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MEDICAL POLICY

CARDIAC COMPUTED TOMOGRAPHY (CT), CORONARY ARTERY CALCIUM SCORING AND CARDIAC CT ANGIOGRAPHY

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Related Medical Policies:

- Transthoracic Echocardiography
- Single Photon Emission Computed Tomography Myocardial Perfusion Imaging (SPECT MPI)

Related Coverage Determination Guidelines:
None

INSTRUCTIONS FOR USE

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COVERAGE RATIONALE

Calcium Scoring

Coronary artery calcium scoring, using electron beam or multislice computed tomography 16-slice or greater technology, is proven for the following:

- risk stratification in asymptomatic patients with moderate risk for coronary heart disease (CHD) based on Framingham score[1]
- as a triage tool for symptomatic patients to rule out obstructive disease and avoid an invasive procedure

Coronary artery calcium scoring is unproven for all other indications, including routine screening. The evidence indicates that screening asymptomatic adults for coronary heart disease is ineffective and that the harms may outweigh the benefits.

Cardiac CT Angiography

Computed tomography angiography (CTA), using 32-slice or greater technology, is proven for assessing the following:

- detecting coronary artery disease in asymptomatic patients with high risk of coronary heart disease (CHD)[1]
- to rule out coronary artery disease in symptomatic patients with a low to intermediate pre-test probability of coronary artery disease (CAD)[2]
- chest pain syndrome following a revascularization procedure (stent placement or angioplasty)
- suspected coronary artery anomaly
- preoperative risk assessment for intermediate or high risk non-cardiac surgery[3]
- morphology of congenital heart disease, including anomalies of coronary circulation, great vessels and cardiac chambers and valves
- assessment of coronary arteries in patients with new onset heart failure to assess etiology

Computed tomography angiography (CTA) is unproven for the following:

- detecting coronary artery disease in symptomatic patients with a high pre-test probability of CAD[2]
- assessing coronary arteries in symptomatic patients with previously diagnosed CAD
- post-revascularization procedure to rule out in-stent restenosis or assess bypass grafts in asymptomatic patients
- routine screening in asymptomatic patients or patients at low risk of CAD

Visualization of the stent lumen is often affected by artifacts, and the positive predictive value is low.

The inability to reliably visualize the native coronary arteries in patients post-CABG poses severe restrictions to the general use of CT angiography in post-bypass patients.

Additional information

Coronary CTA should only be considered when the potential risks posed by catheterization outweigh the potential risks posed by the somewhat less accurate detection of clinically significant CAD by CTA. In addition, coronary CTA is not suitable for patients who are likely to require coronary angioplasty or stenting since CTA will not allow these patients to avoid cardiac catheterization in any event, and this is the primary advantage of coronary CTA.

Cardiac CT

Cardiac computed tomography, with or without contrast, using 32-slice or greater technology, is proven for assessing cardiac *structure/anatomy* for the following:

- pulmonary vein anatomy prior to ablation procedure
- coronary vein mapping prior to placement of biventricular pacemaker or biventricular implantable cardioverter defibrillator
- coronary arterial mapping, including internal mammary artery, prior to repeat sternotomy
- suspected cardiac mass (tumor or thrombus) or pericardial disease in patients with technically limited images from echocardiogram, magnetic resonance imaging (MRI) or transesophageal echocardiogram (TEE)

Cardiac computed tomography, with or without contrast, using 32-slice or greater technology, is proven for assessing cardiac *function* when the primary procedure with which it is associated is proven.

1. The risk for coronary heart disease in asymptomatic patients is based on Framingham risk criteria which estimate the risk of developing CHD within a 10-year time period. In

general, low risk will correlate with a 10-year absolute CHD risk less than 10%, and moderate risk will correlate with a 10-year absolute CHD risk between 10-20%. High risk is defined as the presence of diabetes or a 10-year absolute CHD risk of greater than 20% (Wilson, 1998). The Framingham Scoring Sheet is available at: http://www.framinghamheartstudy.org/risk/index.html. Accessed April 8, 2010.

2. The pre-test probability for CAD in symptomatic patients is based on age, gender and symptoms and is defined as follows:
   - High - greater than 90% pre-test probability
   - Intermediate - between 10% and 90% probability
   - Low - between 5% and 10% pre-test probability
   - Very low - less than 5% pre-test probability

Typical (definite) angina is defined as substernal chest pain or discomfort that is provoked by exertion or stress and relieved by rest and/or nitroglycerin.

Atypical (probable) angina is defined as chest pain or discomfort that *lacks one* of the characteristics of typical angina.

Non-anginal chest pain is defined as chest pain or discomfort that *meets one or none* of the characteristics of typical angina (Gibbons, 2002).

Pretest probability chart

The complete chart is also available at:
http://www.acc.org/qualityandscience/clinical/guidelines/exercise/exercise_clean.pdf. Accessed April 8, 2010.

3. Surgical risk determination is based on a review of the clinical evidence, including medical research cited by the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines, and is defined as follows:
   - Low-risk surgery (reported risk of cardiac death or myocardial infarction (MI) less than 1%) - endoscopic procedures, superficial procedures, cataract surgery, breast surgery, ambulatory surgery.
   - Intermediate-risk surgery (reported risk of cardiac death or myocardial infarction (MI) is 1-5%) - intraperitoneal and intrathoracic surgery, carotid endarterectomy, head and neck surgery, orthopedic surgery, prostate surgery.
   - High-risk surgery (reported risk of cardiac death or myocardial infarction (MI) is greater than 5%) - aortic and other major vascular surgery, peripheral vascular surgery (Fleisher, 2007).

<u>Additional Information</u>

Chest pain syndrome is defined as symptoms consistent with obstructive CAD including, but not limited to, chest pain, chest tightness, burning, dyspnea, shoulder pain and jaw pain (Hendel, 2006).

Materials for Clinical Review

BENEFIT CONSIDERATIONS

State mandates should be reviewed when determining benefit coverage for early detection of cardiovascular disease. In certain limited circumstances, the state of Texas may mandate coverage for computed tomography (CT) scanning or ultrasonography when performed as a screening test for atherosclerosis and abnormal artery structure and function.

CLINICAL EVIDENCE

Coronary artery disease (CAD) is the leading cause of morbidity and mortality in the United States. CAD occurs when the arteries that supply blood to heart muscle become hardened and narrowed due to the buildup of cholesterol and plaque (atherosclerosis). As the buildup grows, less blood can flow through the arteries, depriving the heart muscle of blood and leading to chest pain (angina) or a heart attack (myocardial infarction).

The standard method for assessing the coronary arteries is coronary angiography, also called cardiac catheterization, an invasive and time-consuming procedure. To avoid catheterization and potential complications associated with coronary angiography, less invasive techniques using computed tomography (CT) technology have been developed.

Because the heart is in motion, a fast type of CT scanner is used to create high-quality images. Electron beam computed tomography (EBCT) takes multiple images very rapidly to avoid blurring. Multidetector CT (MDCT) or multislice CT (MSCT) spiral scanners have multiple rows of detectors (e.g., 16, 40, 64) that take many images of the heart at the same time. Dual source CT scanners use two x-ray sources and two detectors at the same time. To enhance visualization of the coronary arteries, an intravenous contrast agent may be used. Although cardiac CT uses radiation, it is a small amount.

<u>Coronary Artery Calcium (CAC) Scoring</u>

Background

Coronary artery calcium scoring uses cardiac CT, a noninvasive, radiographic technique, to detect calcium deposits in coronary arteries. The test does not require the injection of contrast dye. Coronary artery calcification is associated with atherosclerosis, and it has been proposed that detection of coronary calcification may be an early predictor of heart disease. Both EBCT and MDCT are used to detect calcium buildup in the arteries. Following the test, a calcium or Agatston score is given based on the *amount* of calcium found in the coronary arteries. The higher the Agatston score, the greater the amount of atherosclerosis. The calcium coverage score takes into account not only the amount, but also the *distribution*, of calcium build-up in the coronary arteries.

Clinical Evidence

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). A number of studies have demonstrated that EBCT is a sensitive, noninvasive method of detecting coronary calcification, and, in many patients, EBCT-derived coronary calcium scores can accurately predict the extent of CAD. Although EBCT cannot be used in place of conventional coronary angiography, there is evidence that EBCT may aid in risk stratification in symptomatic patients with inconclusive test results or atypical chest pain to determine if additional cardiac testing is indicated. There is also some evidence that EBCT scores are equal or superior to traditional risk factors in predicting cardiac risk in asymptomatic individuals, however, it is unclear how the detection of coronary calcification should influence the management of these individuals, and an overall health benefit has not been proven (Hayes, 2003).

Coronary calcium scores measured with electron-beam computed tomography (EBCT) scanners predict future coronary events such as heart attack and need for revascularization procedures. The predictive value of these scores has been demonstrated in symptomatic and asymptomatic patients at high and low risk of heart disease. Coronary calcium scores appear to have predictive value over and above that of risk factors such as age, blood pressure, and cholesterol levels (and the widely used Framingham risk score, which combines these and other factors) in asymptomatic high-risk patients. However, there is no published evidence that coronary calcium screening lowers coronary artery disease (CAD) mortality or otherwise improves health outcomes. Also, a negative EBCT result does not mean that a patient has zero risk of heart disease. While EBCT may never be used for widespread CAD screening, its use as a diagnostic test will increase for asymptomatic patients at intermediate-to-high risk for developing cardiovascular disease and in symptomatic (e.g., atypical chest pain) patients who undergo exercise stress testing or other cardiac testing with inconclusive results. EBCT may be useful in helping to determine which patients would benefit most from pharmacologic therapy, such as cholesterol-lowering medication, and which patients should undergo coronary angiography to detect obstructive CAD (ECRI, 2004).

Multi-Ethnic Study of Atherosclerosis (MESA)
Sponsored by the National Institutes of Health (NIH), MESA studied the characteristics of subclinical cardiovascular disease (disease detected non-invasively before it has produced clinical signs and symptoms) and the risk factors that predict progression to clinically overt cardiovascular disease or progression of the subclinical disease. MESA researchers studied a diverse, population-based sample of 6,500 asymptomatic men and women aged 45-84 who were recruited from 6 U.S. communities from 2000 to 2002.

Brown, et al. (2008) calculated the calcium coverage score (CCS) for participants in the MESA study in whom calcified plaque was detected with CT. The calcium coverage score represents the percentage of coronary arteries affected by calcified plaque versus an overall measure of plaque burden. The prospective study included 6814 men and women aged 45 to 84 years. Investigators compared CT data from 3252 participants with calcification of the coronary arteries and 3416 subjects without calcification. The purpose of the study was to correlate the new CCS with risk factors and cardiovascular events and to compare this association with traditional calcium scores. While the investigators noted that the CCS does have limitations, especially since it depends on an accurate tracing of the coronary arteries down their entire length, the study showed that the CCS was a better predictor of cardiovascular events compared with calcium scores that account for a generalized burden of calcification. The CCS, as well as the Agatston and mass calcium scores, were significant predictors of coronary heart disease events, but the coverage score was a better predictor of future coronary events than both scores, especially among patients with low Agatston scores.

As part of the MESA trial, Detrano et al. (2008) performed scanning for coronary calcium in a population-based sample of 6722 men and women, of whom 38.6% were white, 27.6% were black, 21.9% were Hispanic, and 11.9% were Chinese. The study subjects had no clinical cardiovascular disease at entry and were followed for a median of 3.8 years. No major differences among racial and ethnic groups in the predictive value of calcium scores were detected.

McClelland et al. (2006) published detailed tables and figures describing the racial/ethnic distribution of coronary calcium in a relatively unbiased population sample.

See the following website for additional information on the MESA study. http://www.mesa-nhlbi.org. Accessed April 16, 2010.

Asymptomatic Patients
Numerous cohort studies have shown that the presence of coronary calcium demonstrated by EBCT in asymptomatic individuals is a prognostic parameter regarding the development of cardiac events (e.g., coronary death, nonfatal MI, the need for revascularization procedures).

A meta-analysis including 6 cohort studies published between 2003 and 2005 in 27622 patients (n=395 CHD death or MI) found that the 3 to 5 year risk of any detectable calcium elevates a patient's CHD risk of events by nearly 4-fold. The analysis also found that patients without detectable calcium have a very low rate of CAD death or MI (0.4%) over 3 to 5 years of observation (n = 49 events/11 815 individuals) (Greenland, 2007).

The Heinz Nixdorf Recall study (HNR) is currently in progress in Germany. This study recruited a total of 4814 participants aged 45-74 years (Schmermund, 2006).

Detrano et al. (2005), as part of the MESA trial, studied 6741 asymptomatic participants. CAC was measured by using duplicate CT scans. Results showed a total of 3355 participants; 49.8% had calcium (Agatston score > 0) detected on at least one of the two scans. Overall agreement between scans was high (95.9%). The authors stated that CT coronary calcium assessments can be performed with equivalent reproducibility using either EBCT or MDCT. Detrano et al. noted that for both types of scanners, volume-based coronary calcium measurements result in only minimally improved rescan reproducibility (< 2% difference) compared with that of Agatston score.

LaMonte et al. (2005) followed 10746 adults for 3.5 years (Copper Clinic Study). There were 81 hard events (i.e., coronary heart disease death, nonfatal MI) and 287 total events (i.e., hard events plus coronary revascularization) that occurred. Age-adjusted rates (per 1,000 person-years) of hard events were computed according to four CAC categories: no detectable CAC and incremental sex-specific thirds of detectable CAC; these rates were, respectively, 0.4, 1.5, 4.8, and 8.7 for men and 0.7, 2.3, 3.1, and 6.3 for women. CAC levels also were positively associated with rates of total CHD events for women and men. The association between CAC and CHD events remained significant after adjustment for CHD risk factors. CAC was associated with CHD events in persons with no baseline CHD risk factors and in younger (aged <40 years) and older (aged >65 years) study participants.

Pletcher et al. (2004) performed a meta-analysis of four of the early cohort studies and found that the risk of major CHD events increased 2.1-fold and 10-fold for scores ranging from 1 to 100 and >400, respectively, as compared with scores of 0. This relationship has been established when predicting all-cause mortality, cardiovascular events, CHD death or nonfatal MI, and overall CHD events.

In a prospective, observational population-based study of 1461 asymptomatic adults with coronary risk factors, Greenland et al. (2004) reported that a high CAC score was predictive of high risk among patients with an intermediate-high FRS greater than 10% (*p* less than 0.001) but not in patients with a low risk FRS (i.e., score less than 10%).

Based on data collected as part of the Prospective Army Coronary Calcium (PACC) study, O'Malley, et al. (2003) focused on the efficacy of using EBCT as a motivational tool to influence asymptomatic individuals to change behavior and modify cardiovascular risk factors. The results of the randomized controlled trial that involved 450 active-duty Army personnel found that the use of coronary calcification screening was not associated with improvement in cardiovascular risk factors at 1 year.

Symptomatic Patients
The utility of coronary artery calcium measurement in symptomatic patients has been widely studied as a noninvasive diagnostic technique for detecting obstructive CAD.

To define CAC test characteristics and compare it with other noninvasive tests, a meta-analysis was performed and published in the 2000 ACC/AHA consensus statement. Patients were included if they had no prior history of CAD or cardiac transplantation. A total of 3683 patients were considered among 16 studies evaluating the diagnostic accuracy of CAC measurement. On average, significant coronary disease (greater than 50% or greater than 70% stenosis by coronary angiography) was reported in 57.2% of the patients. Presence of CAC was reported on average in 65.8% of patients (defined as a score greater than 0 in all but one report). All of the studies evaluated the sensitivity and specificity of electron beam CT (EBCT) to predict CAD. Sensitivities ranged from 68%-100% and specificities ranged from 21%-100%. The pooled statistics revealed a 91% sensitivity and a 49% specificity. The authors concluded that, in a symptomatic population, EBCT was associated with a high sensitivity for CAD, a much lower specificity, and an overall predictive accuracy of approximately 70% in a typical CAD patient population (O'Rouke et al., 2000).

Knez et al. (2004) evaluated 2115 consecutive symptomatic patients with no prior diagnosis of CAD. These patients were being referred to the cardiac catheterization laboratory for diagnosis of possible obstructive coronary artery disease, without knowledge of the CAC scan results. The scan result did not influence the decision to perform angiography. Overall sensitivity was 99%, and specificity was 28% for the presence of any coronary calcium being predictive of obstructive angiographic disease. With volume calcium score greater than 100, the sensitivity to predict significant stenoses on angiography decreased to 87% and the specificity increased to 79%.

Large, multi-center studies have been reported using fast CT for diagnosis of obstructive CAD in symptomatic persons (n = 1851), who underwent coronary angiography for clinical indications. The overall sensitivity was 95%, and specificity was 66% for coronary calcium score to predict obstructive disease on invasive angiography. Increasing the cut-point for calcification markedly improved the specificity, but decreased the sensitivity. In the same study, increasing the CAC cutpoint to greater than 80 decreased the sensitivity to 79% while increasing the specificity to 72% (Budoff, 2002).

In another large study (n = 1764) comparing CAC to angiographic coronary obstructive disease, use of a CAC score greater than 100 resulted in a sensitivity of 95% and a specificity of 79% for the detection of significant obstructive disease by angiography (Haberl, 2001).

Noncalcified Plaque (NCP)
There is growing interest concerning the ability of contrast-enhanced CT coronary angiography to detect (and possibly to quantify and to further characterize) non-calcified coronary atherosclerotic plaque. Data on the accuracy of CT angiography to detect non-calcified plaque are limited to a small number of studies that have compared CT angiography with intravascular ultrasound (IVUS). The fact that there is currently a lack of prospective clinical data that would support the use of contrast-enhanced CT angiography for the assessment of non-stenotic plaque does not allow clinical applications in asymptomatic individuals for the purpose of risk stratification. However, the tremendous potential of CT angiography for visualization and characterization of coronary plaques must be recognized and further research is strongly supported (Schroeder, 2008).

Professional Societies/Government Organizations

American College of Cardiology (ACC)/American Heart Association (AHA)
In a 2007 consensus document, the ACC and the AHA, in collaboration with the Society of Atherosclerosis Imaging and Prevention (SAIP) and the Society of Cardiovascular Computed Tomography (SCCT), made the following clinical recommendations on coronary artery calcium (CAC) scoring:

1. It may be reasonable to consider the use of CAC measurement in asymptomatic patients with intermediate CHD risk (between 10% and 20% 10-year risk of estimated coronary events) based on the available evidence that demonstrates incremental risk prediction information in this patient group. This conclusion is based on the possibility that such patients might be reclassified to a higher risk status based on high CAC score, and subsequent patient management may be modified.

2. The use of CAC measurement in patients with low CHD risk (below 10% 10-year risk of estimated CHD events is not recommended. The committee also does recommend screening of the general population using CAC measurement.

3. CAC measurement in asymptomatic patients with high CHD risk (greater than 20% estimated 10-year risk of estimated CHD events, or established coronary disease or other high-risk diagnoses) is not advised as they are already judged to be candidates for intensive risk reducing therapies based on current NCEP guidelines.

4. No evidence is available that allows the committee to make a consensus judgment to reduce the treatment intensity in patients with calcium score = 0 in patients who are considered intermediate risk before coronary calcium score. Accordingly, the Committee felt that current standard recommendations for treatment of intermediate risk patients should apply in this setting.

5. The question whether there is evidence that coronary calcium measurement is better than other potentially competing tests in intermediate risk patients for modifying cardiovascular disease risk estimate cannot be adequately answered from available data.

6. There is no clear evidence that additional non-invasive testing in high risk patients with high coronary calcium score (e.g., CAC greater than 400) will result in more appropriate selection of therapies.

7. Evidence indicates that patients considered to be at low risk of coronary disease by virtue of atypical cardiac symptoms may benefit from CAC testing to help in ruling out the presence of obstructive coronary disease. Other competing approaches are available, and most of these competing modalities have not been compared head-to-head with CAC.

8. CAC data are strongest for Caucasian, non-Hispanic men. Caution in extrapolating CAC data derived from studies in white men to women and to ethnic minorities is recommended.

9. Current radiology guidelines should be considered when determining need for follow-up of incidental findings on a fast CT study.

For the symptomatic patient, exclusion of measurable coronary calcium may be an effective filter before undertaking invasive diagnostic procedures or hospital admission. Scores less than 100 are typically associated with a low probability (less than 2%) of abnormal perfusion on nuclear stress tests and less than 3% probability of significant obstruction (greater than 50% stenosis) on cardiac catheterization. The presence of CAC by fast CT is extremely sensitive for obstructive (greater than 50% luminal stenosis) CAD (95% to 99%), but has limited specificity. CAC studies of over 7600 symptomatic patients demonstrate negative predictive values of 96% to 100%, allowing for a high level of confidence that an individual with no coronary calcium (score=0) has no obstructive angiographic disease.

Because progression of CAC is not clearly modifiable through standard risk reducing therapies, and CAC measurement involves both costs and radiation exposure, clinical monitoring of CAC progression through serial fast CT scanning is not recommended at this time.

There have been no clinical trials to evaluate the impact of calcium scoring on clinical outcomes in either symptomatic or asymptomatic patients. However, the Writing Committee's position reflects that calcium scoring can be considered reasonable where there is evidence that the test results can have a meaningful impact on medical decision-making (Greenland, 2007).

American Heart Association (AHA)
In a scientific statement (Budoff, 2006), the AHA made the following recommendations on coronary artery calcium (CAC) scoring:

<u>Class IIb Recommendations</u> (Usefulness/efficacy is less well established by evidence/opinion)

1. In clinically selected, intermediate-risk patients, it may be reasonable to measure the atherosclerosis burden using EBCT or MDCT to refine clinical risk prediction and to select patients for more aggressive target values for lipid-lowering therapies.

2. Coronary calcium assessment may be reasonable for the assessment of symptomatic patients, especially in the setting of equivocal treadmill or functional testing.

3. Patients with chest pain with equivocal or normal ECGs and negative cardiac enzyme studies may be considered for CAC assessment.

4. CACP measurement may be considered in the symptomatic patient to determine the cause of cardiomyopathy.

<u>Class III Recommendations</u> (Not useful/effective and in some cases may be harmful)

1. Individuals found to be at low risk (<10% 10-year risk) or at high risk (>20% 10-year risk) do not benefit from coronary calcium assessment.

2. It is not recommended to use CACP measure in asymptomatic persons to establish the presence of obstructive disease for subsequent revascularization.

3. Serial imaging for assessment of progression of coronary calcification is not indicated at this time.

American College of Radiology (ACR)
Unenhanced ECG-gated cardiac CT may be indicated for detecting and quantifying coronary artery calcium ("calcium scoring"). While the role of coronary artery calcium scoring is currently being refined, data support its use for risk stratification and therapeutic decision making in select patients with intermediate risk for a significant ischemic cardiac event. An additional indication is the localization of myocardial and pericardial calcium (ACR, 2006).

National Cholesterol Education Program (NCEP) Adult Treatment Panel III
ATP III supports the conclusions of the American Heart Association's Prevention Conference V and the ACC/AHA report that high coronary calcium scores signify and confirm increased risk for CHD when persons have multiple risk factors. Therefore, measurement of coronary calcium is an option for advanced risk assessment in appropriately selected persons, provided the test is ordered by a physician who is familiar with the strengths and weaknesses of noninvasive testing. In persons with multiple risk factors, high coronary calcium scores (e.g., >=75th percentile for age and sex) denote advanced coronary atherosclerosis and provide a rationale for intensified LDL-lowering therapy.

ATP III does not recommend EBCT for indiscriminate screening for coronary calcium in asymptomatic persons, particularly in persons without multiple risk factors. Its predictive power for persons without multiple risk factors has not been determined in prospective studies (National Heart Lung and Blood Institute, 2002).

U.S. Preventive Services Task Force (USPSTF)
The USPSTF recommends against routine screening with resting electrocardiogram (ECG), exercise treadmill test (ETT), or electron beam computerized tomography (EBCT) scanning for

coronary calcium, either to determine the presence of severe coronary artery stenosis (CAS) or to predict coronary heart disease (CHD) events in adults at low risk. This recommendation was supported by at least fair evidence that screening asymptomatic adults for CHD is ineffective or that harms outweigh benefits. The USPSTF found insufficient evidence to recommend for or against routine screening with ECG, ETT or EBCT scanning for coronary calcium, either to determine the presence of severe CAS or to predict CHD events in adults at increased risk (USPSTF, 2004).

CT Angiography

Background

Computed tomography angiography (CTA), is a noninvasive, radiographic technique that rapidly provides images of the coronary arteries after intravenous injection of a contrast agent. The goal of CTA is to detect heart disease caused by partial or complete blockages in the coronary arteries.

Research

Suspected CAD

Although diagnostic accuracy is vastly improved with new advances in MSCT, MSCT cannot yet replace coronary angiography for diagnosing CAD in every patient presenting with chest pain, particularly in patients who are considered at high risk for CAD. The appearance of stenoses is still impacted by many factors, e.g., degree of calcification in coronary vessel segments, vessel size, and close anatomical relationship to coronary veins, and CAG may be required before a treatment plan is developed. Other limitations of MSCT include the relatively high radiation dosages and the lack of validated algorithms quantifying the degree of lumen narrowing.

However, diagnostic performance of 16- and 64-slice CT may be sufficient (NPV is maintained at 95% to 99%) to enable the technology to serve as a triage tool for eliminating CAD as a cause of chest pain in patients at low risk for CAD. Additional research is needed to establish appropriate patient selection criteria, to specify triage parameters, to investigate the impact on patient health outcomes, and to define the role of MSCT in triaging patients for invasive coronary angiography (Hayes, 2007).

For coronary arteries, CTA requires at least a 16-slice CT system to achieve sufficient temporal resolution to image the beating heart. Temporal resolution refers to the imaging modality's effective scan time - that is, whether images are captured fast enough to avoid blurring. However, a 64-slice CT is preferable in cardiac imaging to obtain high-quality diagnostic images. In addition, 64-slice CT has also been shown to provide better specificity and positive predictive value than 16-slice CT in detecting CAD. Although high-end multislice CT is also available as 32- and 40-slice systems, ECRI Institute experts have found that the current U.S. market for CT systems is essentially divided between 16- and 64-slice (including dual-source CT) systems (ECRI, 2007a; 2009).

Miller, et al. (2008) conducted a prospective, multicenter study to examine the accuracy of 64-row multidetector CT angiography as compared with conventional coronary angiography in patients with suspected CAD. The study included 291 patients who had been referred for conventional coronary angiography; the majority of patients were white males and the median patient age was 59 years. Of 291 patients, 56% were found to have obstructive CAD. The 64-CT scanner was 93% as accurate as traditional angiography in identifying patients with the highest degree of CAD. Overall, the CT angiograms identified 85% of patients with heart disease and 90% of patients who were disease free. The 64-CT scanner was able to positively predict 91% of patients with the most severe disease and only 83% of patients with less severe disease. CT angiography was able to identify 84% of patients who went on to undergo revascularization versus 82% for conventional angiography. There was virtually no difference noted between CT and conventional angiography in the ability to evaluate diseased vessel segments and diseased vessels. Although, multidetector CT angiography accurately identified the presence and severity of obstructive coronary artery disease, the authors concluded that multidetector CT angiography cannot replace conventional coronary angiography at present.

Pooling the data of more than 800 patients from recent studies analyzing the accuracy of 64-slice CT and dual-source CT for the detection of coronary artery stenoses in patients with suspected coronary artery disease, yields a sensitivity of 89% (95% CI 87-90) with a specificity of 96% (95% CI 96-97) and a positive and negative predictive value of 78% (95% CI 76-80) and 98% (95% CI 98-99), respectively. Most of the available data concerning the detection of coronary stenoses by CT angiography have been obtained in patient groups with suspected CAD and stable symptoms. The consistently high negative predictive value in all studies suggests that CT angiography will be clinically useful to rule out coronary stenoses in this patient group. In patients with a very high pre-test likelihood of disease, the use of CT angiography will most likely not result in a 'negative' scan that would help avoid invasive angiography. Therefore, the use of CT angiography should be restricted to patients with an intermediate pre-test likelihood of CAD (Schroeder, 2008).

The prospective multicenter ACCURACY (Assessment by Coronary Computed Tomographic Angiography (CCTA) of Individuals Undergoing Invasive Coronary Angiography) trial evaluated the diagnostic accuracy of 64-multidetector row CCTA in populations with intermediate prevalence of CAD. Results showed that 64-multidetector row CCTA possessed high diagnostic accuracy for detection of obstructive coronary stenosis at both thresholds of 50% and 70% stenosis. Importantly, the 99% negative predictive value at the patient and vessel level establishes CCTA as an effective noninvasive alternative to invasive coronary angiography to rule out obstructive coronary artery stenosis (Budoff, 2008).

Hausleiter, et al (2007) reported the results of the CACTUS trial, a prospective, blinded study that investigated the diagnostic value of coronary MSCT angiography in patients with an intermediate pre-test probability for having CAD when compared with invasive angiography. Of 243 enrolled patients, 129 and 114 patients were studied by 16- and 64-slice CT angiography, respectively. The overall sensitivity, negative predictive value, and specificity for CAD detection by MSCT were 99% (95% CI, 94-99%), 99% (95% CI, 94-99%), and 75% (95% CI, 67-82%), respectively. On a per-segment basis, the use of 64-slice CT was associated with significantly less inconclusive segments (7.4 vs. 11.3%, $P < 0.01$), resulting in a trend to an improved specificity (92 vs. 88%, $P = 0.09$). In addition, the investigators concluded that 64-slice CT appears to be superior for CAD detection when compared with 16-slice CT.

A meta analysis of 29 studies compared multislice spiral computed tomography (MSCT) with conventional invasive coronary angiography (CA) for the diagnosis of coronary artery disease (CAD). The per-segment analysis pooled the results from 27 studies corresponding to a cumulative number of 22,798 segments. Among unassessable segments, 4.2% were excluded from the analysis and 6.4% were classified at the discretion of the investigators, underscoring the shortcomings of MSCT. With this major limitation, the per-segment sensitivity and specificity were 81% (95% confidence interval [CI] 72% to 89%) and 93% (95% CI 90% to 97%), respectively, with positive and negative likelihood ratios of 21.5 (95% CI 13.1 to 35.5) and 0.11 (95% CI 0.06 to 0.21), respectively, and positive and negative predictive values of 67.8% (95% CI 57.6% to 78.0%) and 96.5% (95% CI 94.7% to 98.3%), respectively. The per-patient analysis showed an increased sensitivity of 96% (95% CI 94% to 98%) but a decreased specificity of 74% (95% CI 65% to 84%). Multislice spiral computed tomography has shortcomings difficult to overcome in daily practice and, at the more clinically relevant per-patient analysis, continues to have moderate specificity in patients with high prevalence of CAD. Studies evaluating the diagnostic performance of the newest generation of MSCT, including patients with low to moderate CAD prevalence, will be critical in establishing the clinical role of this emerging technology as an alternative to CA (Hamon, 2006).

Sun and Jiang (2006) conducted a systemic review of the literature and a meta-analysis, evaluating 4- 16- or 64-slice CTA compared with conventional invasive angiography. A total of 47 studies (67 comparisons) were included in the meta-analysis. Results demonstrated assessable segments for CTA in the detection of CAD were 74%, 92%, and 97% with 4-, 16- and 64-slice scanners, respectively. The authors reported separate pooled sensitivity and specificity data for the diagnostic accuracy of 4-, 16- and 64-slice MSCT using coronary angiography as the reference standard. MSCT pooled sensitivity was 76% for 4-slice CT (20 studies) 82% for 16-slice CT (19 studies) and 92% for 64-slice CT (7 studies). Pooled specificity was 93% for 4-slice CT, 95%, for 16-slice and 94% for 64-slice.

Schuijf et al. (2006) conducted a meta-analysis to compare the diagnostic performance of MRI with 4- to 16-slice CT for noninvasive coronary angiography. Overall, 51 studies (28 MRI and 23 MSCT) were included that had been published between January 1990 and January 2005. Based on this analysis, MSCT was superior to MRI for the detection or exclusion of hemodynamically significant CAD. Diagnostic performance for 16-slice CT was as follows (prevalence of CAD ranged from 50% to 98%; median 67%): sensitivity 85%, specificity 94%, PPV 71%, NPV 97%.

A meta-analysis by Stein et al. (2006) including 33 studies (4-slice n=15; 8-slice n=2; 16-slice n=15; 64-slice n=1) reported the diagnostic accuracy by a patient and segmental analysis. Average sensitivity for patient-based detection of significant (>50% or > or =50%) stenosis was 61 of 64 (95%) with 4-slice CT, 276 of 292 (95%) with 16-slice CT, and 47 of 47 (100%) with 64-slice CT. Average specificity was 84% for 4-slice CT, 84% for 16-slice CT, and 100% for 64-slice CT. The sensitivity for a significant stenosis in evaluable segments was 307 of 372 (83%) with 4-slice CT, 1023 of 1160 (88%) with 16-slice CT, and 165 of 176 (94%) with 64-slice CT. Average specificity was 93% or greater with all multidetector CT. Seventy-eight percent of segments were evaluable with 4-slice CT, 91% with 16-slice CT, and 100% with 64-slice CT. Stenoses in proximal and mid-segments were shown with a higher sensitivity than distal segments. Left main stenosis was identified with high sensitivity with all multidetector CT, but sensitivity in other vessels increased with an increasing number of detectors.

A technology assessment report on contrast-enhanced CTA by the Blue Cross Blue Shield Association Technology Evaluation Center (TEC) concluded that the available evidence is inadequate to determine whether CTA improves the net health outcome or is as beneficial as established alternatives for diagnosis of coronary artery stenosis or for evaluation of acute chest pain in the ER. The report evaluated seven studies that compared CTA to angiography for diagnosis of coronary artery stenosis, ranging in size from 30 to 84 patients. In 5 studies reporting a per-patient analysis, the sensitivity of CTA in identifying a 50% stenosis ranged from 88-100%, with 4 of 5 studies reporting sensitivities of at least 95%. Specificity ranged from 86-100%. In a per-segment analysis, sensitivity ranged from 79-99%, and specificity ranged from 95-98%. The report also assessed two studies that evaluated the use of CTA for patients with acute chest pain in the ER. The sample sizes of the studies were 31 and 69. Sensitivity of CTA was 83% and 96%, and specificity was 89% and 96%. The authors stated that it is unknown whether this indicates better or worse performance than an alternative strategy. The authors concluded that the studies evaluating the use of CTA in comparison to angiography are relatively small studies from single centers. These studies only directly address the question of whether CTA can accurately triage patients already referred for angiography. In order to demonstrate improved patient outcomes, valid prognostication tied to improved management and outcomes must be demonstrated. Clinical trials comparing patients undergoing CTA as part of their diagnostic workup compared to patients not undergoing CTA may be required to demonstrate improved patient outcomes. There is no evidence except in the ER regarding the use of CTA in the early workup of patients in whom CAD is being considered. Current published studies of CTA in the management of acute chest pain in the ER are clearly inadequate to determine utility (Blue Cross, 2006).

Follow-Up After Revascularization Procedure

Carrabba et al. (2010) evaluated the diagnostic accuracy of 64-slice multi-detector row computed tomography (MDCT) compared with invasive coronary angiography for in-stent restenosis (ISR) detection. Nine studies with a total of 598 patients with 978 stents were considered eligible. 64-MDCT had a good diagnostic accuracy for ISR detection with a particularly high negative predictive value. However, a relatively large proportion of stents remained uninterpretable.

Kumbhani et al. (2009) conducted a meta-analysis to determine the diagnostic efficacy of 64-slice computed tomography (CT) in evaluation of in-stent restenosis (ISR). 14 studies with a total of 895 patients (1,447 stents) were included. Of these, 1,231 (91.4%) stents were adequately assessed by 64-slice CT. Overall sensitivity was 91%, specificity was 91%, positive predictive value (PPV) was 68% and negative predictive value (NPV) was 98%. When nonassessable segments were included, overall sensitivity and specificity decreased to 87% and 84%, with a PPV of 53% and an NPV of 97% respectively. 64-slice CT allows optimal noninvasive assessment of coronary artery disease. However, a variety of artifacts limit evaluation of stented coronary segments.

Although in single, carefully selected cases (e.g., large diameter stents in a proximal vessel segment, low and stable heart rate, and absence of excessive image noise) coronary CT angiography may be a possibility to rule out in-stent restenosis, routine application of CT to assess patients with coronary stents can currently not be recommended. Visualization of the stent lumen is often affected by artifacts, and especially the positive predictive value is low (Schroeder, 2008).

Although the clinical application of CT angiography may be useful in very selected patients in whom only bypass graft assessment is necessary (e.g. failed visualization of a graft in invasive angiography), the inability to reliably visualize the native coronary arteries in patients post-CABG poses severe restrictions to the general use of CT angiography in post-bypass patients (Schroeder, 2008).

Jones et al. (2007) reported results of a meta-analysis comparing angiography to 8-slice, 16-slice, and 64-slice MSCT in the assessment of coronary grafts. Fifteen studies were selected for inclusion. In assessing occlusion, 14 studies produced pooled sensitivity of 97.6%, and specificity of 98.5%. Ninety-six percent of all grafts were visualized for occlusion assessment. Beta blockers, symptomatic status, and postoperative period did not significantly affect diagnostic performance. Stenosis assessment produced sensitivity of 88.7% and specificity of 97.4%. Eighty-eight percent of patent grafts could be assessed for stenosis.

Coronary Artery Anomalies

While anomalous coronary arteries can be a differential diagnosis in patients with suspected coronary disease, chest pain, or syncope, the detailed assessment of anomalous coronary arteries can be difficult with invasive coronary angiography. The robust visualization and classification of anomalous coronary arteries make CT angiography a first-choice imaging modality for the investigation of known or suspected coronary artery anomalies. Radiation dose must be considered often in the young patients, and measures to keep dose as low as possible must be employed (Schroeder, 2008).

As opposed to magnetic resonance imaging, which also permits the analysis of coronary anomalies in tomographic images, CT requires radiation and a contrast agent. However, the high resolution of the datasets (permitting analysis even of small details) and the speed of image acquisition make it reasonable to use CT as one of the first-choice imaging modalities in the workup of known and suspected coronary anomalies (Budoff, 2006).

Professional Societies/Government Organizations

American College of Cardiology (ACC)

The American College of Cardiology Foundation (ACCF), together with key specialty societies, published appropriateness criteria for cardiac computed tomography (CCT). For the 39 indications for CCT, 13 were found to be appropriate, 12 were uncertain, and 14 inappropriate.

Appropriate: test is generally acceptable and is a reasonable approach for the indication.
Uncertain: test may be generally acceptable and may be a reasonable approach for the indication. Uncertainty also implies that more research and/or patient information is needed to

classify the indication definitively. Inappropriate: test is not generally acceptable and is not a reasonable approach for the indication (Hendel, 2006). Available at: http://content.onlinejacc.org/cgi/reprint/48/7/1475.pdf. Accessed April 16, 2010.

As a follow-up to the 2006 multisociety clinical guideline (Hendel, 2006), the Society of Cardiovascular Computed Tomography (SCCT) and the North American Society for Cardiac Imaging (NASCI) published a consensus statement detailing the utility and appropriateness of CTA in everyday clinical practice (Poon, 2007).

American Heart Association (AHA)
In a scientific statement (Budoff, 2006), the AHA made the following recommendations on CT angiography of the coronary arteries:

Class IIa Recommendations (Weight of evidence/opinion is in favor of usefulness/efficacy). CTA is reasonable for:

1. Assessment of obstructive disease in symptomatic patients.

2. Assessment of known and suspected coronary anomalies.

Class IIb Recommendations (Usefulness/efficacy is less well established by evidence/opinion) CTA might be reasonable for:

1. Follow-up after bypass surgery.

Class III Recommendations (Not useful/effective and in some cases may be harmful) CTA is not recommended for:

1. Follow-up of percutaneous coronary intervention (stent placement).

2. Assessment of noncalcified plaque (NCP) to track atherosclerosis or stenosis over time.

3. Screening in asymptomatic persons for atherosclerosis (noncalcific plaque).

4. Use of hybrid scanning to assess cardiovascular risk or presence of obstructive disease.

American College of Radiology (ACR, 2005)
Indications for CT angiography of cardiac and extracardiac vessels include, but are not limited to, the diagnosis, characterization, and/or surveillance of:

1. Arterial and venous aneurysms
2. Atherosclerotic occlusive disease
3. Nonatherosclerotic, noninflammatory vasculopathy
4. Traumatic injuries to arteries and veins
5. Arterial dissection and intramural hematoma
6. Arterial and venous thromboembolism
7. Congenital vascular anomalies
8. Vascular anatomic variants
9. Vascular interventions (percutaneous and surgical
10. Vasculitis and collagen vascular diseases
11. Vascular infection

In a statement on noninvasive cardiac imaging, ACR described cardiac CT as a proven and important imaging modality for the detection and characterization of cardiac disease. CT may be used as either the primary modality for detecting disease or as an adjunct to other imaging modalities to better characterize disease and help assess change over time. CT can be used to assess both cardiac structure and function, as well as evaluate disease processes within the field of view but outside of the heart and pericardium (Weinreb, 2005).

Agency for Healthcare Research and Quality (AHRQ)
AHRQ sponsored a technology assessment report for the Medicare Coverage Advisory Committee (MCAC) on non-invasive imaging tests (NITs) for coronary artery disease. The authors identified 29 studies using 16-slice or greater multi-detector computed tomography (MDCT) assessing coronary CTA for evaluation of coronary arteries. These studies were generally small, performed at single centers, and often did not include information that would serve to provide confident assessments of the key questions. In particular, the authors did not identify any studies evaluating the clinical impact of diagnostic strategies including CTA compared with strategies that did not include this technique. The vast majority of CTA studies were performed on 16-MDCT scanners, with 6 studies using 64-MDCT scanners for CTA. To provide a clearer picture of the most recent and thus most relevant literature, only the 64-array MDCT studies along with the 5 prospective 16-array MDCT studies that enrolled at least 100 patients were selected for detailed review. The report concluded that at present, there is limited evidence regarding test performance of NITs for identifying, quantifying, or otherwise characterizing coronary artery stenoses. The available evidence provides preliminary data on the ability of coronary CTA using at least 16-slice MDCT technology to detect obstructive coronary artery lesion in the proximal to mid coronary arteries. The evidence regarding detection of coronary lesions in branch vessels or distal coronary arteries remains unclear and may well improve as the technology improves. Studies conducted to date primarily fall into the "proof of concept" category with study patients having a high pre-test probability of CAD. Patients providing suboptimal images were often excluded from calculations of test accuracy. Future work will need to examine these tests in larger, less selected populations representing the clinical settings in which they are actually expected to be used. The effect of biases in selection of study patients and in the publication of accuracy results for these tests was not assessed in this preliminary analysis. With regard to electron beam computed tomography (EBCT) the authors stated that to date, this technology has not achieved the level of resolution required to image coronary artery anatomy directly. Further, its role in clinical screening for CAD remains controversial (Matchar, 2006).

Cardiac CT

Background
Cardiac CT, with or without contrast, is a chest CT performed primarily for the morphologic evaluation of the cardiac chambers, valves, ventricular myocardium, coronary arteries and veins, aortic root, central pulmonary arteries and veins and pericardium. Contrast-enhanced CT is performed after intravenous (IV) administration of iodinated contrast to optimize evaluation of the cardiac chambers, myocardium, valves and pericardium. In addition to coronary calcium scoring, unenhanced cardiac CT is also used to evaluate cardiac valves, pericardium, and cardiac masses (ACR, 2006).

Research
Structure and Morphology
The assessment of aortic valve stenosis using MDCT is feasible with good diagnostic accuracy. The sensitivity of MDCT for the identification of patients with aortic stenosis was 100%, specificity was 93.7%, positive and negative predictive values were 97 and 100%. CT imaging may develop into an alternative imaging tool in patients who require exact assessment of the opening or regurgitant orifice of the aortic or mitral valve and in whom other more commonly used methods, such as echocardiography and magnetic resonance imaging, fail to provide all relevant information. Currently, available clinical data are too limited to allow identification of specific

patient subsets in which CT imaging would be the first-choice diagnostic test (Schroeder, 2008).

Anatomy of the coronary venous system can be accurately assessed with MDCT. The absence of a left marginal vein in patients with a history of infarction may hamper the positioning of a left ventricular lead for cardiac resynchronization therapy if necessary. In this respect, MDCT may be a valuable tool for the non-invasive assessment of coronary venous anatomy before the implantation of a left ventricular lead or other interventions that make use of the cardiac veins. Even though there is currently rather limited data, exact anatomy of the coronary veins cannot be obtained with imaging methods other than cardiac MDCT. If such information is desired, contrast-enhanced MDCT imaging will be a test of choice (Schroeder, 2008).

Radiofrequency catheter ablation procedures are performed in an increasing number of patients with drug refractory atrial fibrillation. MDCT can provide a detailed 'roadmap' for these ablation procedures by visualizing the highly variable pulmonary vein anatomy with the use of volume-rendered three-dimensional reconstructions and cross-sectional images There is growing evidence that MDCT imaging is useful in anatomical imaging of the heart, including pulmonary veins and the coronary venous system, and the adjacent organs, e.g. prior to invasive electrophysiology procedures or in the follow-up after pulmonary vein ablation (Schroeder, 2008).

Because of the high spatial and temporal resolution, rapid image acquisition, and advanced post-processing tools, MDCT has become an important non-invasive diagnostic examination both in children and in adults with congenital heart disease. Although MDCT provides detailed anatomic information, which is of major importance in the care of patients with congenital heart disease, it has to be taken into account that exposure to radiation during follow-up of these patients mainly stems from CT scans and angiography. In particular, when serial evaluation over time is needed, non-ionizing imaging procedures (such as magnetic resonance imaging and echocardiography) should be considered. On the other hand, MDCT scanning is not hampered by the presence of pacemakers and metal artifacts and therefore may be indicated in patients with implanted devices if echocardiography does not provide all clinically necessary information. The utility of CT imaging in patients with congenital heart disease may well extend beyond the heart itself, to include structures such as the pulmonary vessels which are often affected in these patients and may be difficult to evaluate by echocardiography (Schroeder, 2008).

Cardiac Function

Ventricular function is adjunct information that can be obtained from standard coronary CT angiography investigations without altering the image acquisition protocol, and the ability of CT to provide accurate right ventricular assessment might be useful in several clinical conditions including congenital heart disease, carcinoid heart disease, or prior to lung transplantation. Various studies have shown that for these left ventricular functional parameters, MDCT correlated well with magnetic resonance imaging, echocardiography, or gated SPECT. Although CT imaging allows accurate assessment of left and right ventricular function, CT examinations will in most cases not be performed specifically for that purpose. Other diagnostic tests without radiation exposure or the need for contrast injection (i.e. echocardiography) are the methods of choice (Schroeder, 2008).

While several pre-clinical and clinical studies have documented that MDCT allows assessment of myocardial viability, clinical data are currently too limited to allow recommendations on the use of CT for the assessment of perfusion and viability (Schroeder, 2008).

Coronary artery disease (CAD) is believed to be the underlying cause in approximately two-thirds of patients with heart failure and low ejection fraction. Ghostine, et al. (2008) evaluated the diagnostic accuracy of 64-slice CT in identifying ischaemic heart failure (IHF) in patients with left ventricular systolic dysfunction but without clinical suspicion of CAD compared with conventional coronary angiography. Overall, accuracy, sensitivity, specificity, positive predictive value, and negative predictive value of CT for identifying CAD by segment was 96, 73, 99, 92, and 97%, respectively; by patient was 95, 98, 92, 91, and 98%, respectively; and for identifying IHF was 95, 90, 97, 93, and 95%, respectively. Non-invasive 64-slice CT assessment of the extent of CAD may offer a valid alternative to angiography for the diagnosis of IHF.

Andreini, et al. (2007) assessed the safety, feasibility, and diagnostic accuracy of 16-slice MDCT in patients with dilated cardiomyopathy (DCM) of unknown etiology. The study included 61 unknown origin DCM patients (ejection fraction: 33.9 +/- 8.6%, group 1) and 139 patients with normal cardiac function with indications for coronary angiography (group 2, control population). In group 1, all cases with normal (44 cases) or pathological (17 cases) coronary arteries by conventional coronary angiography were correctly detected by MDCT, with, in 1 case, disparity of stenosis severity. In group 1, sensitivity, specificity, and positive and negative predictive values of MDCT for the identification of >50% stenosis were 99%, 96.2%, 81.2%, and 99.8%, respectively. In group 2, sensitivity and negative predictive values were lower than in group 1 (86.1% vs. 99% and 96.4% vs. 99.8%, respectively); specificity (96.4%) and positive predictive value (86.1%) were not significantly different versus group 1. The investigators concluded that MDCT is feasible, safe, and accurate for identification of idiopathic versus ischemic DCM, and may represent an alternative to coronary angiography.

Advances in CT technology have significantly improved temporal and spatial resolutions. In a meta analysis and review of the literature, van de Vleuten et al. (2006) compared MDCT and MRI for evaluating left ventricular function. The analysis indicated that the global left ventricular functional parameters measured by contemporary multi-detector row systems combined with adequate reconstruction algorithms and post-processing tools show a narrow diagnostic window and are interchangeable with those obtained by MRI.

Professional Societies

American College of Radiology (ACR, 2006)

Indications for contrast-enhanced cardiac CT include, but are not limited to, the diagnosis, characterization, and/or surveillance of:

1. Arterial and venous aneurysms
2. Atherosclerotic disease
3. Traumatic injuries of arteries and veins
4. Arterial dissection and intramural hematoma
5. Arterial and venous thromboembolism
6. Vascular congenital anomalies and variants
7. Vascular interventions (percutaneous and surgical, e.g., angioplasty, coronary stenting, coronary bypass grafts [CABGs], ablation therapy for cardiac dysrhythmia, valve surgery, aortic root replacement, pacemaker placement planning,)
8. Vascular infection, vasculitis, and collagen vascular diseases
9. Sequelae of ischemic coronary disease (myocardial scarring, ventricular aneurysms, thrombi)
10. Cardiac tumors and thrombi
11. Pericardial diseases
12. Cardiac functional evaluation, especially in patients in whom cardiac function may not be assessed by magnetic resonance imaging(automatic implantable defibrillator, pacemaker, general MRI contraindications, etc.) or echocardiography (e.g., poor acoustic window)

Indications for contrast-enhanced cardiac CT include cardiac functional evaluation, especially in patients in whom cardiac function may not be assessed by magnetic resonance imaging (automatic implantable defibrillator, pacemaker, general MRI contraindications, etc.) or echocardiography (e.g., poor acoustic window) (ACR, 2006).

The role of CT scanning in patients is increasing due to the development of multidetector CT with better spatial and temporal resolution and ECG gating. These advances permit assessment of left ventricular function, including stroke volume and ejection fraction. Despite much early enthusiasm, there are as yet few studies documenting the value of cardiac CTA in assessing congestive heart failure. Thus, the role of cardiac CT as compared to nuclear cardiology is in evolution (ACR, 2003).

Number of Slices

It is a common misconception that 64-slice CT scanners are better than 16-slice CT scanners in diagnostic quality and for a variety of exams. However, in applications in which patient movement is less of a critical issue, 16-slice scanners provide the same diagnostic quality as 64-slice systems. According to ECRI Institute's Health Devices clinical engineering staff, 16-slice scanners are appropriate for coronary artery calcium scoring, while 64-slice scanners are recommended for cardiac imaging (ECRI, 2008).

There is evidence that a 40-slice computed tomography scanner can detect the presence of and/or the progression of coronary artery disease within patients who are symptomatic or who have undergone previous cardiac interventions. There were no studies that specifically evaluated the diagnostic performance of 32-slice scanners and therefore insufficient evidence that the use of a 32-slice scanner can accurately detect the presence or progression of coronary artery disease (Hayes, 2008).

In a 2007 meta-analysis, Vanhoenacker, et al. (2007) demonstrated a significant improvement in the accuracy for the detection of coronary artery stenosis for 64-slice CT when compared with previous scanner generations. Fifty-four studies were included in the meta-analysis: 22 studies with four-detector CT angiography, 26 with 16-detector CT angiography, and six with 64-detector CT angiography. The pooled sensitivity and specificity for detecting a greater than 50% stenosis per segment were 0.93 (95% confidence interval [CI]: 0.88, 0.97) and 0.96 (95% CI: 0.96, 0.97) for 64-detector CT angiography, 0.83 (95% CI: 0.76, 0.90) and 0.96 (95% CI: 0.95, 0.97) for 16-detector CT angiography, and 0.84 (95% CI: 0.81, 0.88) and 0.93 (95% CI: 0.91, 0.95) for four-detector CT angiography, respectively. Results indicated that with newer generations of scanners, the diagnostic performance for assessing coronary artery disease has significantly improved, and the proportion of nonassessable segments has decreased.

Grosse, et al (2007) conducted a prospective study of 40 patients (28 men, 12 women) to measure both the quality and the accuracy of images taken with a 40-slice MSCT. The researchers compared the images from all 40 patients taken during the MSCT to those obtained during a conventional intracoronary angiography (ICA) in the detection of clinically significant CAD. Patients currently taking oral beta-blockers were not excluded from the study. No additional administration of beta-blockers was used during the MSCT. One cardiologist and 2 radiologists who were blinded to each patient's IAC results analyzed the MSCT images. Images from the ICA revealed significant CAD in 30/40 patients (75%). MSCT correctly diagnosed 39/40 patients, with 29 patients having significant stenosis and 10 patients having no significant CAD. Of the 545 vessel segments studied during the MSCT, 43 segments (7.9%) could not be evaluated due to motion artifacts (n=15), small vessel size and poor contrast enhancement (n=14), severe calcifications (n=10), and opacity of adjacent structures (n=4). MSCT detected significant stenosis (> 50%) in all vessels yielding a sensitivity, specificity, positive predictive value (PPV), and NPV of 87%, 99%, 98%, and 95%, respectively. When the researchers measured MSCT findings for stenosis of the proximal coronary segments, sensitivity, specificity, and NPV increased to 96%, 99%, and 99% respectively. Patient analysis also produced a high NPV (91%) for the exclusion of significant CAD. Forty-slice CT demonstrated a high diagnostic accuracy in the detection of clinically significant CAD per patient and per vessel segment.

Watkins et al. (2007) performed a prospective, blinded study (n=85) at 2 institutions to determine the feasibility and diagnostic accuracy of coronary angiography using 40-channel multidetector computer tomography with multi-segment reconstruction for the detection of obstructive coronary artery disease (CAD). Of 1,145 segments that were suitable for analysis, 1,045 (91.3%) were evaluable on multidetector computer tomography. In a patient-based analysis, the sensitivity, specificity, and positive and negative predictive values for detecting subjects with > or =1 segment with > or =50% stenosis were 98%, 93%, 94% and 93%, respectively. Coronary angiography using 40-channel multidetector computer tomography with multi-segment reconstruction accurately detects coronary segments and patients with obstructive CAD, with a small number of non-evaluable cases.

In a prospective study, Lim, et al. (2006) compared the accuracy of 40-slice CT angiography with invasive selective coronary angiography in the detection of significant coronary stenosis (> or =50% lumen diameter narrowing). Thirty consecutive patients with suspected coronary artery disease underwent both invasive coronary angiography and MSCT. Average sensitivity, specificity, positive predictive value, and negative predictive value of MSCT were 99, 98, 94, and 99%, respectively.

Professional Societies

Society of Cardiovascular Computed Tomography (SCCT)

In a 2009 guideline on CT angiography, the SCCT states that the minimum detector requirement is a 16-slice scanner; however, systems with at least 32 detector rows or more are recommended (collimations of 32 x 2 or 64 x 1, or newer generation) (Abbara, 2009).

Additional search terms

calcified plaque, calcium scan, CAT scan, computerized axial tomography, coronary artery scan, CT scan, helical, spiral, ultrafast CT

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Cardiac computed tomography equipment is regulated by the FDA, but products are too numerous to list. See the following web site for more information (use product code JAK). Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed April 16, 2010.

Multislice CT technology has evolved rapidly over the past several years, beginning with 4-slice scanners that were first introduced in 1998. Since then, 8-, 10-, 16, 32-, 40-, and 64-slice scanners have been approved and available for diagnostic use. Advances in technology, including the availability of dual source CT scanners, are expected to continue at a rapid pace.

In July 2008, the U.S. Food and Drug Administration (FDA) notified health professionals, warning them of the possibility that x-rays used during CT examinations may cause some implanted and external electronic medical devices to malfunction. Devices affected include pacemakers, defibrillators, neurostimulators, and implanted or externally worn drug infusion pumps. The notice provides recommendations for reducing potential risk. Available at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061994.htm. Accessed April 16, 2010.

Additional Products

eSpeed, LightSpeed, BrightSpeed and HiSpeed series (GE Imatron, Inc.); Brilliance CT (Phillips Medical); SOMATOM series (Siemens); Aquilon series (Toshiba)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for Multislice Computed Tomography, Electron Beam Computed Tomography or Cardiac Computed Tomography Angiography. On March 12, 2008, CMS determined that an NCD on the use of cardiac computed tomography angiography for coronary artery disease was not appropriate and that coverage should be determined by local contractors through the local coverage determination process or case-by-case adjudication. See the NCD for Computed Tomography (220.1) at http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=220.1&ncd_version=2&basket=ncd:220.1:2:C

omputed+Tomography. (Accessed April 5, 2010)

Local Coverage Determinations (LCDs) exist for (1) Computed Tomographic Angiography or Cardiac Computed Tomography (available at: http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from=alphalmrp&letter=C) and (2) Multidetector Computed Tomography of Heart and Great Vessels and (3) Multislice or Multidetector Computed Tomography of Heart and Great Vessels (available at http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from=alphalmrp&letter=M). Compliance with these policies is required where applicable. (Accessed April 5, 2010)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

CPT® Code	Description
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)

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HCPCS Code	Description
S8092	Electron beam computed tomography (also known as ultrafast ct, cine ct)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
05/28/2010	• No changes to coverage rationale or lists of applicable codes • Archived previous policy version 2010T0488F