretest 10-year coronary event probabilities (Table 2).3 Similar probabilities were presented for results of exercise electrocardiography. For calcium score ≥80 (a moderate score), if the 10-year pretest coronary event probability was 7%, post-test probability increased to 20%. That individual’s risk has gone from low to a high, because post-test there is 20% 10-year risk of a coronary event. On the other hand, EBCT is weaker, in every category of pretest probability, than an abnormal treadmill test. For 7% pre-test probability, EBCT calcium score ≥80 increases post-test 10-year event probability to 20%. An abnormal treadmill test performed when pretest probability is 15%, increased post-test probability of an event to 44%, whereas post-test probability increased to 38% with EBCT calcium score ≥80. EBCT calcium score ≥80 does increase post-test probability, but less so than a positive treadmill test.

A recent observational study of 1195 subjects compared perfusion scanning and calcium score performed within 6 months of each other. The study included symptomatic and asymptomatic men and women. This was not an outcome study, but a direct comparison of coronary calcium scores and perfusion scan results. They observed that a positive perfusion scan was rare, 2% or less, if calcium score <100, for all patients in the study. A symptomatic patient with a CAC score between 10 and 99 had a tripling of the frequency of a positive perfusion scan compared to asymptomatic patients. But, when pooled together, for those with calcium scores <100, the probability of a positive perfusion scan was less than 2%.

Absolute calcium score was found to be more predictive than the age- and gender-based percentile, and better predicted positive perfusion scans. Low calcium score with a high percentile rank in the young could indicate long-term, but not short-term risk. For a 30 year old, a calcium score of 10 is not an absolute high score, but it is in a high percentile rank. Short-term risk is likely low, but long-term risk may be increased. They also found that patients who had a score greater than 1000, a very high score, 85% who were asymptomatic had a normal perfusion scan, and 68% who had symptoms had a normal perfusion scan. So, two thirds of symptomatic patients with calcium score >1000 have a negative perfusion scan. These investigators also thought that calcium scores between 100 and 400 were a large “gray zone” in terms of risk prediction.
MORTALITY RISK

In 2003 Shaw published an observational study in *Radiology* of 10,377 asymptomatic patients who had coronary artery calcium scans. Subjects were referred for calcium scans by internists because of risk factors and were followed for a mean of 5 years. For each 10-year age group, women had a mean CAC score less than men, even over age 80 years. For those over age 80, the mean score for men is 1070 and only 291 for women. This adds emphasis to the point that women calcify less than men.

In a univariate Cox proportional hazards model for all-cause mortality for calcium scores of 100 to 400, the relative risk of death was 3.55. For calcium scores over 400, the relative risk of death was 6; and for calcium scores over 1000, relative risk of death was 12.29. Similar findings were seen with a multivariate Cox proportional hazard model adjusted for age, gender, and traditional coronary risk factors. There is a sharp increase in relative risk of death at calcium scores over 400 observed, as well. Comparison of cumulative survival curves shows that women fare worse than men at a given score, that is, the survival of women with calcium score of 400 is less than men with a score of 400. Because women calcify less, they have worse disease by the time they have a similar high score.

BEST USES OF CAC ASSESSMENT

What do we conclude about coronary artery calcium scanning? Existing tests such as exercise testing, perfusion scintigraphy, and exercise echocardiography are extraordinarily well validated with respect to prognostic implications. EBCT is simply not as well studied, and there are no randomized controlled trials. EBCT is not superior to other currently available diagnostic procedures for diagnosis of angiographically confirmed coronary artery disease. EBCT doesn’t predict obstructive coronary disease better than the other tests.

As mentioned in the ACC/AHA 2000 consensus statement, “Misuse or abuse of coronary artery calcium technologies as broad based screening tools has created considerable controversy.” The main limitations are lack of specificity, it is self-pay, it is very expensive, and there is no evidence that intervention based on calcium scores improves outcomes. Hopefully, the ongoing MESA trial or the European trial will provide this information in the future.

The main benefit from EBCT is its negative predictive value. If it is truly negative, the result is reassuring, especially in those who are asymptomatic. A reasonable conclusion may be that future guidelines for the use of EBCT may suggest that, for example, a patient with an intermediate Framingham risk and a calcium score of perhaps 100, will move that individual into the >20% 10-year coronary event risk group, a coronary equivalent. This doesn’t mean these individuals should have angiography or other testing, it means that they should be treated as high-risk patients. Increased EBCT calcium score also appears to predict mortality and myocardial infarction.

The best current use of EBCT is in the setting of an abnormal myocardial perfusion study or stress echo in a patient with a low pretest probability of disease. An example of a common situation is a 38-year-old woman with a low Framingham risk profile presenting with chest pain that is likely noncardiac, and an abnormal myocardial perfusion study. If an EBCT or a multidetector CT shows a calcium score of <100, there may be as low as a 2% chance of obstructive coronary disease. The EBCT result would save these individuals from having an angiogram.

Additional uses include triggering further testing or intensification of therapy for scores in the fourth quartile for age and gender, for an absolute score >400, or perhaps in those at intermediate Framingham risk to determine whether or not these patients may have a coronary equivalent. EBCT may also be helpful in the elderly, since traditional risk factors lose some of their predictive power in this group of people.

Editor’s Note: Based on a presentation to the American Academy of Insurance Medicine at Denver, Colorado, on October 4, 2004.
REFERENCES


