

## OVERVIEW

### *Coronary Computed Tomographic Angiography*

#### **Introduction**

Coronary computed tomographic angiography (CCTA) involves the use of CT scans in conjunction with the rapid injection of contrast material into a small peripheral vein to develop computer-aided, 3-dimensional images of the arterial anatomy of the heart. While CCTA can be used to define coronary artery anomalies and to generate “calcium scores” as a predictor of cardiac risk, its most significant application is as a minimally invasive method to diagnose coronary artery disease (CAD), the leading cause of death among both men and women in the U.S.

CCTA is envisioned as a complement or replacement for other non- or minimally-invasive procedures such as stress testing and radio-nuclide scans, as it can produce a direct image of the heart and related vessels, thereby allowing for visualization of areas of stenosis. CCTA is touted as having the potential to “rule out” significant CAD among many patients, thereby reducing the need for invasive coronary angiography (ICA) and its associated complications including arterial puncture, plaque embolization, bleeding, and vessel dissection.

Clinical interest in the use of CCTA is high; however, there are uncertainties regarding CCTA’s diagnostic accuracy and its potential harms, including the costs and effects of false-positive and false-negative results, radiation dose received, and incidental findings (i.e., outside of the arterial anatomy). Additional questions remain regarding the appropriate placement of this test along the diagnostic pathway for CAD, identification of an appropriate target population for the test based on level of risk and symptoms, and the relative clinical effectiveness and comparative value of CCTA in comparison to existing or emerging clinical alternatives.

#### **Professional Organizations and Agency Recommendations:**

- American College of Cardiology Foundation/ American Heart Association (2007): A clinical expert panel convened for the purpose of evaluating CT scanning for coronary artery calcium (CAC) scoring concluded that there was evidence supporting the use of such testing in asymptomatic patients at 10-20% risk of CAD (i.e., *intermediate* risk).

<http://www.americanheart.org/downloadable/heart/1168626471943CECD%20on%20EBCT%20rev3.pdf>

- American Heart Association (2006): The AHA Joint Committee on Cardiovascular Imaging and Intervention, Cardiovascular Radiology and Intervention, and Clinical

Cardiology conclude that the level and quality of evidence supports the use of CCTA for the following purposes:

- CAC scoring in patients at *intermediate* risk of CAD
- Assessment of obstructive disease in symptomatic patients, especially in those with a *low-to-intermediate* probability of hemodynamically relevant stenoses

<http://circ.ahajournals.org/cgi/reprint/114/16/1761>

- Multi-Society Statement of Appropriateness Criteria for Cardiac Computed Tomography (2006): A working group from the ACC, ACR, and several specialty imaging societies conducted appropriateness reviews for both CCTA and cardiac magnetic resonance imaging. CCTA was deemed to be acceptable and appropriate for the detection of CAD in the following patient populations:
  - Presenting with chest pain syndrome with *intermediate* pre-test probability of CAD (i.e., based on age, gender, and symptoms) *and* uninterpretable ECG or inability to exercise
  - Presenting with chest pain syndrome *and* uninterpretable or equivocal stress test results
  - Evaluation of suspected coronary anomalies in symptomatic patients
  - Presenting with acute chest pain with *intermediate* pre-test probability of CAD *and* no ECG changes *and* serial enzymes negative

<http://www.acc.org/qualityandscience/clinical/pdfs/CCT.CMR.pdf>

- SCCT/NASCI Consensus Update (2007): Two participants in the multi-society working group provided an update to the 2006 paper, and found CCTA to be appropriate for the following populations:
  - CAC scoring in asymptomatic patients at *intermediate* risk of CAD
  - In *symptomatic* patients with suspected CAD, CCTA is useful for:
    - Ruling out the presence of significant coronary stenosis
    - Evaluating patients with equivocal or discordant results on a stress perfusion or wall motion study
    - For ruling out stenosis in patients with a *low* pre-test likelihood of CAD
    - As a possible replacement for diagnostic catheterization in patients undergoing non-coronary cardiac surgery

- To evaluate patients presenting with acute chest pain in an emergency setting who would be considered for stress myocardial perfusion imaging or echocardiography

[http://www.scct.org/advocacy/consensus\\_update\\_appropriate\\_usage\\_cardiac\\_cta.pdf](http://www.scct.org/advocacy/consensus_update_appropriate_usage_cardiac_cta.pdf)

## Coverage Policies

- Medicare: In December 2007, citing CCTA as a promising but unproven technology, CMS announced its intent to create a national coverage decision (NCD) allowing for coverage with evidence development. After a period of public comment and discussion, CMS reversed its decision in March 2008, and stated that the local coverage determination process (LCD) would be left in place. Current LCDs allow for coverage of CCTA in patients with suspected or known CAD.
- United Healthcare: CCTA is considered proven using 64-slice or greater technology for:
  - Evaluating chest pain syndrome in patients with an *intermediate* pre-test probability of CAD and uninterpretable ECG results or patient is unable to exercise
  - Evaluating chest pain syndrome in patients with prior uninterpretable or equivocal stress test results (exercise, perfusion, or stress echo)
  - Assessing acute chest pain in patients with an *intermediate* pre-test probability of CAD, no ECG changes, and negative serial enzymes
- Aetna: 64-slice or greater CCTA is medically necessary for:
  - Ruling out significant CAD in patients with *low* pre-test probability and equivocal stress test finding or contraindications to stress testing
  - Conducting pre-operative assessment for non-coronary cardiac surgery
  - Detecting coronary anomalies in persons <30 years of age
  - Evaluating cardiac structures in patients with congenital heart disease
  - Calcium scoring (restricted to assessment of whether an adequate arterial image can be taken for diagnostic CCTA)
- Cigna: 64-slice or greater CCTA is medically necessary for:
  - Detecting CAD in symptomatic patients with *intermediate* pre-test probability and equivocal or contraindicated ECG, or with no ECG changes and serial enzymes negative

- Detecting CAD with prior uninterpretable or equivocal stress test findings for evaluation of chest pain syndrome or suspected silent ischemia
- Evaluating coronary arteries in new onset heart failure with ischemia as suspected etiology and no planned catheterization or nuclear stress testing
- Examining coronary arteries in cases of suspected congenital anomalies

### **Recent Technology Assessments**

- National Health Service Research & Development Health Technology Assessment Program (NHS R&D HTA, United Kingdom) (2008): This evaluation concludes that the “main value of 64-slice CT may be at present to rule out significant CAD”; evaluations of CCTA’s potential cost-effectiveness suggest that it may be cost-saving in presenting populations with a relatively low prevalence of CAD.
- California Technology Assessment Forum (CTAF, United States) (2007): CCTA for diagnosis of coronary artery stenosis and evaluation of acute chest pain does not meet criteria for sufficient evidence to draw conclusions regarding effectiveness in improving absolute or net health outcomes, or attainment of benefit equivalent to or greater than established alternatives.
- Medicare Coverage Advisory Committee (MedCAC, United States) (2006): This assessment, which focused on both 16-slice and higher CCTA as well as 1.5T magnetic resonance angiography, concluded that “the evidence base for noninvasive direct coronary imaging technologies is currently inadequate for routine use in the diagnosis and management of CAD”.
- Blue Cross Blue Shield Technology Evaluation Center (TEC, United States) (2006): CCTA for use in either the diagnosis of coronary artery stenosis or for evaluation of acute chest pain does not meet TEC criteria.
- Ontario Health Technology Advisory Committee (OHTAC, Canada) (2005): There is insufficient evidence to suggest that 16- or 64-slice CT angiography is equal to or better than coronary angiography to diagnose CAD in those with symptoms or to monitor progression in persons with prior cardiac interventions.

### **Research in Progress**

There are currently 30 clinical studies of CCTA for detection of coronary artery disease that are actively recruiting patients (source: [www.clintrials.gov](http://www.clintrials.gov)); of these, 4 are randomized studies, as follow below:

- CT-IMPACT (Beaumont Hospitals): *Population*--n=200 with inconclusive or indeterminate stress test results; *Intervention*--CCTA vs. ICA initially; *Follow-up*--up to 5 years; *Outcomes*—Diagnostic/prognostic performance, prediction of major cardiovascular events
- Seoul National University: *Population*—n=1,000 diabetics without coronary symptoms; *Intervention*—CCTA+standard care vs. standard care only; *Follow-up*—up to 5 years; *Outcomes*—Myocardial infarction, late revascularization, cardiac death
- InterMountain Healthcare: *Population*—n=1,100 asymptomatic, high-risk diabetics; *Intervention*—Screening w/CCTA or calcium scoring vs. standard care; *Follow-up*—up to 2 years; *Outcomes*--all-cause death, non-fatal MI, unstable angina
- CT-STAT (Beaumont): *Population*—n=750 ED patients with acute chest pain and low-to-intermediate CAD risk; *Intervention*—CCTA vs. standard triage care; *Follow-up*—up to 6 months; *Outcomes*—multiple efficacy, safety, and economic endpoints

Other large studies are employing within-subject designs for comparative purposes, as described below:

- OMCAS (Ontario): *Population*—n=900 scheduled for ICA; *Control*—CCTA vs. ICA, single-blinded comparison; *Follow-up*—unknown; *Outcomes*—sensitivity, specificity
- PICTURE (GE Healthcare): *Population*—n=300 with intermediate CAD risk and referred for myocardial perfusion scanning (MPS); *Control*—CCTA vs. MPS, single-blinded comparison; *Follow-up*—up to 3 years; *Outcomes*--sensitivity, specificity, and NPV, downstream cardiac testing, major cardiac events

Finally, several large cohort studies are ongoing to document the use of CCTA in clinical practice, characteristics of patients receiving the test, and relevant outcomes, as follow below:

- SPARC (Brigham & Women's, USC): *Population*—n=4,000 is referred for stress perfusion (SPECT, PET), CCTA, or combined perfusion-anatomy (PET/CT) studies with intermediate-to-high pretest probability of CAD; *Follow-up*—up to 2 years; *Outcomes*—referral to cardiac catheterization within 90 days of index test, predictive ability for cardiac death and non-fatal MI, relative cost-effectiveness of each approach
- Advanced Cardiovascular Imaging Consortium (ACIC) CCTA Registry (Blue Cross/Blue Shield of Michigan): *Population*—n=12,000 referred or self-referred for CCTA; *Follow-up*—up to 3 years; *Outcomes*—patient characteristics, scanning acquisition techniques, quality of physician scan interpretation, 90-day clinical outcomes