Subject: Electron Beam Computed Tomography for Detection of Coronary Artery Disease

Background: Electron beam computed tomography (EBCT) is a noninvasive imaging technique that can detect calcium deposits in coronary arteries. These calcium deposits are often associated with atherosclerotic plaques, and it has been proposed that detection of coronary calcification can provide an early and sensitive method of diagnosing coronary artery disease (CAD). Although there have been earlier studies examining the diagnostic and prognostic value of EBCT screening for coronary artery calcification (CAC), it may be considered obsolete.

Policy and Coverage Criteria:
Harvard Pilgrim Health Care (HPHC) considers electron beam computed tomography (EBCT) experimental/investigational, and it is therefore not covered.

Supporting Information:
Electron beam computed tomography (EBCT), also referred to as cine or ultrafast computed tomography (CT), is intended as a noninvasive imaging modality for patients with heart disease. EBCT can provide information regarding cardiac structure and function, myocardial perfusion, and the patency of vascular grafts. The rationale for the use of EBCT to detect calcium in coronary arteries is that calcium is deposited early in the formation of atherosclerotic plaques, and, therefore, calcification may be useful as a marker of the atherosclerotic process. For EBCT scanning, the patient is placed on the scanning table or couch, which then is positioned at an angle by tilt or rotation to achieve the best view of the desired images. An electron beam is generated proximal to the head of the supine patient. The beam passes through a magnetic coil, which permits focusing, angulating, and steering of the beam across a series of tungsten targets. The EBCT scanner allows three different modes for the acquisition of data: the volume mode, the flow mode, and the cine mode. High-resolution, or volume mode scanning, is best for showing anatomic detail such as coronary artery calcification (CAC). For this indication, a scanning time of 100 ms is used, x-rays are directed toward a single detector ring, and the scanning couch moves during the scanning sequence to encompass axial anatomy. Data from each scan are converted to digital information via computer analysis and reconstructed on a television-like monitor screen as a tomographic image. The volume mode produces up to 40 thin slices, which can be reformatted in any plane, and provides excellent spatial resolution with minimal motion artifacts. Quantification of coronary artery calcification is based on the x-ray attenuation coefficient or CT number, and the area of calcified deposits.

The goal of calcium scoring is to detect coronary artery disease (CAD) at an early stage when there are no symptoms and to determine its severity. A negative cardiac CT scan that shows no calcification within the...
coronary arteries suggests that atherosclerotic plaque is minimal at most, and that the chance of CAD developing over the next two to five years is very low. A positive test means that CAD is present, even if the patient has no symptoms. It is proposed that the amount of calcification, expressed as a score, may help to predict the likelihood of myocardial infarction (MI) in the coming years.

<table>
<thead>
<tr>
<th>Calcium Score</th>
<th>Presence of Plaque</th>
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<tbody>
<tr>
<td>0</td>
<td>No evidence of plaque</td>
</tr>
<tr>
<td>1-10</td>
<td>Minimal evidence of plaque</td>
</tr>
<tr>
<td>11-100</td>
<td>Mild evidence of plaque</td>
</tr>
<tr>
<td>101-400</td>
<td>Moderate evidence of plaque</td>
</tr>
<tr>
<td>Over 400</td>
<td>Extensive evidence of plaque</td>
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Literature shows a number of studies of asymptomatic populations which validate that coronary calcium in these individuals is a parameter with significant predictive power regarding the development of future cardiac events. Yet, the results do not illuminate what actions, if any, should be taken, based on the resulting CAC scores. It is not clear whether calcium screening with EBCT adds any useful information beyond that provided by standard risk factors. Results of studies of symptomatic populations also do not provide any significant information than from other risk indicators. While most clinicians agree that people with higher calcium scores are at a greater risk for myocardial infarction, there is little evidence that calcium scores lead to more effective treatments and better outcomes from cardiac events. Consensus is lacking on whether the addition of CAC scores to traditional CHD risk factors leads to any improvement in treatment or care.

A 2008 review by Elkeles stated that while a CAC score has been shown to be a powerful predictor of coronary heart disease events in the general population, different ethnic populations, and in type 2 diabetics, it only adds incremental value to conventional risk factors and risk scores. EBCT’s role in monitoring therapy has yet to be proven. A 2008 study by Geluk et al. reported on a cohort of 304 symptomatic, low-risk patients comparing CAC scores with exercise testing as the initial diagnostic tool. The combined endpoint was defined as coronary event of obstructive CAD at coronary angiography (CAG). CAC scores greater than 400 were found in 42 patients with a combined endpoint occurring in 25. CAC scores between 10 and 399 were reported in 103 patients with the combined endpoint occurring in 14. 159 patients had CAC scores of less than 10. No combined endpoint occurred in that group. The authors found that EBCT screening for CAC provided effective triage in patients with suspected CAD with normal ECG and normal cardiac markers. However, they did note that the absence of a gold standard in every patient since the procedure to determine the endpoints was influenced by the test results. Kronmal et al. (2007) evaluated risk factors for the progression of CAC in 5756 participants from MESA. EBCT and MDCT were both utilized in the analysis. Diabetes was the strongest risk factor for CAC progression. Results showed the annual amount of CAC progression increased linearly across age, with a similar trend for men and women. With the exception of diabetes mellitus, risk factor relationships were largely the same across racial/ethnic groups. Budoff et al. (2007) conducted an observational, outcome data series of a cohort of 25,253 consecutive, symptomatic individuals referred by their PCPs for CAC scanning by EBCT. More than ½ of the patients had detectable CAC. In subsets with more extensive CAC scores, patients were older and had more frequent cardiac risk factors. The mean follow up for patients was 6.8 ± 3 years. After adjustment for risk factors, including age, results showed that CAC was an independent predictor of mortality. Based on this and
other results, the authors concluded that CAC is an independent estimator of all-cause mortality. They felt this results support the idea that increasing coronary atherosclerosis is a strong and independent predictor of future cardiac events. However, they did note that the majority of the patients screened in this study had cardiac risk factors and may not be representative of the general population. Nasir, et al. (2007) also conducted an observational, outcome data series of a cohort of 14,812 asymptomatic patients referred for CAC screening with EBCT. The all were referred on the basis of the presence of established risk factors. The mean follow-up period was 6.8 ± .002 years. 57% of the patients screened had a CAC score of 10 or less. The prevalence of CAC scores of 11 to 100, 101 to 400, 401 to 999, and ≥ 1000 was 20%, 14%, 6% and 3% respectively. When comparing prognosis by CAC score in ethnic minorities as compared with non-Hispanic whites, relative risk rations were highest for African Americans with CAC scores ≥ 400 exceeding 16.1. The authors felt their results provided support for the development of ethnic-specific guidelines and more aggressive population-specific screening and educations programs focused on ethnic minorities. Also, that a greater intensity of treatment in the presence of CAC may reduce the excess morbidity and mortality for ethnic minority patients. Studies by Arad et al. (2000), Wong et al. (2000), Kondo, et al. (2003), and Goldin et al. (2001) found that the presence of coronary calcium detected by EBCT in asymptomatic patients is a prognostic parameter with significant predictive power regarding the development of cardiac events. For a median of five years, Shaw et al. (2003) followed 10,377 asymptomatic patients considered at above-average risk for CAD prior to calcium scoring. Based on their results, they concluded that the scoring of coronary calcium provided independent incremental information in addition to the traditional risk factors in the prediction of all-case mortality.

Budoff et al. (1996) reported on the EBCT conducted on 710 symptomatic patients undergoing coronary angiography for clinical indications. Of these, 427 had significant angiographic disease. CAC was detected in 404 of the 427. Only 23 of the 427 patients with angiographically significant disease had no calcifications detected by EBCT. Of the 283 patients without angiographically significant disease, 124 had negative EBCT coronary studies. EBCT sensitivities (any calcium present) for detecting one, two, three and four vessel angiographic disease were 89%, 99%, 97%, and 100% respectively. Based on these results, the authors stated that EBCT in a noninvasive, non-exercise-dependent test with excellent sensitivity for the detection of CAD. A 1998 study by Achenbach et al. conducted EBCT on 125 symptomatic patients admitted for inpatient diagnostic coronary angiography. EBCT demonstrated a sensitivity of 92%, a specificity of 94%, a positive predictive value or 78%, and a negative predictive value of 98% for the detection of substantial coronary lesions in evaluable arteries. These findings led the authors to conclude that EBCT may be useful to detect or rule out high-grade coronary-artery stenoses and occlusions when image quality is adequate. As part of a NHLBI study, Hopkins et al. (2006) observed 3359 patients who underwent MDCT for CAC scoring, including 389 with clinically diagnosed coronary heart disease. A cohort of 2254 of the patients who were initially free of diagnosed coronary heart disease were also part of the 3359. In cross-sectional analyses, the authors examined associations between CAC and coronary heart disease in the entire group and in the subgroup seen at the initial examination. Their analyses found that CAC was strongly associated with coronary heart disease even after adjustment for standard risk factors; and family history contributed independently to coronary heart disease risk. The also noted that familial factors transmitted risk either by mechanisms that are not entirely reflected in CAC and standard risk factors or though complex interactions of such factors.

The U.S. Preventive Services Task Force (USPSTF) concludes that the evidence is insufficient to assess the balance of benefits and harms of using the nontraditional risk factors discussed in this statement to screen asymptomatic men and women with no history of congenital heart disease (CHD) to prevent CHD events.
nontraditional risk factors included in this recommendation are high-sensitivity C-reactive protein (hs-CRP), ankle-brachial index (ABI), leukocyte count, fasting blood glucose level, periodontal disease, carotid intima-media thickness (carotid IMT), coronary artery calcification (CAC) score on electron-beam computed tomography (EBCT), homocysteine level, and lipoprotein(a) level.

Coding:
Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>Description</th>
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<tr>
<td>S8092 Electron beam computed tomography (also known as ultrafast CT, cine CT)</td>
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References:

HPHC Clinical Medical Policy

Electron Bean Computed Tomography for Detection of Coronary Artery Disease

HPHC policies are based on medical science, and written for the majority of people with a given condition.

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.

Summary of Changes

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>5/ 2/17</td>
<td>Background information and references updated</td>
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Approved by UMCPC: 5/2/17
Reviewed/Revised: 5/01; 5/03; 4/09; 3/11; 3/13; 4/15; 5/17
Initiated: 5/01