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July 13, 2007

Joseph Chin, M.D.
JoAnna Baldwin, M.S.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Dr. Chin and Ms. Baldwin:

On behalf of Philips Medical Systems ("Philips"), I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) National Coverage Analysis (NCA) on Cardiac Computed Tomography Angiography (CAG-00385N).

Philips Medical Systems operates in four main business areas: Diagnostic Imaging Systems, Clinical Solutions, Healthcare Information and Customer Services. Our product line includes best-in-class technologies in X-ray, ultrasound, magnetic resonance, computed tomography, nuclear medicine, PET, radiation oncology systems, patient monitoring, information management and resuscitation products. With approximately 33,000 employees worldwide and a presence in more than 100 countries around the world, Philips Medical Systems is firmly established as a worldwide leader in many of the markets it serves

Preliminarily, we wish to express concern about the June 13 notice announcing CMS's interest in opening a National Coverage Assessment (NCA) for CCTA. That notice specifically states:

> CMS is concerned that despite the lack of clinical evidence to demonstrate improved patient health outcomes with CTA, the procedure has been rapidly adopted by the clinical community.

(Emphasis added.) Not only does this language suggest a degree of prejudgment of the clinical value of CCTA, we respectfully suggest that it frames the issue improperly.

In our view, it is inappropriate to require that a diagnostic technology, such as CCTA, demonstrate "improved patient health outcomes" –especially for complex diseases, such as Coronary Artery Disease (CAD)—which are difficult to diagnose and manage. In fact, numerous factors contribute to ultimate health outcomes, including most prominently the quality and efficacy of the available therapies available and patient compliance with medication and other instructions provided by health care professionals. It is perhaps for this reason that the Medicare Act does not cover only those diagnostic services that can demonstrate "improved patient health outcomes" but rather those that are "reasonable and necessary" for the diagnosis or treatment of disease or injury.

We respectfully suggest that, to determine whether the "reasonable and necessary" standard is met, the appropriate question is whether CCTA has the potential to facilitate diagnosis of CAD or other

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cardiac conditions with a high degree of sensitivity and specificity, and whether it provides valuable information that may affect clinical decision-making—not whether CCTA can be demonstrated to result in "improved health outcomes".

We also note that the June 13 notice appears to reflect a reversal of CMS's prior thinking regarding the need for a NCD for CCTA. As recently as last year, CMS announced that it had no intention of issuing a NCD for CCTA , but would instead allow Medicare contractors discretion concerning whether, and under what conditions, Medicare coverage would be permitted.

While the CCTA Local Coverage Determinations (LCDs) established by the various Medicare carriers differ in some details, they generally concur on the clinical utility of CCTA in the diagnosis of Coronary Artery Disease (CAD). Moreover, the indications for coverage set forth in the current LCDs are generally consistent with the Model LCD for CCTA formulated by the American College of Cardiology (ACC). We do not believe that there is a pressing need to override existing CCTA LCDs, which have been developed on the local level, sometimes with significant input from the local physician community. However, if CMS decides to move forward with the development of a NCD, we hope that the agency will consider using the existing LCDs as potential models for the NCD.

Having said that, we would like to point out that there is one area where the LCDs do not provide a useful precedent: equipment standards. Unfortunately, there is a wide variation in CCTA equipment requirements established by the local carriers that are unrelated to the diagnostic quality of the studies produced. Local contractors have established various and different requirements relating to the number of detectors, gantry speed, and collimation size.

Significantly, the critical equipment-related issue in the clinical efficacy of CTA as a diagnostic tool is temporal resolution-- that is the ability to deliver image detail in the smallest "window" of time. Excellent temporal resolution results from a combination of factors-- not simply the number of detectors or gantry speed. While these variables certainly contribute to the degree of temporal resolution that is achieved, there is no clinical or technical justification for using them in isolation as the predictive variable. As explained in Attachment A, "Considerations in Cardiac CT: Understanding Temporal Resolution and Rotation Speed For Improved Cardiac Imaging, temporal resolution is affected by many factors, including the acquisition and image reconstruction software. In short, despite the distinctions drawn by the carriers among various types of scanners, the mechanics of the scanner itself cannot be used as a reliable proxy for temporal resolution.

In light of the constant evolution of the technology, we believe that virtually any CCTA equipment standard likely would be quickly outdated. For this reason, we urge CMS to refrain from imposing specific equipment requirements in the NCD, beyond any such requirements that are clearly supported in the clinical literature or by expert consensus, as reflected in the statements of relevant professional associations.

In addition, we urge the agency to follow a number of guidelines in formulating the NCD:

- We are aware that CCTA was included in a Technology Assessment conducted last year entitled "Non-invasive imaging for Coronary Artery Disease." We caution against using this Technology Assessment as the basis for a NCD, since it was intended to be a

preliminary assessment directed at six specific questions. Moreover, this report is outdated, since there have been numerous articles on CCTA published since it was issued. For example, a study published in JAMA last year confirmed the fact that CTA, using a 16-detector scanner, can play a pivotal role in reducing the number of unnecessary cardiac catheterizations.[1] See also the articles listed at Attachment B, which provides references for a number of recent articles on the specificity, sensitivity, and clinical utility of CCTA. Even more importantly, the experience of clinicians in utilizing CCTA in the treatment of Medicare beneficiaries and other patients has grown substantially over the past several years, further solidifying the role of this new technology in the diagnosis of CAD. This more recent experience of clinicians in utilizing CCTA for patient care was not considered in the 2006 Technology Assessment.

- For the reasons set forth above, we urge CMS to refrain from establishing equipment requirements related solely to the mechanics of the scanner itself , except as endorsed by relevant professional associations, and should consult closely with the Medical Imaging Technology Association (MITA) for technical input if it is determined that further equipment standards are necessary. Care should be taken to ensure that any equipment standards that are adopted do not unfairly discriminate against a particular manufacturer's equipment based on arbitrary standards unrelated to the diagnostic quality of the studies produced.

- We urge CMS to consult closely with the relevant national professional associations, including the American College of Cardiology and the American College of Radiology, in formulating the list of appropriate indications for CCTA.

- In the event that CMS decides that the peer-reviewed published literature is insufficient at this point to support full coverage for CCTA for the diagnosis of CAD, we urge CMS to formulate an appropriate CED to facilitate the gathering of clinical data from practicing cardiologist who utilize this technology for patient care. In this regard, we urge the agency to work closely with existing registries and professional societies to establish a data collection process that minimizes the administrative burden involved for facilities that provide this important service, and that collects the data needed by CMS as cost-efficiently as possible. We would be delighted to work with CMS and other affected groups to formulate the data elements and to facilitate the use of the registry among our customers.

- We strongly urge CMS to instruct Medicare carriers to continue to provide coverage for CCTA based on their own LCDs, pending issuance of any NCD or CED. The authors of the JAMA study referenced above indicate that if CCTA had been implemented into clinical practice for the entire patient population included in the study, invasive coronary angiography could have been avoided in 37% of the study population. This conclusion is reinforced by data obtained by Philips from the CCTA Data Registry for the first quarter of 2007, which indicates that, during that period, the majority of CCTA cases (65%) were substitutions for nuclear perfusion testing as the entry point in the diagnostic imaging system. Thus, the continued use of CCTA pending the issuance of any NCD has the

[1] "*Accuracy of 16-Row Multidetector Computed Tomography for the Assessment of Coronary Artery Stenosis*", Mario J. Garcia, MD, et. al,; JAMA, July 26, 2006-Vol 296, No.4.

potential to result in significant continued savings to the Medicare Program. For this reason, coverage for CCTA should continue to be provided on the basis of the existing LCDs, pending the issuance of any NCD.

- While there are a number of accepted clinical indications for CCTA, the field is evolving rapidly, and any NCD established at this time likely will be quickly outdated. Therefore we believe that any NCD established for CCTA should be reviewed at least annually to ensure that Medicare beneficiaries have timely access to CCTA in appropriate cases.

Philips appreciates the opportunity to comment on this important issue, and we offer our further assistance to CMS in the event that the agency does decide to move forward with a CCTA NCD or CED.

Sincerely,

signed

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Considerations in Cardiac CT:

Understanding Temporal Resolution and Rotation Speed

For Improved Cardiac Imaging

Introduction

Historically, Computed tomography (CT) was primarily concerned with only two resolutions – *spatial* and *contrast.* However, now with Cardiac CT imaging, another resolution – *temporal* – enters the picture.

Cardiac CT imaging has emerged as one of the most promising methods of detection of coronary artery disease (CAD). Rapid, noninvasive, and accurate, this imaging technology enables clinicians to arrive at a quick cardiac diagnosis, as well as to assist in treatment planning and follow up. Recent advances in CT equipment and image processing have resulted in significant improvements temporal resolution. Correspondingly, there is a need to understand temporal resolution for Cardiac CT imaging. This paper takes a closer look at the temporal resolution as it relates to Cardiac CT imaging.

A Fuller View of CT Temporal Resolution

The efficacy of any cardiac imaging technology relates to its ability to deliver image detail (as expressed in spatial resolution) in the smallest "window" of time – expressed as temporal resolution, often by a number of milliseconds (ms).

Among most cardiac CT manufacturers, many clinicians and the lay press have translated cardiac temporal resolution into a race to design scanners with significantly more detectors and/or faster rotation times, so the X-ray beam can capture the maximum amount of data "slices" in the shortest amount of time, thus reducing patient breath hold. A glance at the top four vendors with 64-slice scanners clearly shows this design trend.

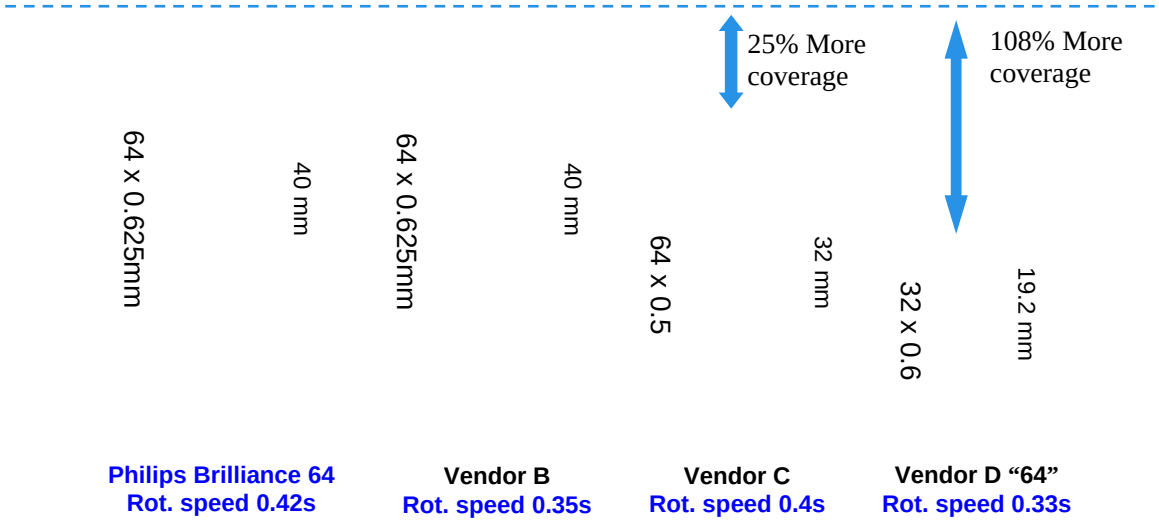

Figure 2: Comparison of "64" detector CT systems currently on market (12/06)

However, temporal resolution of a particular scanner is not synonymous with the number of detectors, nor is it related to rotation speed alone, but is impacted by a number of factors. In CT imaging, an image can be reconstructed with a minimum 180° of acquired data. For a scanner exhibiting 0.5s (500ms) rotation speed, the temporal resolution would be stated as 250ms (one half of the rotation speed/360°). This simple form of Cardiac CT data reconstruction is defined as "Single Segment Reconstruction".

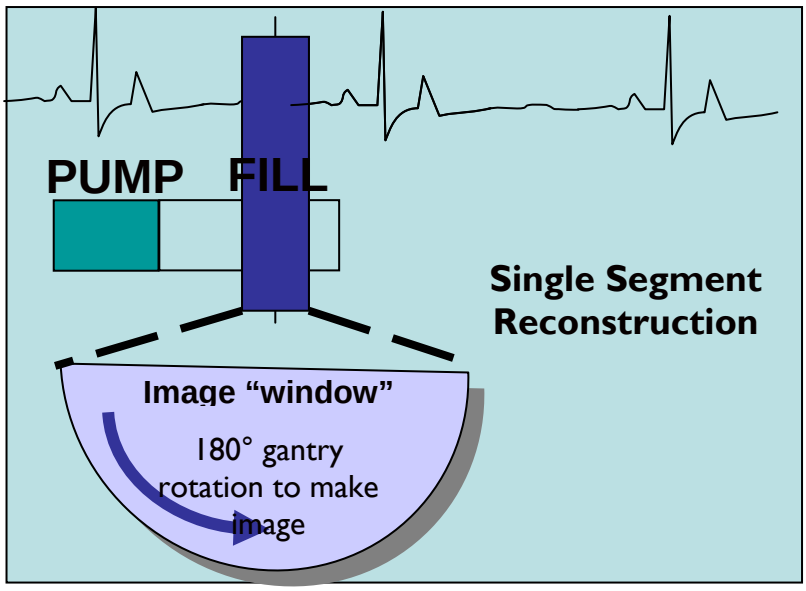

Figure 1: single cycle reconstruction relies exclusively on the speed of gantry design

On the contrary, exclusively defining temporal resolution by expression of rotation speed alone is as limiting as evaluating automobile performance based on engine displacement.

Another analogy would be two bicyclists racing without considering the gears they use.

Figure 3: Multi-cycle and bicycle gears

Question: If two bicyclists pedal at the same rate on identical bikes, who wins?

Answer: They will tie if both bikes are in the same "gear". However, a bicyclist may win the race yet pedal slower by better use of gears on her bike.

Analogy: Multi-cycle reconstruction is like using "gears" for cardiac CT imaging.

In reality, excellent temporal resolution can be achieved through a number of patient-centric techniques. These techniques rely on sophisticated acquisition and image reconstruction software and not solely on the mechanics of the scanner itself.

Software vs. Hardware-Focused Temporal Resolution

One patient-adaptive technique, for example, captures images in two or more cycles rather than acquiring 100 percent of the cardiovascular data in a single cardiac cycle. Multi-cycle, gated reconstruction techniques are utilized in other types of cardiac imaging as well, such as Nuclear SPECT, Cardiac MRI, and 3D Cardiac Ultrasound. A multicycle approach reduces the rotational arc of the gantry required to produce an image.

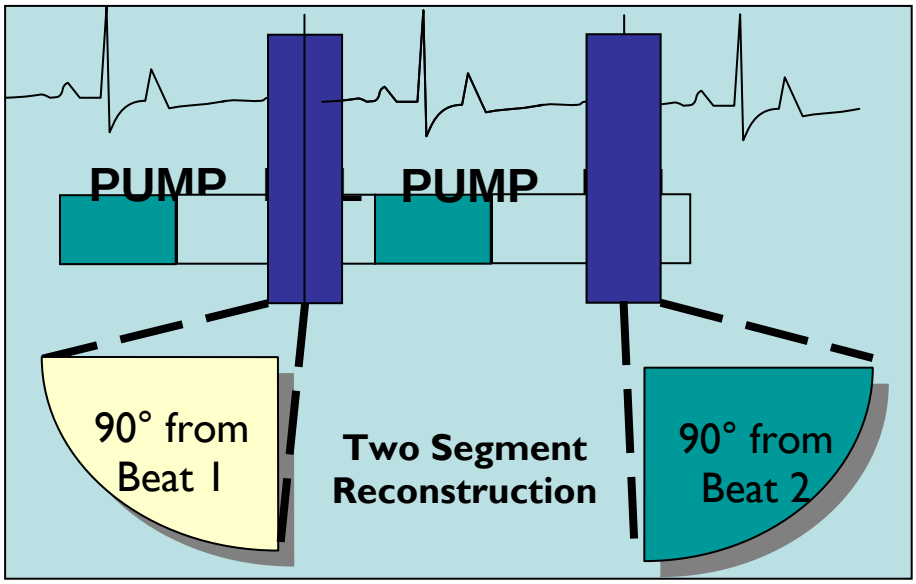

Figure 4: 2-cycle reconstruction improves temporal resolution by 50% versus single-cycle

Unlike single cycle approaches that use data from a single cardiac cycle in reconstructing an image, adaptive multicycle algorithms can produce a whole image from as many as five cycles of the cardiac cycle[i,ii,iii]. Philips' employs advanced acquisition software to automatically adjust to a patient's heart rate – called Rate Responsive™ technologies. It delivers the best temporal resolution possible all of the time (as low as 42ms) for stable, clear cardiac imaging. This adaptive multi-segment reconstruction technique makes it ideal for applications where patients present with irregular heart beats or elevated heart rates up to 120bpm, or for patients contraindicated for beta-blockers to reduce heart rates[ix].

Clinical Proof of Patient-Adaptive Advancements

Patient-focused advancements have resulted in improvements in the detection of cardiovascular disease in a significant number of clinical studies.

A study conducted at the University of Ulm, Germany in 2004 concluded that motion-free coronary angiograms could be obtained consistently in patients with heart rates up to 80 beats per minute (bpm) with a Philip's 16-detector row CT scanners utilizing Rate Responsive adaptive multicycle reconstruction algorithms[iv].

A comparison of the diagnostic accuracy and image quality of two reconstruction algorithms (multi-segment and single segment half scan) for CT coronary angiography in

patients without beta-blocker medication was conducted at Medical School of the Freie Universitat and Humboldt-Universitat in Berlin, Germany. As revealed in the April 2004 *Investigative Radiology*, statistically significant better image quality was achieved using the multi-segment reconstruction versus single cycle reconstruction to determine vessel continuity as well as visibility of side branches.[v]

In back-to-back oral presentations at the 2005 Radiological Society of North America, Phillips Brilliance CT 40-channel scanner showed significantly better visualization of coronary artery stenosis than did the Siemens' Sensation 64. Using multi-segment reconstruction, the Philips system rotating at 0.42s was able to achieve a better average temporal resolution of 95ms (range 1.5 to 3.1 multi-cycles) versus the single cycle reconstruction employed on the Siemens system rotating at 0.33s for a temporal resolution of 165ms.[vi, vii]

	Pts	Heart Rate (bpm)	Breath hold (s)	Detector coverage/ rotation	Non-Evaluable Segments	Sensitivity	Temporal Resolution (ms)
Philips Brilliance 40	100	71 (53-109)	11.4	25.0mm (40 x 0.625mm)	5.3%	93%	95ms (1.5-3.1 cycles)
Siemens Sensation 64	50	n/a	13.6	19.2mm (32 x 0.60mm)	13%	83%	165 (1 cycle)
					p < 0.05	p < 0.05	

Table 1: Cardiac CT abstracts presented at RSNA 2005: Cluzel[vi]; Nikolaou[vii]

Furthermore, the temporal resolution capability and benefits of the Brilliance 40-channel CT scanner has been further reinforced in a recent publication by clinicians from Singapore.[viii]

Finally, a paper published in the Journal of the American College of Cardiology by researchers from the Cleveland Clinic Foundation determined the feasibility of detecting occlusive coronary disease in heart transplant recipients with average heart rate of 90bpm using a Philip's 16-slice scanner with multi-segment reconstruction. In fact, the authors summarize, "…[normally] elevated heart rates would be considered a limitation to

MDCT imaging, but in this patient population [i.e. high heart rates and contraindicated for beta blockers] it seemed to facilitate multi-segment imaging with improved temporal resolution."[ix]

Conclusion

Cardiac CT is emerging as one of the most promising noninvasive cardiac imaging technologies, exhibiting relatively high levels of precision in identifying and diagnosing cardiovascular disease. Cardiac CT works by taking traditional x-ray images of cross sectional views of the cardiac anatomy. In order to improve temporal resolution, many scanner vendors have focused exclusively on gantry rotation speed, capturing all of the data necessary to reconstruct a volume image of the heart in a single cardiac cycle. Thus for some vendors, gantry speed is synonymous with temporal resolution. However, a more extensive investigation of temporal resolution reveals that other factors – such as more sophisticated reconstruction techniques, can – and do – deliver exceptional temporal resolution, thus good, clinical cardiac CT image quality. This technology may be especially helpful for patients with elevated heart rates and contra-indicated for beta-blockers.

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[i] Chandra S., Heuscher, DJ., "Multi-phase cardiac imager,'' United States Patent #6,510,337, granted: 2003.

[ii] Vembar M, Garcia MJ, Heuscher DJ *et al*. "A Dynamic Approach to Identifying Desired Physiological Phases for Cardiac Imaging using Multi-Slice Spiral CT", Medical Physics 30 (7) July 2003.

[iii] Grass M, Manzke R, Nielsen T, Koken P, Proksa R, Natanzon M, Shechter G; *"Helical cardiac cone beam reconstruction using retrospective ECG gating"* Physics in Medicine and Biology, 48 (2003); 3069–3084

[iv] Hoffmann MHK, Shi H, Schmitz BL, *et al*, Noninvasive Coronary Angiography with Multislice Computed Tomography, JAMA (2005) vol. 293 (20):2471-2478.

[v] Dewey M, Laule M, Krug M, *et al*, Multi-segment and Half-scan Reconstruction of 16-Slice Computed Tomography for Detection of Coronary Artery Stenoses, Investigative Radiology, (2004) vol. 39(4):223-229.

[vi] Cluzel, Cocheteux, Boutekadjert, *et al*, Prospective Assessment of Coronary Artery Stenoses with ECG-gated 40-slice Spiral CT, *presented orally at RSNA 2005, session SSC05-05.*

[vii] Nikolaou, Wintersperger, Rist, *et al*, Sixty-four slice Computed Tomography in the Diagnosis of Ischemic Heart Disease: Impact on Clinical Decision-making, *presented orally at RSNA 2005, session SSC05-05.*

[viii] Lim MCL, Wong TW, Yaneza LO, De Larrazabal C, Lau JK, Boey HK. "Non-invasive detection of significant coronary artery disease with multi-section computed tomography angiography in patients with suspected coronary artery disease." Clinical Radiology (2006) 61: 174-180.

[ix] Sigurdsson, Carrascosa, Garcia, et al., "Detection of Transplant Coronary Artery Disease Using Multidetector Computed Tomography With Adaptative Multisegment Reconstruction, JACC (2006) 8:772-778

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The Prevalence and Anatomical Patterns of Intramuscular Coronary Arteries

A Coronary Computed Tomography Angiographic Study

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Objectives This study sought to report prevalence and radiologic patterns of intramuscular coronary arteries (myocardial bridging) on coronary computed tomographic angiography (CCTA).

Background Reported prevalence of intramuscular coronary arteries varies between 5% and 86% in autopsy and 0.8% and 4.9% in coronary angiography. Intramuscular coronary arteries can cause technical problems during coronary bypass surgery, including inadvertent perforation of the right ventricle.

Methods One hundred and eighteen consecutive patients were studied with CCTA using Brilliance 40/64 multidetector computed tomography (Philips Medical Systems, Cleveland, Ohio). Parameters evaluated were number, length, and depth of intramuscular coronary segments; diameter and evidence of atherosclerosis in the involved artery proximal and within the intramuscular segment; and its course in relation to the interventricular septum and right ventricular wall.

Results Forty-seven intramuscular segments were identified in 36 of 118 (30.5%) patients. Most were located in mid left anterior descending coronary artery (LAD), 27 of 47 (57%), and distal LAD, 7 of 47 (15%). The CCTA features in the LAD showed 3 patterns: superficial septal, 10 of 34 (29.4%); deep septal, 14 of 34 (41.1%); and right ventricular type, 10 of 34 (29.4%). Intramuscular segment length ranged from 13 to 40 mm. Coronary diameter proximal and within the affected segment was 2.2 0.5 mm versus 1.6 0.6 mm for the LAD, and 1.9 0.3 mm versus 1.5 0.6 mm for the remaining arteries, respectively. Depth ranged from 0.1 to 5.6 mm.

Conclusions Prevalence of intramuscular coronary arteries on CCTA is in concordance with most pathological reports and higher than in angiographic series. The CCTA clearly showed presence, course, and anatomical features of intramuscular coronary arteries. Coronary computed tomographic angiography may provide potentially useful information in the preoperative evaluation of candidates for coronary bypass surgery. (J Am Coll Cardiol 2007;49: 587–93) © 2007 by the American College of Cardiology Foundation

Coronary arteries in the human characteristically have an epicardial course. Not infrequently, however, segments of these arteries run intramuscularly. This variant is known as myocardial bridging and is most commonly seen in the left anterior descending coronary artery (LAD) (1–5). The clinical significance of myocardial bridging is controversial. In most of the cases, myocardial bridging represents an incidental finding that may be considered a normal variant or a benign coronary anomaly (4–5). Cases have been reported, however, of myocardial bridging causing myocardial ischemia, myocardial infarction, arrhythmias, or sudden death (6,7). Reduced coronary flow reserve and altered vasoreactivity has been documented in arteries with an intramuscular segment (3–5,8). In addition, myocardial bridging may present a technical challenge during coronary arterial bypass because surgical exposure of the intramuscular coronary artery may be difficult and may require the use of intraoperative echocardiography (9,10). Accidental opening of the right ventricle during dissection of intramuscular LAD is an undesired complication (11,12).

The true prevalence of myocardial bridging is not known. In autopsy series, myocardial bridging was found in 5% to 86% of the cases (3–5). It is commonly recognized that myocardial bridging is underdiagnosed in vivo. In vivo diagnosis is usually made with coronary angiography showing the characteristic "milking" effect (13). Additionally, a typical intravascular ultrasound (IVUS) appearance (the half-moon sign) and a characteristic spike-and-dome pat-

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Abbreviations and Acronyms

CCTA coronary computed tomographic angiography
CT computed tomography
IVUS intravascular ultrasound
LAD left anterior descending coronary artery
MPR multiplanar reformations

tern of diastolic flow with intracoronary Doppler wire have been reported (14). The incidence of myocardial bridging reported in angiographic series ranged from 0.8% to 4.9%. Few reports in cardiac surgery literature suggested the presence of an intracavitary subtype with an estimated prevalence of 0.2% to 0.3% (12).

Recently, coronary computed tomographic angiography (CCTA) using multidetector computed tomography (CT) has been introduced for the noninvasive visualization of coronary arteries. At variance with conventional coronary angiography, CCTA is able to visualize in the same image not only the lumen of coronary arteries but also their walls, the neighboring myocardium, and the heart chambers. A CCTA therefore should be able to visualize myocardial bridging in a more sensitive and comprehensive way than coronary angiography, in which the diagnosis is not made by the direct visualization of the intramuscular course but the indirect finding of systolic compression of the coronary artery indicated by the milking effect. A few case reports of myocardial bridging diagnosed by CCTA have been recently published (15–17). The goal of this study is to report the prevalence and the morphologic characteristics of myocardial bridging diagnosed at CCTA in a consecutive series of 118 patients.

Methods

One hundred eighteen consecutive patients who underwent CCTA for suspected or known coronary artery disease were studied for the presence of intramuscular coronary arteries. Two additional patients were excluded from analysis because of poor image quality. A beta-blocker drug was administered to all patients with heart rate 65 beats/min (metoprolol 100 mg orally or 5 to 10 mg intravenously, 1 h or immediately before scanning, respectively). A CCTA was obtained with a 40-slice (72 patients) or 64-slice (46 patients) multidetector CT scanner (Brilliance 40/64, Philips Medical Systems, Cleveland, Ohio). Scanning was performed with both scanner types at 120 kV, using 600 to 800 mA, with a detector collimation of 0.625 mm and gantry rotation speed of 0.42 s. Minimal slice thickness was 0.67 mm, and the reconstruction interval was 0.4 mm. A volume of 80 to 120 ml of contrast media (Iomeron 400, Bracco Imaging SpA, Milan, Italy) was injected intravenously at a rate of 4 to 5 ml/s. Using retrospective electrocardiographic gating, reconstructions were performed routinely at 40%, 70%, 75%, and 80% phases of the R-R interval period. Additional reconstructions during the end-systolic phase (20% to 30% of the R-R interval) were excluded from analysis because of their limited image quality, which did not allow reliable measurements of vessel caliber and anatomical delineation. Analysis of scans was performed on a dedicated workstation (Philips Extended Brilliance Workspace). Reconstructed images were viewed using the original axial slices, curved multiplanar reformations (MPR) along the axis of each vessel, and volume-rendered images. Scans were analyzed by a consensus of an experienced radiologist (4 years of experience with CCTA) and a cardiologist (30 years of experience in cardiac catheterization).

Myocardial bridging was diagnosed and evaluated when an intramuscular segment of a coronary artery was visualized on axial and MPR images. Arterial segments located in a deep gorge but covered only by a thin layer of muscle or fibrous-fatty tissue were included because it was reported that they also may be compressed during systole by the surrounding muscle (4).

For each intramuscular segment, the following parameters were recorded: the coronary artery and the segment involved, the length and the diameter of the intramuscular segment, the diameter of the artery immediately proximal to the intramuscular entry, presence of atherosclerosis in the intramuscular segment, and in a 2-cm-long segment proximal to the entry of the intramuscular segment. The ability to correlate the myocardial bridging localization in multiplanar reformats with the display in volume-rendered images was also evaluated. In addition, for intramuscular segments in LAD, the following anatomical findings were analyzed: the depth of the intramuscular segment (1 or 1 mm), its course within the interventricular septum (proximity to the right or left ventricular endocardium), and its relationship with the right ventricular anterior wall. All scans were analyzed for a hypodense myocardial segment suggestive of myocardial infarction. Values are represented as mean SD.

Results

Patient population. Patient characteristics are shown in Table 1. Patients were referred to CCTA because of chest

Patient Data

	All Patients, n (%)	Myocardial Bridging Patients, n (%)
Patients	118	36 (30.5%)
Mean age, yrs	53	51
Male gender	107 (91%)	32 (89%)
Referral		
Chest pain and equivocal test results	26 (22%)	8 (22%)
Risk factors	62 (52%)	15 (50%)
Known coronary disease	30 (25%)	10 (27%)
Coronary arteries		
Normal	52 (44%)	18 (50%)
50% stenosis	40 (34%)	12 (33%)
50% stenosis	26 (22%)	6 (17%)
Hypertrophic cardiomyopathy	2	1

pain with or without equivocal noninvasive diagnostic test results, follow-up of known coronary artery disease, or multiple risk factors but no symptoms. One hundred seven patients (91%) were male, with an average age of 53 ± 11 years. **CT diagnosis.** The average heart rate during CT scan was 62 ± 8 beats/min (range 45 to 85 beats/min). A normal pattern of epicardial coronary artery or the presence of an intramuscular segment could be identified clearly both on axial views and on MPR images (Figs. 1 to 4). In all cases, the intramuscular segment could also be identified on volume-rendering reformations, allowing a 3-dimensional anatomical evaluation of its location (Fig. 5). **Prevalence.** Myocardial bridging was found in 36 of 118 (30.5%) patients. Intramuscular segments totaled 47, thus, in 8 patients more than 1 intramuscular segment was found. Most of the intramuscular segments were in the mid LAD (n = 27) (Figs. 2 to 4) followed by distal LAD (n = 7), diagonal branches (n = 6), intermediate artery (n = 4), and obtuse marginal artery (n = 3). No myocardial bridging was detected in the right coronary artery. **Anatomical and pathological features.** The length of the intramuscular segments ranged from 13 to 50 mm (average 23 ± 9 mm). The mean diameter of the intramuscular segments was 2 ± 1.8 mm and 1.5 ± 0.6 mm for LAD and the remaining arteries, respectively. The diameter of the proximal segments was significantly larger than that of the intramuscular segment, being 2.8 ± 0.5 mm for the LAD and 1.9 ± 0.3 mm for the remaining arteries ($p > 0.001$). The depth of the intramuscular segments ranged from 0.1 to 6.2 mm.

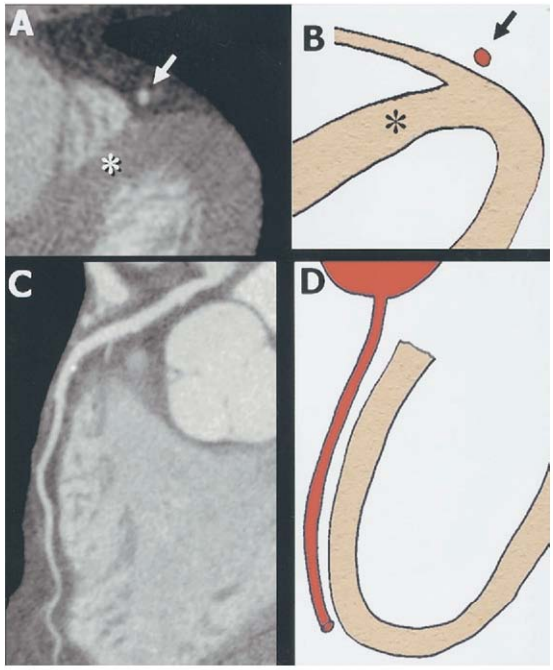

Figure 1 CCTA and Schematic Drawings: Normal LAD

Normal pattern of the left anterior descending artery (LAD) as seen on axial plane **(A, B)** and multiplanar reformation **(C, D)**. The left anterior descending artery **(arrow)** is embedded through all of its length in the epicardial fat. *Interventricular septum. CCTA = coronary computed tomographic angiography.

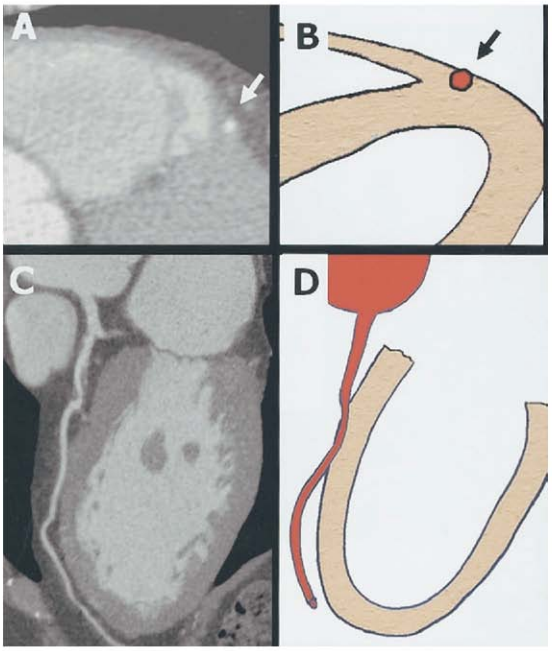

Figure 2 CCTA and Schematic Drawings: Intramuscular LAD, Superficial Type

Intramuscula LAD, superficial type, as seen on axial plane **(A, B)** and multipla nar reformation **(C, D)**. The mid LAD **(arrow)** shows a typical deviation and straitening and is only partially surrounded by myocardium. Of note, an athero sclerotic plaque in the proximal LAD, whereas the intramuscular segment is free of disease. Abbreviations as in Figure 1.

For the LAD, 3 anatomical patterns of intramuscular segments were identified according to the depth and the course of the intramuscular segment: 1) the superficial type (Fig. 2), seen in 10 of 34 (29%) of all intramuscular LAD segments, in which the intramuscular artery had a superficial course along the interventricular septum and was covered by a thin layer of tissue (<1 mm thick); 2) the deep type (Fig. 3), seen in 14 of 34 (41%) of all intramuscular LAD segments, in which the intramuscular segment penetrated the interventricular septum at a depth between 1 and 6.2 mm (In the deeper segments of this group the intramuscular artery tended to deviate toward the right ventricular aspect of the interventricular septum.); and 3) the right ventricular type (Fig. 4) seen in 10 of 34 (29%) of all intramuscular LAD segments, in which the intramuscular artery crossed through the right ventricular anterior wall adjacent to the interventricular septum.

Evidence of coronary artery atherosclerosis was found in 66 of 118 (55.9%) patients. Coronary arteriosclerosis was shown in 48 of 82 (58.5%) patients without bridging and in 18 of 36 (50%) of those with bridging. In 7 cases, athero

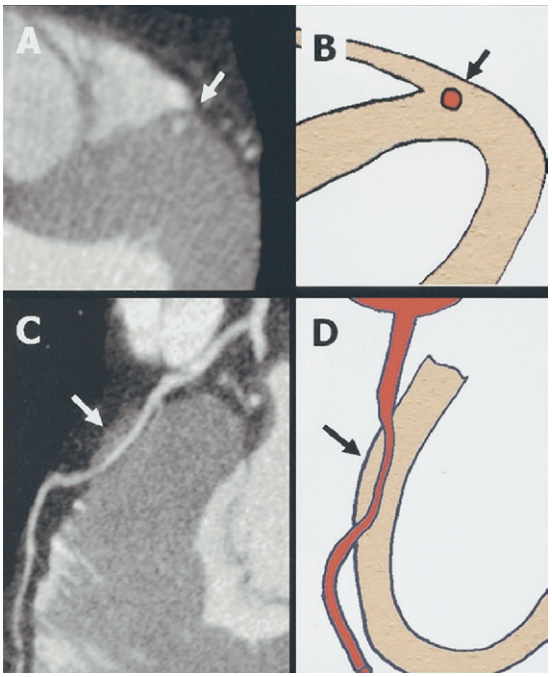

Figure 3 **CCTA and Schematic Drawings: Intramuscular LAD, Deep Type**

Intramuscular LAD, deep type, as seen on axial plane **(A, B)** and multiplanar reformation **(C, D)**. The mid LAD crosses deeply into the myocardium **(arrows)**. Abbreviations as in Figure 1.

sclerotic plaques were noted in a 2-cm-long segment proximal to the beginning of the intramuscular segment (Fig. 6), and in 1 patient (a 69-year-old man) the plaque extended into the proximal part of the intramuscular segment. Atherosclerotic plaques were not detected in the intramuscular segment in any of the other cases. No evidence of myocardial infarct was found in the myocardial territory subtended by the intramuscular artery.

Discussion

This study shows that the intramuscular course of coronary arteries can be detected and characterized by CCTA. Our data suggest that CCTA is an easy and reliable tool for comprehensive in vivo diagnosis of the intramuscular course of coronary arteries. It is generally estimated that the myocardial bridging can be detected in about one-third of the adults in autopsy series, whereas the reported incidence in angiographic series is much lower, 5% (4,5). The incidence of myocardial bridging in our study (30.5%) is in concordance with the reported incidence in autopsy series, but is at variance with the much lower incidence reported in angiographic series. Major differences from this incidence in some angiographic and autopsy series may be dependent on the selection of the cases studied in those series (4,18,19). The present study was performed on a series of consecutive patients who underwent CCTA for known or suspected coronary artery disease. In most patients (55%), no evidence of coronary atherosclerosis was found, whereas significant coronary artery disease (50%) was detected in only 22%. Two cases only were affected by hypertrophic cardiomyopathy, a condition that was associated with an increased prevalence of bridging (7,20–22). The incidence of myocardial bridging in the present series therefore may be closer to the incidence in the general population than reported previously in published clinical studies.

Anatomical and pathological features. In our series, in concordance with previous reports, the length of myocardial bridging was 2 to 3 cm on average (3). We have also found a significant decrease in the diameter of the intramuscular segment compared with the adjacent proximal segment. Similar observations were reported in the literature. Structural differences between intramuscular and epicardial segments and reduced diameter of the intramuscular segments have been detected in pathological studies (23,24). Moreover, a persistent diastolic reduction of 34% to 41% within the bridged segment after a systolic diameter reduction of 70% to 80% has been shown with angiography and IVUS (3,14,25,26). In addition, it cannot be excluded that normal tapering in the arterial diameter may have influenced our results.

Myocardial bridging was found in our series mainly in the LAD coronary artery. We were able to classify the intramuscular LAD segments into 3 distinct types according to their depth and their anatomical course in relation to the

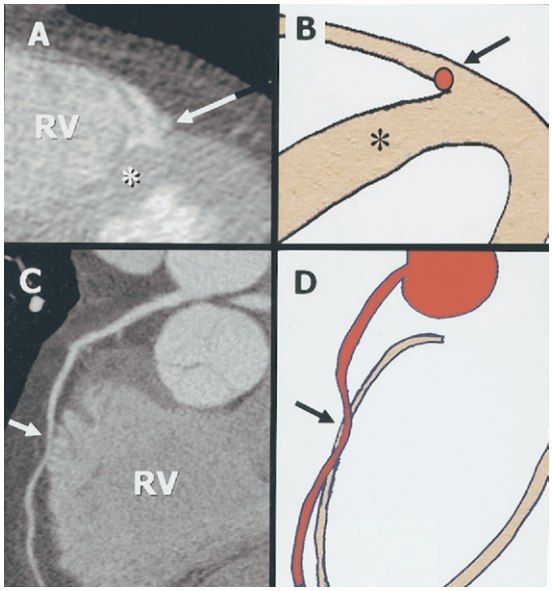

Figure 4 **CCTA and Schematic Drawings: Intramuscular LAD, Right Ventricular Type**

Intramuscular LAD, right ventricular type **(arrow)**. In this variant it is frequently difficult to follow the LAD on sequential axial images **(A, B)** because it disappears between the right ventricular trabeculae, whereas the multiplanar reformation images easily show its intraventricular course **(C, D)**. *Interventricular septum. RV right ventricle; other abbreviations as in Figure 1.

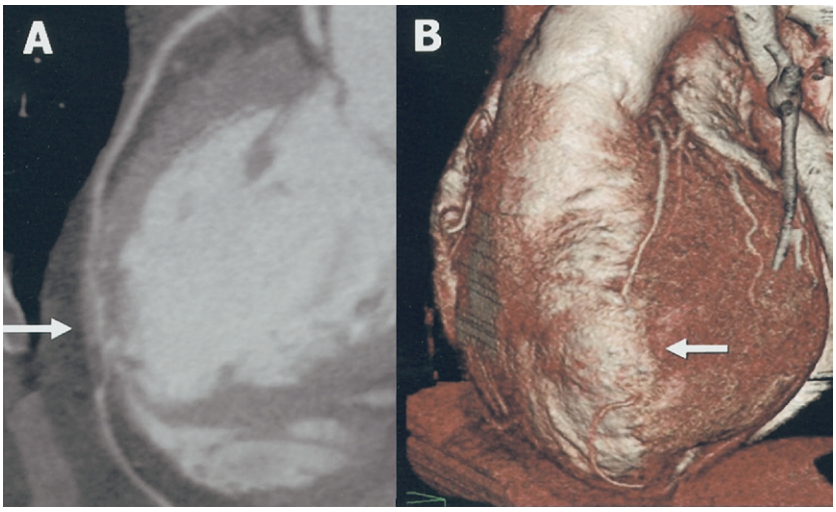

Figure 5 **CCTA MPR and Volume-Rendering Reformations: Intramuscular LAD, Deep Type**

Distal intramuscular LAD, deep type **(arrow)**, as seen on multiplanar reformation (MPR) **(A)** and volume-rendering reformation **(B)**. The latter allows an easy 3-dimensional demonstration of the anatomical relationship between the intramuscular segment and the apex, a useful information for the cardiac surgeon when planning coronary artery bypass grafting. Other abbreviations as in Figure 1.

interventricular septum and the anterior right ventricular wall. In the first 2 types the tunneled arteries run their entire course in the interventricular septum, superficially or deeply, whereas in the third type the tunneled artery penetrated into the right ventricular anterior wall, sometimes crossing within the right ventricular cavity. This CCTA-based classification partially corresponds with previous studies that suggested various anatomical classifications for intramuscular LAD arteries (1,12,27). Ferreira et al. (27) divided the intramuscular LAD into 2 types: the superficial type, in which the intramuscular segment runs on the interventricular groove, and the deep type, in which the intramuscular segment deviates toward the right ventricle and is crossed by a muscle bundle arising from the right ventricle. An intracavitary course of a coronary artery is a rare condition that to date was diagnosed only in vivo at surgery (10–12). Our third type, defined as an intramuscular segment running in the right ventricular wall or in the right ventricular cavity, may partially correspond to the Ferreira deep type of myocardial bridging and/or to the intracavitary LAD described by Ochsner and Mills (10) and Tovar et al. (12). Our series represents the first noninvasive in vivo observation of a right ventricular intracavitary course of the LAD coronary artery.

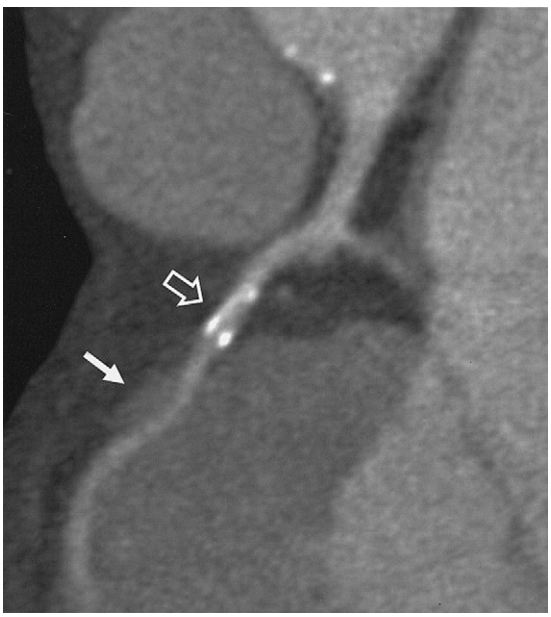

Figure 6 **Intramuscular Left Anterior Descending Artery**

A calcified plaque is located just proximal to the intramuscular segment **(open arrow)**. No evidence of atherosclerosis is noted in the intramuscular segment **(solid arrow)**.

We did not find any intramuscular segment in the right coronary artery. Bridging in the right coronary artery was less frequent than in the left system in the anatomical literature and exceptional in angiographic series (4,5). Absence of right coronary bridging in our moderately sized series was most probably incidental and not because of an intrinsic limitation of the CT technique.

All but one intramuscular artery were without evidence of atherosclerosis. Atherosclerotic plaques immediately proximal to the beginning of the intramuscular segment were found in 7 of 36 cases (19%). It has been reported that intramuscular arteries are protected from the atherosclerotic process and that the immediately proximal segments are at

higher risk of arteriosclerosis (4,5,23). Although our data correspond with the reported rarity of atherosclerosis in the intramuscular artery, they do not allow statistical analysis or understanding of a possible protection mechanism.

Clinical implications. Most of the reported cases of myocardial bridging had no clinical consequences, thus in most cases myocardial bridging could be considered a normal variant or a benign coronary anomaly. Some reports have suggested that bridging may merely represent an evolutionary remnant, being rare or missing in mammalians (28). However, it has been reported that myocardial bridging may be responsible for flow disturbances and myocardial ischemia (3–8). Current CT technology allows precise anatomical delineation but is lacking the ability of physiological evaluation. Thus, the physiological significance of myocardial bridging and its specific subtypes, detected by CCTA, remains elusive.

Occasionally myocardial bridging has caused technical problems during coronary bypass surgery (10,11). A deep intramuscular artery may be difficult to localize, therefore the use of intraoperative echocardiographic Doppler has been proposed to visualize the artery (9,29,30). An intracavitary course of the LAD has been the cause of complications during coronary surgery, including perforation of the right ventricular wall during attempts of isolation of the intramuscular artery (11,31–33). Preoperative knowledge of this abnormal course, as detected on CCTA, may theoretically help surgeons to overcome such a complication. However, none of our patients with myocardial bridging underwent surgery, so we do not have any objective confirmation of the practical usefulness of our findings. In addition, an intramuscular coronary artery is considered a relative contraindication to minimally invasive coronary surgery. It has been suggested that a preoperative diagnosis of myocardial bridging on CCTA may help in making the decision between coronary artery bypass grafting through the midsternotomy with or without cardiopulmonary bypass (coronary artery bypass graft or off-pump coronary bypass graft, respectively) or a minimally invasive approach through the small left anterior thoracotomy, but no data are available to support this hypothesis (34,35).

Study limitations. This study is a descriptive one because comparison of our findings with other modalities was not available. None of our patients with myocardial bridging underwent cardiac catheterization or coronary surgery after CCTA. Nevertheless, CCTA has been validated as a reliable modality for coronary artery imaging, therefore it is highly unlikely that our findings represent artifacts and not true and faithful imaging of the coronary artery course.

Coronary arteries are best evaluated on CCTA during the end-diastolic phase. The current limited temporal resolution of CT scanners does not allow reliable coronary anatomical delineation during the end-systolic phase. For this reason we could not evaluate in this study the presence or degree of systolic compression of the intramuscular coronary artery, and we could not produce the milking sign as seen on coronary angiography. Future studies using scanners with improved temporal resolution should address this issue.

Conclusions. A CCTA clearly showed the presence, the course, and the anatomical features of myocardial bridging. Prevalence of intramuscular coronary arteries on CCTA in the present study is in concordance with most pathological reports and higher than in angiographic series. A CCTA offers several advantages over other techniques (coronary angiography, IVUS, and intracoronary Doppler) used for in vivo diagnosis of myocardial bridging, including increased sensitivity, ability to diagnose those cases without overt systolic compression, and recognition of right ventricular intracavitary course. Additionally, CCTA is a noninvasive procedure with a minimal rate of complications. It seems that CCTA may become the technique of choice for in vivo diagnosis of myocardial bridging. However, CCTA is unable to determine the physiological significance of an intramural coronary artery; thus, functional tests for ischemia may be needed to assess the clinical impact of the bridged segments.

Further data are needed to establish the usefulness of this technique in the preoperative evaluation as a guide to the surgeon in localizing intramuscular and/or intracavitary segments of the coronary artery during coronary bypass surgery.

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Non-invasive detection of significant coronary artery disease with multi-section computed tomography angiography in patients with suspected coronary artery disease

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AIM: The objective of this prospective study was to compare the accuracy of multi-section computed tomography (MSCT) coronary angiography with invasive selective coronary angiography in the detection of significant coronary stenosis ($\geq$50% lumen diameter narrowing).

METHODS: Thirty consecutive patients (mean age 59$\pm$10 years) with suspected coronary artery disease underwent both invasive coronary angiography and MSCT using a 40-section multidetector row machine with temporal resolution of 53 ms. Reconstruction images were performed in eight phases of the cardiac cycle. Images of MSCT and invasive coronary angiography were analysed using the 16-segment model of the American Heart Association.

RESULTS: A total of 480 segments from 30 patients were evaluated. Coronary segments distal to a vessel occlusion and segments with coronary stent were not considered for analysis (20 segments in total). Ninety-four (20.4%) segments showed significant ($\geq$50%) stenosis by invasive coronary angiogram. The accuracy of coronary MSCT was computed on a per segment basis. Average sensitivity, specificity, positive predictive value, and negative predictive value of MSCT were 99, 98, 94, and 99%, respectively.

CONCLUSION: This study demonstrated that MSCT is as reliable as coronary angiography at detecting significant obstructive coronary artery disease. In selected groups of patients, it may replace the more invasive and potentially more dangerous conventional coronary angiography.

Introduction

Invasive coronary angiography has been the gold standard in the detection of significant coronary artery disease. Approximately 40–50% of all coronary angiograms were performed to exclude significant stenosis and were not followed by an intervention.[1] As this invasive procedure is costly and is not without risk, non-invasive multi-section computed tomography (MSCT) coronary angiography is now gaining acceptance as an alternative in the evaluation of patients with suspected coronary artery disease (CAD).[2]

Diagnosing ischaemic heart disease may be difficult in patients who cannot provide a good history, and physical examination is usually not helpful. Conventional methods for diagnosing significant CAD such as treadmill stress test, stress echocardiography and nuclear myocardial perfusion scanning also suffer from the limitation of being unable to visualize the coronary artery. With the advent of 16-section MSCT machine, the anatomy of the coronary vessels can be determined in a non-invasive manner, and it has become possible to perform with promising results.[2] MSCT has made the diagnosis of CAD easier and safer.

The aim of this blinded study was to compare the accuracy of 40-section MSCT coronary angiography

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with invasive selective coronary angiography in the detection of significant coronary stenosis ($\geq$ 50% lumen diameter narrowing).

Methods

Thirty consecutive patients were studied from November 2004 to March 2005 at our institution. Study protocols were approved by our institutional ethics committee. Informed consent was obtained from all study participants. Inclusion criteria were patients with two or more cardiovascular risk factors and symptomatic angina with suspected CAD. Patients were excluded if they had unstable angina, irregular heart rhythm and had contra-indications to the administration of contrast agents. If the heart rate was more than 70 beats/min, patients were premedicated with 50 mg atenolol or 100–200 mg diltiazem orally 1 h before the examination.

MSCT protocol

The CT examination was performed using 40-section MSCT (Philips Medical System NV, Eindhoven, The Netherlands) with a tube energy of 120 kV and an effective tube current of 650 mAs at a single breath hold. Images were acquired with 40$\times$ 0.625 mm section collimation, gantry rotation time of 420 ms, slice thickness of 0.67 mm, table increment of 0.33 mm. The contrast material (iopromide 0.769 g/ml or 370 mg iodine/ml) was administered through an 18 G needle placed in the antecubital vein. It was infused at 5 ml/s followed by 40 ml saline bolus using a double barrel Medrad Stellant (Indianola, USA) injector. The volume of nonionic contrast media used ranged from 80–100 ml depending on the patient's weight. The examination was initiated 1 cm below the carina and extended to the base of the heart with bolus tracking.

Image reconstruction was retrospectively gated to the ECG. The multidetector machine will automatically process eight phases of the R-wave to R-wave interval (37.5, 40, 50, 60, 62.5, 70, 75, 87.5%).

Data acquisition and analysis

Overlapping transaxial images were reconstructed by using the best images that showed near or total absence of motion or stair-step artefacts. Temporal resolution was 53 ms. The reconstructed data were transferred to an offline image analysis workstation (Philips Brilliance). The images were analysed by two investigators (a cardiologist and a radiologist). The data sets were evaluated for the presence of significant coronary stenosis that could be identified in at least two independent orthogonal planes. Manual measurements were performed on coronary segments classified according to the 16-segment model of the American Heart Association (AHA).

Selective coronary angiography

Selective coronary angiography was performed on these patients with standard techniques through a transfemoral approach. The degree of diameter stenosis in the diseased coronary segments was assessed in two orthogonal planes by two experienced cardiologists. Significant coronary lesions were defined by diameter stenosis of $\geq$ 50%.

Statistical evaluation

Statistical analysis was performed using a PC-based software program (SPSS 10.0). We calculated the

Table 1 Reasons for exclusion of coronary segments

Reasons	Location ($n=20$)
Presence of stents (5)	Proximal RCA (1)
	Proximal LAD (2)
	1st Diagonal branch (2)
Non-visualization of arteries due to total proximal occlusion (13)	Mid-right coronary artery (1)
	Distal right coronary artery (2)
	Right posterolateral (2)
	Right posterior descending artery (2)
	Distal left circumflex artery (1)
	1st Obtuse marginal branch (1)
	2nd Obtuse marginal branch (1)
	Mid-left anterior descending artery (1)
	Distal left anterior descending artery (2)
Arteries absent in both techniques (2)	2nd Diagonal branch (2)

sensitivity, specificity, negative predictive value and positive predictive value to determine the usefulness of MSCT in predicting significant CAD.

Results

A total of 30 patients with 480 coronary segments were reviewed (20 males, 10 females, mean age: 59 ± 10 years, mean weight: 78 ± 14 kg). The median interval between MSCT and invasive coronary angiogram was 2 days (range 0–26 days). The average imaging time was 13 s. Mean heart rate at the onset of the examination was 61 ± 10 beats/min. Coronary segments distal to a vessel occlusion and segment with a coronary stent were not considered for analysis. Locations of the 20 excluded coronary segments are listed in Table 1. All the segments included in the study were technically interpretable. Three hundred and sixty-six (79.6%) segments showed <50% stenosis, and 94 (20.4%) segments showed significant (≥50%) stenosis as evidenced using coronary angiogram.

Table 2 lists the number of segments per artery with significant stenosis as evidenced using conventional coronary angiography. The accuracy of coronary MSCT was compared with coronary angiogram on a per segment basis. Figs. 1 and 2 compare the two techniques for left circumflex and right coronary artery respectively. Table 3 lists the sensitivity, specificity, positive predictive value, and negative predictive value of the 16-segment coronary MSCT for the detection of significant coronary stenosis (≥50%). Average sensitivity, specificity, positive predictive value, and negative predictive value of MSCT were 99, 98, 94, and 99%, respectively.

Table 2 Segments with significant ≥50% stenosis by coronary angiogram

Coronary artery	Segments	*n*≥50%
Left main coronary artery		4
Left anterior descending	Proximal	10
	Mid	14
	Distal	3
	1st Diagonal	10
	2nd Diagonal	1
Left circumflex artery	Proximal	3
	Mid	11
	Distal	4
	1st Obtuse marginal	4
	2nd Obtuse marginal	3
Right coronary artery	Proximal	9
	Mid	6
	Distal	4
	Right posterolateral	3
	Right posterior descending	5
Total		94

Discussion

Invasive coronary angiogram, which is regarded the gold standard in detecting coronary disease, is being challenged by the introduction of newer non-invasive techniques to evaluate suspected coronary artery disease. These non-invasive techniques include electron beam computed tomography (EBCT), cardiac magnetic resonance angiography (MRA), and CT angiography. However, cardiac MRA is hampered by poor spatial resolution, long imaging times, image degeneration by metal objects and its inability to visualize calcification. Likewise, the current limitations of EBCT imaging include the limited reproducibility of coronary calcium quantification, the inability to detect non-calcified atherosclerotic plaques and the limited spatial resolution of three-dimensional visualization of the coronary arteries.[3]

MSCT angiography is currently gaining acceptance as an important clinical tool. However, the conventional CT (using single section or four section machines) requires longer exposure times that are unable to acquire images of the beating heart without motion artefacts. To virtually freeze cardiac motion and to avoid motion artefacts, very short exposure time is needed for the acquisition of transaxial slices.[1]

Another limitation of CT angiography in the adequate assessment of coronary arteries is the occurrence of the "blooming" effect that is seen in certain stented and calcified arteries.[4–7] In some stents, especially the old ones, beam hardening and partial volume artefacts hampered visualization of the lumen within the stent.[8] The increase in rotation time shortens the imaging time and further shortens the breath-hold duration. This improves image quality as it reduces motion artefacts, and in addition, requires less contrast agent. Additionally, the reduction of section thickness with the available multi-section machines reduces partial volume effects.

Extensive calcified plaques are often present in areas of remodelling and cause no significant stenosis until the very late and severe stages of atherosclerosis.[9] Calcification causes overestimation of luminal narrowing and contrast-related image deterioration, which is one of the reasons

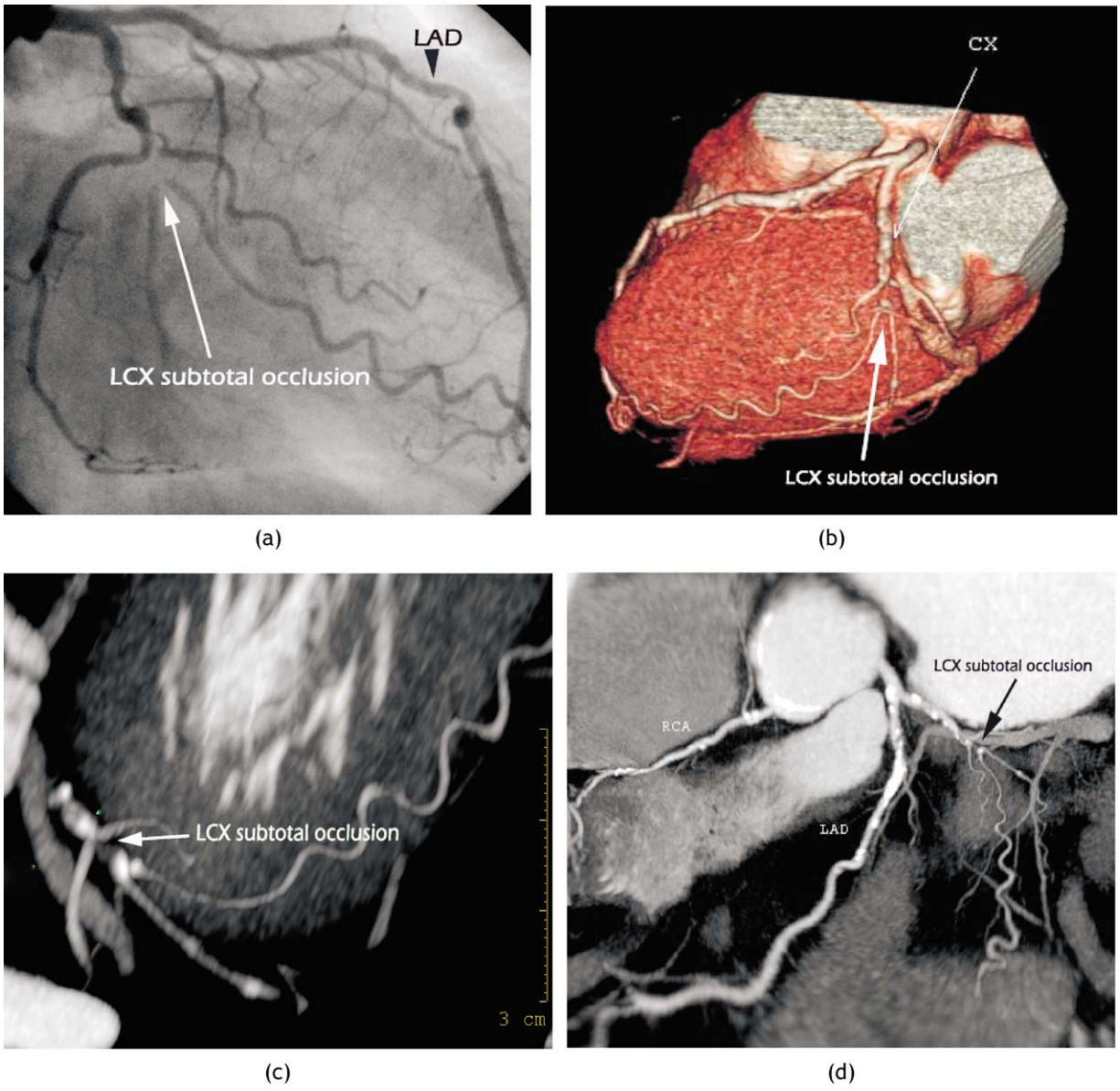

Figure 1 Left circumflex artery. Subtotal occlusion at bifurcation with obtuse marginal branch. (a) Right anterior olique caudal view of invasive coronary angiography. (b) Reconstructed volume rendered three-dimensional image. (c) Transaxial thin-slice MDCT image. (d) Reconstructed globe view of all the coronary arteries.

for false-positive findings. The improved spatial resolution through the reduction of partial volume effects potentially reduces the problems caused by calcification.[2]

The 16-section MSCT permits the detection of significant CAD in proximal segments with higher sensitivity (82%) and specificity (93%) compared with studies using 4 section MSCT technology. However, in one published study the negative predictive value of the 16 section machine was moderate (75%) and even demonstrated that it is insensitive to the degree of significant narrowing (50 versus 70) in selective angiography.[6] In the present study, a 40-section multidetector row machine was used which provided significant advantages over 4 or 16 section machines because it can have three to 10 times more detector rows and smaller detector width.

In a previous study by Nieman et al.,[8] the right coronary artery (RCA) was noted to be more sensitive to motion artefacts, which resulted in a lower proportion of interpretable segments (71%). Also, the left circumflex artery (LCX) was the most difficult to examine as this artery is often small and easily blends with adjacent contrast-filled structures, such as the great cardiac vein and the left atrium. In the present data, all of the segments included in the study were interpretable.

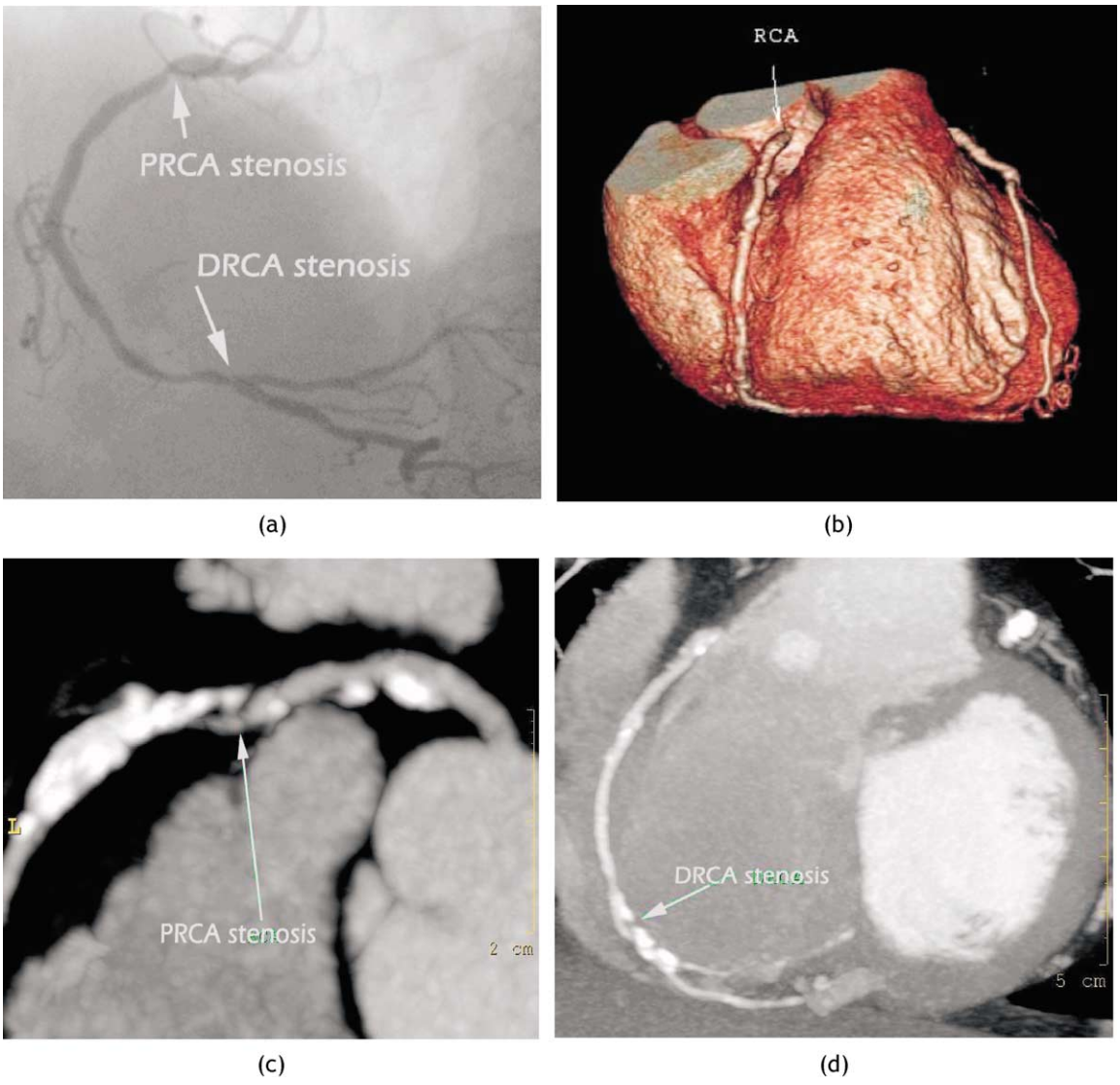

Figure 2 Right coronary artery with proximal and distal stenosis (a) left anterior olique view of invasive coronary angiography (b) reconstructed volume rendered 3D image (c) transaxial thin slice MDCT image of proximal right coronary artery (d) transaxial thin slice MDCT image of distal right coronary artery.

Increased temporal and spatial resolution led to higher sensitivity, specificity and predictive values of over 90% in our population. Our overall sensitivity and negative predictive value were both high at 99 and 99%, respectively. Our findings are consistent with recent publications using 16-section MSCT.[10-15] Many of the existing papers compare the results of four or 16-section MSCT machines with invasive coronary angiography. In the present study, the promising results may be due to the use of the 40-section machine.

The reason for a false-negative result in one segment located at the first diagonal artery was suboptimal contrast enhancement in small calibre vessels of approximately 1.5 mm in diameter. Further sub-analysis of the left main, proximal and mid-segment of the three major coronary arteries showed that sensitivity and negative predictive value were 100 and 100%, respectively.

Specificity and positive predictive value were relatively lower at 98 and 94%, respectively, because MSCT tends to overestimate the severity of stenosis in vessels affected by calcifications.[5] However, we found that false-positive segments were only misdiagnosed in arterial segments that were heavily calcified. In most of the less calcified lesions, the severity of stenosis with MSCT could be correctly estimated. This was technically possible at higher spatial resolution

Table 3 The sensitivity, specificity, negative predictive value, positive predictive value of multi-section computed tomography

Artery	Segments	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Left Main		100 (4/4)	100 (26/26)	100 (4/4)	100 (26/26)
Left anterior descending	Proximal	100 (10/10)	89 (16/18)	83 (10/12)	100 (16/16)
	Mid	100 (14/14)	93 (13/14)	94 (14/15)	100 (13/13)
	Distal	100 (3/3)	100 (25/25)	100 (3/3)	100 (25/25)
	1st Diagonal branch	90 (9/10)	100 (18/18)	100 (9/9)	95 (18/19)
	2nd Diagonal branch	100 (1/1)	100 (27/27)	100 (1/1)	100 (27/27)
Left circumflex artery	Proximal	100 (2/2)	96 (27/28)	67 (2/3)	96 (27/28)
	Mid	100 (10/10)	100 (20/20)	100 (10/10)	100 (20/20)
	Distal	100 (3/3)	96 (25/26)	75 (3/4)	100(25/25)
	1st Obtuse marginal branch	100 (3/3)	100 (26/26)	100 (3/3)	100 (26/26)
	2nd Obtuse marginal branch	100 (2/2)	100 (27/27)	100 (2/2)	100 (27/27)
Right coronary artery	Proximal	100 (9/9)	100 (20/20)	100 (9/9)	100 (20/20)
	Mid	100 (6/6)	100 (23/23)	100 (6/6)	100 (23/23)
	Distal	100 (4/4)	96 (23/24)	80 (4/5)	100 (23/23)
	Posterolateral	100 (3/3)	100 (25/25)	100 (3/3)	100 (25/25)
	Posterior descending	100 (5/5)	100 (23/23)	100 5/5)	100 (23/23)
Average		99	98	94	99

using 40-section MSCT compared with 16-section MSCT by using wide window settings for image analysis.

Post-study, we reviewed the segments without significant calcifications in the proximal left anterior descending (LAD), mid-LAD artery and proximal LCX where the findings of the invasive coronary angiogram and the MSCT coronary angiography differed in the quantification of the degree of stenosis. Consensus view of the independent reviewers with regards to these affected coronary segments was that there was no significant coronary stenosis on the invasive coronary angiography. On review of the MSCT coronary angiography, for the first segment in the proximal LAD artery, the stenosis was overestimated as a result of motion artefact. In the second segment at the tortuous proximal LCX artery, the diameter stenosis was overestimated in the MSCT as a result of partial volume effects during post-processing, when the section thickness was increased to visualize the tortuous segment. The pitfall was resolved when the section thickness was reduced to 3–5 mm range.

In the remaining two coronary segments, image quality was not affected by calcified plaque, motion artefacts, stair-step artefacts or image noise. The difference in stenosis was probably secondary to vessel overlap with the diagonal arteries.

Limitations of the study

Coronary stenosis on invasive angiography was estimated visually, which is inferior to quantitative coronary angiography. The sample size of this study is relatively small, and large-scale prospective trials are needed to further evaluate the usefulness of newer 64 section or greater machines. Although it might be difficult to perform large-scale studies in view of the dynamic technical development of CT technology, such large trials are necessary to establish cardiac MSCT as a clinical application. Further studies will help to establish the role of MSCT in various patient groups such as asymptomatic patients with multiple high risk factors, asymptomatic patients with known coronary artery disease, patients with stable angina and acute coronary syndromes.

In conclusion MSCT coronary angiography has high diagnostic accuracy, comparable with invasive coronary angiography, for the detection of significant CAD. Although some experts have argued that a 16-section system is sufficient, the 40-section system seems to offer new and superior clinical benefits. The present study suggests that in patients with suspected CAD, high sensitivity and high negative predictive value using 40-section MSCT will provide a significant impact on clinical decision-

making. We foresee that MSCT will be able to replace conventional non-invasive tests for patients with intermediate clinical probability of CAD.

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Detection of Coronary Artery Stenosis Using 40-Channel Computed Tomography With Multisegment Reconstruction

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Coronary angiographic studies performed with 16-channel multidetector computer tomographic scanners have demonstrated accurate detection of coronary vessel stenosis but are limited by a significant number of nonevaluable segments. To date, only single-center experience with multidetector computer tomography has been reported. We performed a prospective, blinded study at 2 institutions to determine the feasibility and diagnostic accuracy of coronary angiography using 40-channel multidetector computer tomography with multisegment reconstruction for the detection of obstructive coronary artery disease (CAD). Multidetector computer tomographic studies were performed in 85 patients who were referred for invasive coronary angiography with clinically suspected CAD. Datasets were analyzed by blinded, independent review. Of 1,145 segments that were suitable for analysis as determined by angiography, 1,045 (91.3%) were evaluable on multidetector computer tomography. Segment-based sensitivity, specificity, and positive and negative predictive values for detecting ≥50% luminal stenoses were 86%, 97%, 75%, and 97%, respectively. The area under the receiver-operating characteristic curves for the detection of ≥50% angiographic stenosis by multidetector computer tomography was 0.94. In a patient-based analysis, the sensitivity, specificity, and positive and negative predictive values for detecting subjects with ≥1 segment with ≥50% stenosis were 98%, 93%, 94% and 93%, respectively. In conclusion, coronary angiography using 40-channel multidetector computer tomography with multisegment reconstruction accurately detects coronary segments and patients with obstructive CAD, with a small number of nonevaluable cases. **(Am J Cardiol 2007;99:175–181)**

Coronary artery disease (CAD) is a leading cause of death and disability in the industrialized world. Stress testing is useful to establish prognosis in patients with suspected CAD but has limited diagnostic utility.[1] Cine coronary angiography is often required to establish the diagnosis of CAD, but its wide use is limited by cost, risks, and discomfort.[2,3] Recent advances in multidetector computed tomography have made electrocardiographically gated acquisition feasible, with excellent visualization of the coronary arteries. Reported sensitivities and specificities for the detection of obstructive coronary lesions using 16-channel multidetector computed tomographic (MDCT) scanners are 30% to 95% and 86% to 98%, respectively.[4–14] In most published studies, anywhere from 5% to 33% of coronary segments were nonevaluable due to limited image quality. More recently, newer generation MDCT scanners have been introduced, which are capable of performing contrast-enhanced coronary studies in 10 seconds with higher spatial and temporal resolution. The latter may be attained by increased gantry rotation speed or multisegment reconstruction. Studies performed with 32-channel scanners capable of fast gantry rotation have shown improved accuracy parameters and increased percentage of interpretable segments.[15–17] In the present report, we report the feasibility and diagnostic accuracy of 40-channel multidetector computed tomography with multisegment reconstruction for the detection of obstructive CAD.

Methods

Eighty-five consecutive patients who were clinically referred for cine coronary angiography with known or suspected CAD were enrolled in this study. Patients were excluded from participation if they were men 30 years of age, women of childbearing potential, or if they had previous coronary bypass surgery, cardiac rhythm other than sinus, serum creatinine level 1.5 mg/dl, decompensated heart failure, or contraindications to iodine contrast or blockers. The study group included 25 patients with previous coronary stents involving 35 coronary segments. The primary study hypotheses were that sensitivity and specificity of 40-channel MDCT coronary angiography for detecting segments with 50% luminal stenosis would be 80% and 90%, respectively. All patients provided informed consent. Institutional review boards from the 2 participating centers approved the study. Serum creatinine

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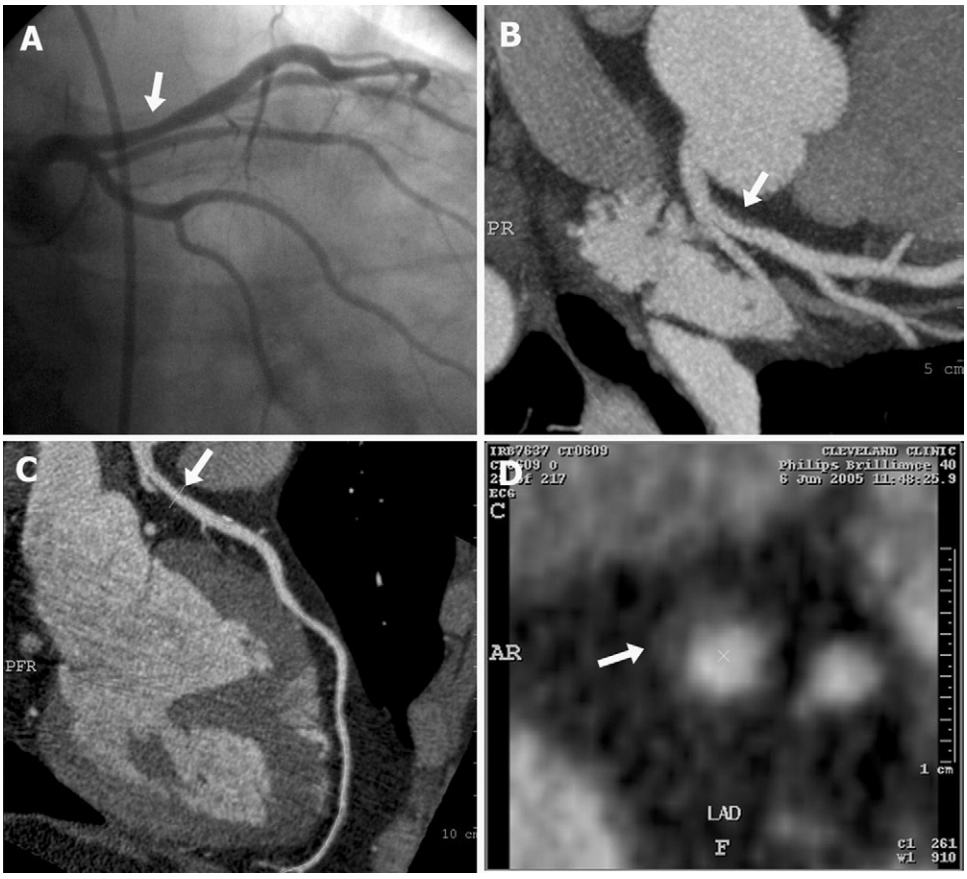

Figure 1. Study patient with mild stenosis in the proximal left anterior descending artery shown on *(A)* cine fluoroscopic view, *(B)* MDCT maximum intensity projection image, *(C)* MDCT curved multiplanar reconstruction image, and *(D)* cross-sectional vessel view indicating eccentric noncalcified plaque.

measurements were obtained before each procedure. Research nurses monitored all patients during preparation and for up to 30 minutes after the computed tomographic procedure.

All studies were performed using 40-channel MDCT scanners (Brilliance CT, Philips Medical Systems, Cleveland, Ohio). An intravenous 18-gauge catheter was inserted in an antecubital vein and connected to a dual-head power injector (Stellant D, Medrad, Indianola, Pennsylvania). Patients with a heart rate 65 beats/min at rest received intravenous blockers (metoprolol 5 to 20 mg) until their heart rates were 65 beats/min or a maximum of 20 mg was administered. For MDCT angiography, 100 to 120 ml of nonionic iodinated contrast material (iopamidol [Isovue 370 mg/ml, Bracco Diagnostics, Princeton, New Jersey], iohexol [Omnipaque 350 mg/dl, GE Healthcare AS, Oslo, Norway], or ioversol [Optiray 350 mg/dl, Mallinckrodt, Hazelwood, Missouri]) was injected at 5 to 6 ml/s. This was immediately followed by a 30-ml normal saline flush. A 40- 0.6-mm collimation was used for scan acquisition. Other scan parameters were adjusted according to a patient's body habitus (tube voltage 120 to 140 kVp, 555 to 1,000 mAs). Spiral pitch (0.2 to 0.3) was adjusted according to a patient's heart rate, resulting in an average temporal resolution of 125 to 210 ms, using an adaptive multisegment reconstruction algorithm[18] and a gantry rotation time of 0.42 second. In 74 patients with a heart rate 75 beats/min at rest and no observed arrhythmia during scan preparation, electrocardiographically based dose modulation was implemented at a single phase or dual phases according to the patient's heart rate. Image acquisition was automatically initiated using bolus tracking in a region of interest in the descending aorta, and the scan was performed during a single breath-hold. Images were reconstructed at a thickness of 0.8 mm and a 180- to 220-mm field of view at several predetermined consistent physiologic phases[19] of the cardiac cycle according to heart rate.

MDCT datasets were analyzed independently at each institution by investigators who were blinded to the clinical information and the cine coronary angiographic images and results. Multiple image sets corresponding to different cardiac phases were simultaneously examined in a dedicated workstation (Brilliance Workspace, Philips Medical Systems), and the cardiac phases with the best segment-specific image quality were selected for analysis. Maximum intensity projection, multiplanar reformatted, and curved multiplanar reformatted images were obtained for each coronary segment. Quantitative analysis of each segment was performed by visual estimate based on the 17-segment model derived from the 15-segment American Heart Association classification.[20] Segments were considered unsuitable for interpretation based on poor contrast opacification or on motion or calcium-blooming artifacts.

All studies were performed using digital cine fluoroscopic equipment. Multiple projections were recorded for each vessel using standard orientations. Selected views

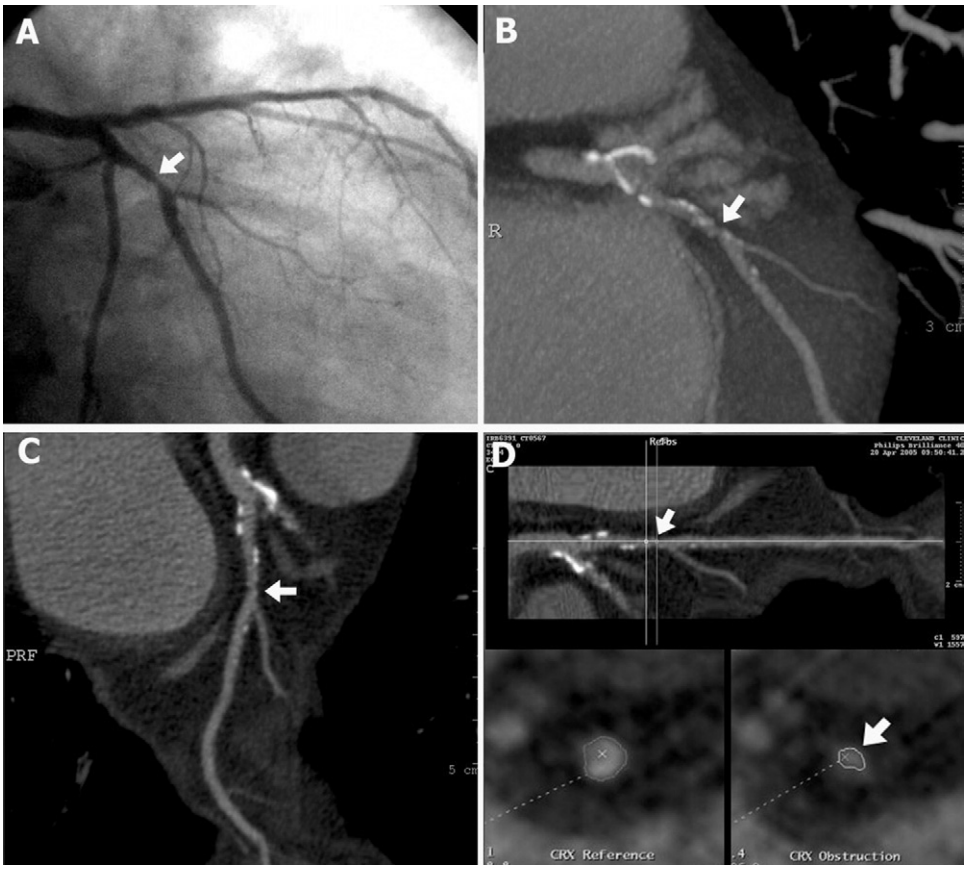

Figure 2. Study patient with moderate stenosis in the proximal left circumflex coronary artery shown on *(A)* cine fluoroscopic view, *(B)* MDCT maximum intensity projection image, *(C)* MDCT curved multiplanar reconstruction image, and *(D)* cross-sectional vessel views of a normal reference region and a stenotic lesion *(arrows)*.

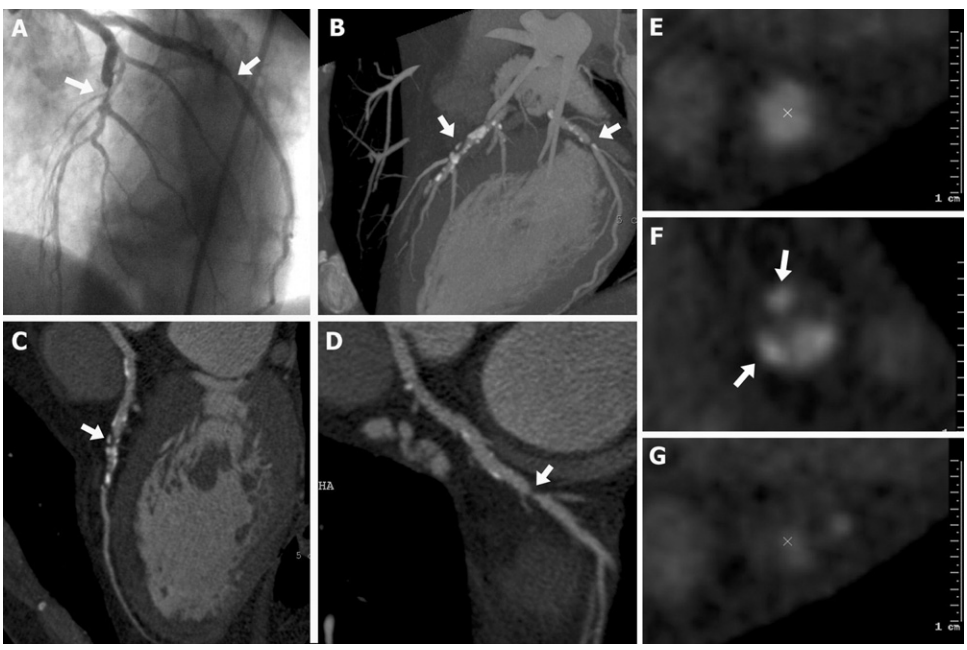

Figure 3. Study patient with severe stenoses in the proximal left anterior descending artery and proximal left circumflex artery shown on *(A)* cine fluoroscopic view, *(B)* MDCT maximum intensity projection image, MDCT curved multiplanar reconstruction images of the *(C)* left anterior descending artery and *(D)* left circumflex artery, and cross-sectional vessel views of *(E)* a normal reference region, *(F)* left anterior descending arterial stenosis with calcified components within a large mixed plaque *(arrows)*, and *(G)* left circumflex arterial stenosis (caused by noncalcified plaque).

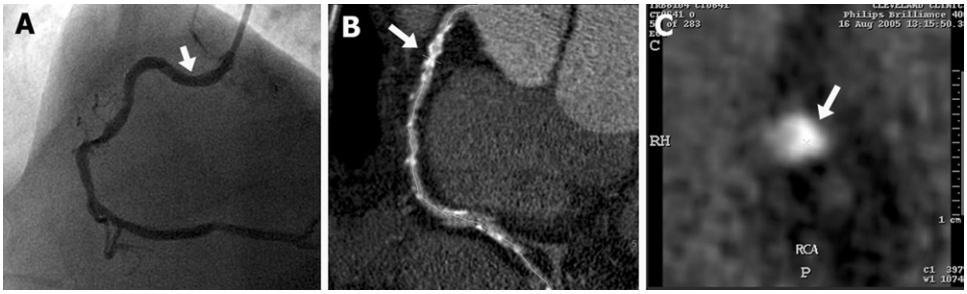

Figure 4. Study patient with mild irregularities caused by eccentric calcified plaques in the proximal right coronary artery shown on *(A)* cine fluoroscopic view (*arrows,* coronary stenosis), *(B)* MDCT curved multiplanar reconstruction image, and *(C)* cross-sectional vessel view indicating eccentric noncalcified plaque *(white area)* that appears to occupy 50% of the cross-sectional area.

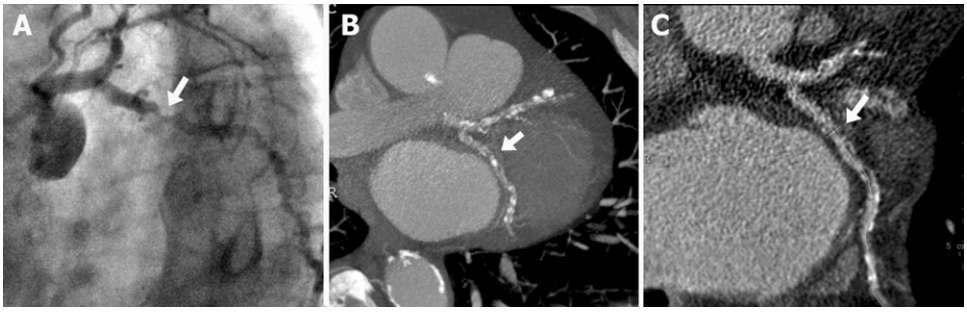

Figure 5. Study patient with severe stenosis in the proximal left circumflex coronary artery shown on *(A)* cine fluoroscopic view, *(B)* MDCT maximum intensity projection image, and *(C)* MDCT curved multiplanar reconstruction image. Multidetector computed tomography underestimated stenosis severity due to limited image quality caused by this patient's obesity, dysrhythmias, and coronary calcifications.

were acquired to optimize visualization of different coronary arterial segments. Diameters of the catheters used were documented for calibration purposes. Cine loop and still-frame images were recorded digitally and analyzed offline by investigators blinded to the MDCT images and results. Maximum percent lumen reduction was determined for each stenotic segment using standard quantitative coronary angiographic software (CAAS QCA for Research 1.3.0.0, PIE Medical Imaging, BV, Maastricht, The Netherlands).

Continuous variables are expressed as mean SD. Quantitative measurements of percent diameter stenosis determined by multidetector computed tomography and quantitative coronary angiography (QCA) were compared for each segment using Pearson's correlation and Bland-Altman plots.[21] Only those segments not contained within a coronary artery stent and with a reference diameter 1.5 mm, as defined on cine coronary angiogram, were included. Vessel segments containing multiple lesions were classified by the most severe stenosis present. True-positive and true-negative findings were defined as correct identification by multidetector computed tomography of segments with 50% and 50% stenosis, respectively. Unmatched interpretable segments were classified as false-positive or false-negative findings, with QCA as the gold standard. In addition to segment-based analysis, patient-based analysis was performed. For the purpose of patient-based analysis, a true-positive result was defined as finding 1 segment with 50% stenosis by the 2 modalities regardless of location. A true-negative finding was defined as an absence of any segment with 50% stenosis by either modality. In a secondary analysis, we also determined the segment- and patient-based accuracies of multidetector computed tomography for detecting stenosis 70%. The area under the receiver-operating characteristic curve was calculated for multidetector computed tomography to detect obstructive lesions.[22] Calculation was conducted at 50% and 70% thresholds defined by QCA.

Table 1
Multidetector computed tomographic accuracy parameters for segment-based detection of coronary stenosis

Variable	Stenosis 50% (n 1,045)	Stenosis 70% (n 1,045)
Stenoses by angiography	111	70
Stenoses by MDCT	127	77
False-positive result	32	24
False-negative result	16	17
Sensitivity	86% (79–92)	76% (66–86)
Specificity	97% (95–98)	98% (97–99)
Positive predictive value	75% (67–82)	69% (58–80)
Negative predictive value	97% (97–99)	98% (97–99)

The 95% confidence intervals are presented in parentheses.
MDCT multidetector computed tomography.

Results

There were 85 patients (59 9 years old; 85% men) enrolled in the study, with a mean body mass index of 28.8 kg/m^2 (range 20.2 to 46.7). Heart rate was 59 7 beats/min at the time of MDCT acquisition. Average estimated radiation exposure[23] for contrast-enhanced MDCT scans was

Table 2
Comparison of segment-based accuracy parameters for detection of stenosis 50% according to institution, coronary vessel, and proximal versus distal branch location

	Prevalence	Sensitivity	Specificity	PPV	NPV
Institution A	47/456	83%	96%	72%	96%
Institution B	64/589	88%	97%	77%	97%
Left main trunk	1/85	100%	99%	50%	99%
Left anterior descending coronary artery	54/357	91%	96%	79%	96%
Left circumflex/ramus coronary artery	26/302	69%	96%	62%	96%
Right coronary artery	30/301	90%	97%	79%	97%
Proximal and middle segments	60/514	93%	96%	76%	96%
Distal segments and branches	51/531	93%	94%	74%	97%

NPV negative predictive value; PPV positive predictive value.

10.8 mSv (range 5.5 to 16). There were no clinical complications associated with MDCT acquisition.

In total, 1,145 nonstented segments were available for analysis based on QCA. Of these, 100 (8.7%) were deemed nonevaluable by multidetector computed tomography due to suboptimal image quality. Most nonevaluable segments (89%) were located distally or were branch vessels. Poor vessel opacification was noted as the most common cause (63%), followed by motion artifacts (22%) and excessive calcification (15%). Four of the 22 segments that were nonevaluable due to motion artifacts were related to the occurrence of premature atrial or ventricular beats. There were 111 evaluable segments (10.6%) determined as having stenosis 50% by QCA, 95 of which were correctly identified by multidetector computed tomography. Figures 1 to 3 show representative examples of stenotic segments seen by multidetector computed tomography and QCA. There was a good correlation between MDCT and quantitative coronary angiographic measurements of percent luminal stenosis (r 0.80, p 0.001) with no significant bias (1.1%, limits of agreement 17.0 to 14.8). There were 32 false-positive lesions and 16 false-negative lesions. The most common findings associated with incorrect interpretations were lesion calcification (62%) and poor vessel opacification (32%; Figures 4 and 5). Accuracy parameters for segment-based evaluation using 50% and 70% stenosis thresholds are listed in Table 1. Areas under the receiver-operating characteristic curve for identification of segments with 50% and 70% stenosis were 0.94 (95% confidence interval 0.91 to 0.97) and 0.95 (95% confidence interval 0.92 to 0.99), respectively.

Accuracy parameters were similar for studies performed in the 2 institutions (sensitivity 83% vs 88%, specificity 96% vs 97%). Sensitivity was greater for detection of stenosis in proximal and middle segments compared with distal segments and branches (93% vs 76%). Sensitivity was lower for detection of stenosis in the circumflex coronary artery distribution (69%) compared with the left anterior descending (91%) and right coronary (90%) arteries (Table 2). The observed decrease in sensitivity for the circumflex artery correlates well with previous findings in the literature.[6,11]

There were 45 patients (53%) in the study group who had 1 included segment with 50% stenosis by QCA. Of these, 44 were correctly identified by multidetector computed tomography. Accuracy parameters for patient-based evaluation are listed in Table 3. Only 3 patients with 70% single-vessel stenoses by multidetector computed tomography were incorrectly classified at the 70% threshold. In 2 of these 3 patients, stenosis was classified as 50% but as 70% by multidetector computed tomography.

Table 3
Multidetector computed tomographic accuracy parameters for patient-based detection of coronary stenosis

	Coronary Stenosis	
	50%	70%
Stenoses by angiography	45	33
Stenoses by MDCT	47	32
False-positive result	3	3
False-negative result	1	4
Sensitivity	98% (93–100)	88% (75–100)
Specificity	93% (83–100)	94% (87–100)
Positive predictive value	94% (86–100)	91% (79–100)
Negative predictive value	93% (91–100)	94% (84–100)

All patients were included, and unevaluable segments were sanctioned as negative. The 95% confidence intervals are presented in parentheses.
Abbreviation as in Table 1.

Discussion

Our study demonstrates high sensitivity and specificity of 40-channel multidetector computed tomography for the detection of coronary stenosis. We found a smaller number of nonevaluable segments than previously reported in 16-channel MDCT studies[4–14] and numbers similar to those recently reported with 32-channel multidetector computed tomography.[15–17] Our findings indicate that a negative MDCT coronary angiographic finding has adequate discriminative power to exclude significant CAD in patients with clinically suspected CAD and who might otherwise require cine coronary angiography. This is supported by our receiver-operating characteristic analysis, which is independent of disease prevalence,[22] and by the remarkably similar accuracy parameters obtained from 2 different institutions. In our study group, if it were clinically implemented, a negative MDCT study might have avoided invasive angiography in 34 of 60 nonstented patients (57%) and missed only 1 patient with single-vessel obstructive CAD (1.1%). One must take into account that these results apply only to

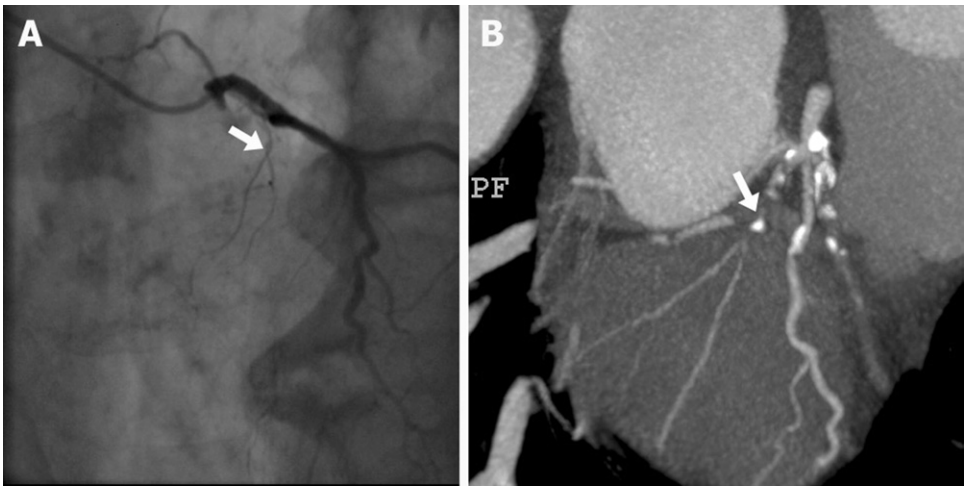

Figure 6. Study patient with occluded proximal left anterior descending artery seen on *(A)* cine fluoroscopic view and *(B)* MDCT maximum intensity projection image showing the mid and distal left anterior descending arterial segments filled by collaterals *(arrows)*.

patients with intermediate to high probability of having CAD, because referral for diagnostic angiography excludes most low-probability subjects. Accordingly, multidetector computed tomography may be best clinically implemented in those patients with intermediate or high CAD risk, in particular, those with equivocal or nondiagnostic stress test results.

An important advantage of the new generation 32-, 40-, and 64-channel MDCT systems is their greater craniocaudal coverage per rotation, which allows shorter breath-holds and thus higher contrast injection rates, smaller contrast injection volumes, and fewer artifacts related to patient breath-hold compliance and heart rate variability. Limited spatial resolution of multidetector computed tomography versus cine coronary angiography remains a challenge. Our results indicate that the accuracy for detection of coronary stenosis is lower for distal vessels and branches, probably related to the smaller caliber of these vessels. However, the 3-dimensional information inherent in multidetector computed tomography may potentially identify ostial branch lesions that are underestimated by cine coronary angiography due to vessel overlap and/or uncaptured 2-dimensional projections. In addition, multidetector computed tomography may visualize anomalous coronary arteries, which cannot be selectively engaged, and distal segments of occluded vessels that fill by collaterals (Figure 6). In the present series, 2 patients demonstrated an anomalous right coronary artery that was well visualized on multidetector computed tomography and not seen on cine angiography.

The limited temporal resolution of multidetector computed tomography may result in motion artifacts that render segments uninterpretable. One approach that increases temporal resolution uses faster gantry rotation.[15] We used a different approach based on multisegment reconstruction, which increases temporal resolution by combining data from several cardiac cycles, resulting in a variable temporal resolution of 125 to 210 ms.

Another important challenge of MDCT coronary angiography is radiation exposure, which may increase exponentially with MDCT systems using faster rotational speed. Radiation exposure was on average 1.5 to 2 times higher with multidetector computed tomography in our study than the typical radiation exposure with diagnostic catheterization (range 4 to 8 mSv). Because radiation exposure and estimated cancer risks are not negligible, the use of MDCT coronary angiography is not justified as a screening tool in low-risk, asymptomatic individuals.[24] However, use of prospective, electrocardiographically based, dose modulation techniques can be successfully used to decrease radiation exposure and, hence, broaden the appropriate indications of multidetector computed tomography.

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Michigan Heart
A Partner for *Health*.
A Partner for *Life*.

July 13, 2007

Leslie V. Norwalk, Esquire
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Baltimore, MD 21244-8015

Re: NCA Tracking Sheet for Cardiac Computed Tomographic Angiography (CAG-00385N)

Dear Ms. Norwalk:

Michigan Heart, P.C. appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Agency's analysis of Cardiac Computed Tomographic Angiography (CCTA).

Michigan Heart, P.C. represents 38 private practice cardiologists in the greater Adrian, Ann Arbor, Brighton, Canton, Jackson and Livonia areas. Our physicians are using non-invasive CCTA as a valuable tool to diagnose and treat Coronary Artery Disease (CAD) and believe CCTA provides superior analysis of the coronary arteries. Please see attached spreadsheet with details on cost savings that are incurred from the use of CCTA. You will find two sheets, "Approvals" and "Declined."

On the "Approvals" sheet, you will find 5 cases in which CCTA was approved and used appropriately. The use of CCTA instead of more invasive procedures resulted in a total savings of $6,493, or approximately $1,299 per patient.

Under the "Declined" sheet, you will see an example of 4 patients whose insurance company declined CCTA. As you can see, multiple additional tests including invasive heart catheterization are planned, leading to significantly higher cost to the insurance company and the health care system.

Our cardiologists and the patients they serve are eager to avail themselves of this potentially life-saving technology.

In 2006, all 50 states, including Michigan, adopted Local Coverage Decisions (LCD) for CCTA that include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA. **Our practice believes it is critical that CMS allow its**

current process of utilizing local experts to adopt LCDs and refrain from issuing National Coverage Decisions.

As a non-invasive procedure, CCTA costs less than the diagnostic alternative of interventional catheterization, and has improved patient diagnosis and outcomes with reduced morbidity/mortality. The accuracy and sensitivity of CCTA technology can reduce physicians' reliance on invasive catheterization to diagnose CAD, and thus may save Medicare costs associated with the more invasive procedure. This is borne out on review of the CCTA registries that several of our practices maintain. Peer reviewed abstracts and articles, utilizing these registry data points, conclude that CCTA is not an additive test and can exhibit cost savings from $489 to $1,454 per patient.

Michigan Heart, P.C. recognizes that inappropriate utilization of CT technology is a concern of the medical community, CMS, and Congress. Our physicians believe that **accreditation of CT labs, credentialing of physicians, and utilization of the published appropriateness criteria would significantly reduce the potential for inappropriate use of CCTA** and support these endeavors. It is important to note the leading position of the cardiology specialty clinical and credentialing organizations, such as the American College of Cardiology, SCCT, ASNC, SCAI and the Intersocietal Accreditation Commission, which have completed clinical guidelines, physician credentialing criteria, and lab accreditation processes specific to CCTA. We encourage Medicare to continue looking to them for assistance.

In summary, Michigan Heart, P.C. requests that CMS:

1. Support the continued use of the states' Local Coverage Decisions on CCTA.
2. Use professionally accepted credentialing and appropriateness guidelines for CCTA, including those set forth by the American College of Cardiology. This will standardize appropriateness criteria and discourage inappropriate use of CCTA.
3. Support the model LCD proposed by the American College of Cardiology or the current National Government Services' LCD, which in particular identify clinically appropriate indications and diagnoses while addressing appropriate technical requirements.

Thank you for the opportunity to comment on the CCTA National Coverage Analysis. Please contact Tauqir Goraya, M.D., Ph.D at tgoraya@michiganheart.com for more information.

Sincerely,

Tauqir Goraya, M.D., Ph.D
Steven Girard, M.D., Ph.D
Benjamin D. McCallister Jr., M.D.
Barbara A. Kong, M.D.

Case #	Description	CV Risk Factors	Prior Stress Test	Clinical Decision by Primary Cardiologist	CCTA Date / Result	Subsequent Health Care Utilization for Chest Pain	ACCF/ACR/SCCT/ASNC Appropriateness Criteria Category	Cost Savings vs (Additional Cost) for CCTA vs Direct Invasive Cath
1	CG a 61 year old female with atypical chest pain	HTN Dyslipidemia Obesity	Equivocally abnormal Exercise Myocardial Perfusion Imaging (MPI) test with apical ischemia.	Invasive cardiac Cath versus Coronary CTA (CCTA)	12.15.2005 / No significant CAD	None	Appropriate	$2,681.00
2	RR a 62 year old male with atypical chest pain	DM HTN Dyslipidemia FH Prior tobacco use Obesity	Exercise MPI discordant data - positive EKG but negative MPI	Invasive Cath versus CCTA	3.17.2005 / Mild soft plaque. No significant stenosis. Intramyocardial LAD	None	Appropriate	$2,681
3	RO a 58 year old male with atypical chest pain	DM HTN Dyslipidemia FH	Small apical ischemia	Invasive Cath vs CCTA	8.16.2005 / Moderate non-obstructive disease in LAD on CCTA, RCA could not be seen	LHC 12.12.05 - obstructive LAD and RCA disease > Medical Mgmt	Appropriate	($775)
4	JZ a 40 year old male with typical	Dyslipidemia FH	1.23.04 - Negative - no	Discordant data: high	3.15.2005 / Severe mid-	LHC 3.18.05: severe mid-	Appropriate	($775)

	angina at high workload	Prior tobacco use	ischemia	clinical suspician with normal MPI at high workload. Invasive cath vs CCTA	LAD stenosis	LAD > stent deployed. No further testing since then.		
5	CH a 58 year old female with atypical chest pain and significant use of long and short acting nitrates	HTN Dyslipidemia FH	7.21.04 - Normal MPI	Invasive Cath vs CCTA	10.13.2005 / Normal	None	Appropriate	$2,681

NET SAVING vs (ADDITIONAL COST): $6,493

Case #	Description	CV Risk Factors	Prior Stress Test	Clinical Decision by Primary Cardiologist	CCTA Result	Subsequent Health Care Utilization for Chest Pain	ACCF/ACR/SCCT/ASNC Appropriateness Criteria Category
1	BS a 52 year old male with longstanding history of atypical chest pain	Dyslipidemia	All Normal: Exercise MPI 5/17/02 Exercise echo 4.25.04 Exercise MPI 2.8.05	CCTA (preferred) vs Invasive Cath	HAP Declined	Invasive Cath planned	Appropriate
2	BW a 63 year old female with atypical chest pain	Known CAD S/P CABG HTN Dyslipidemia	None recently	CCTA vs Exercise MPI	HAP Declined	1) Exercise MPI done - equivocally abnormal. 2) Invasive cath offered - pt declined. 3) Now stress echo scheduled	Appropriate

3	RW a 54 year old male with atypical chest pain	Former tobacco HTN Dyslipidemia	Abnormal exercise MPI - equivocally abnormal	Invasive Cath vs CCTA	HAP Declined	Invasive Cath scheduled	Appropriate
4	KB a 47 year old female	New CHF with new dx of Cardiomyopathy	None	Invasive Cath vs CCTA to R/O CAD	HAP Declined	Decision pending	Appropriate

Illinois
HEART AND
VASCULAR
Formerly West Suburban Cardiologists

July 13, 2007

G. William Cotts, M.D.
Raymond J. Rapacz, M.D.
Patrick K. Quirke, M.D.
Paul A. Freier, M.D.
Jerome L. Hines, M.D.
Gregory M. Lewis, M.D.
Karen L. Lambert, M.D.
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Frank S. Saltiel, M.D.
Peter S. Diamond, M.D.
Daniel E. Krauss, M.D.
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Thomas N. Levin, M.D.
Ian D. Cohen, M.D.
Laura E. Gonzalez, M.D.
G. Gary Gibbs, M.D.
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Re: NCA Tracking Sheet for Cardiac Computed Tomographic Angiography (CAG-00385N)

Dear Ms. Norwalk:

Illinois Heart and Vascular appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Agency's analysis of Cardiac Computed Tomographic Angiography (CCTA).

Illinois Heart and Vascular represents 27 private practice cardiologists in the greater Chicago area. Our physicians are using non-invasive CCTA as an integral tool to diagnose and treat Coronary Artery Disease (CAD) and believe CCTA provides superior analysis of the coronary arteries. Our 2 data analysis and review clearly shows that CCTA is not an additive test and in fact has resulted in a 9.9% decrease in cardiac catheterizations, 0.7% decrease in overall stress nuclear tests, an increase in cardiac cath to intervention ratio, and a decrease in normal cath rates. Several peer-reviewed studies support this finding and cardiologists and the patients they serve are eager to avail themselves of this potentially life-saving technology.

In 2006, all 50 states, including Illinois have adopted Local Coverage Decisions (LCD) for CCTA that include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA. **Our practice believes it is critical that CMS allow its current process of utilizing local experts to adopt LCDs and refrain from issuing National Coverage Decisions.**

As a non-invasive procedure, CCTA costs less than the diagnostic alternative of interventional catheterization, and has improved patient diagnosis and outcomes with reduced morbidity/mortality. The accuracy and sensitivity of CCTA technology can reduce physicians'

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Medicare costs associated with the more invasive procedure. This is borne out on review of the CCTA registries that our practices maintain, as do others. Peer reviewed abstracts and articles, utilizing these registry data points, conclude that CCTA is not an additive test and can exhibit cost savings from $489 to $1,454 per patient. Our data, using similar methodologies exhibits a cost savings of $1,348 per patient.

Illinois Heart and Vascular recognizes that inappropriate utilization of CT technology is a concern of the medical community, CMS, and Congress. Our physicians believe that **accreditation of CT labs, credentialing of physicians, and utilization of the published appropriateness criteria would significantly reduce the potential for inappropriate use of CCTA** and support these endeavors. Our physicians are Level 3 trained and verified by SCCT, we are in the process of accrediting our lab, and are committed to following the Appropriateness Criteria published by ACCF.

It is important to note the leading position of the cardiology specialty clinical and credentialing organizations, such as the American College of Cardiology, SCCT, ASNC, SCAI and the Intersocietal Accreditation Commission, which have completed clinical guidelines, physician credentialing criteria, and lab accreditation processes specific to CCTA. We encourage Medicare to continue looking to them for assistance.

In summary, Illinois Heart and Vascular requests that CMS:

1. Support the continued use of the states' Local Coverage Decisions on CCTA, including ours under WPS and Administar.
2. Use professionally accepted credentialing and appropriateness guidelines for CCTA, including those set forth by the American College of Cardiology. This will standardize appropriateness criteria and discourage inappropriate use of CCTA.
3. Support the model LCD proposed by the American College of Cardiology or the current National Government Services' LCD, which in particular identify clinically appropriate indications and diagnoses while addressing appropriate technical requirements.

Thank you for the opportunity to comment on the CCTA National Coverage Analysis. Please contact Dr. Jerome Hines at jhines@illinoisheart.com or Cathleen Biga cbiga@cardiacmgmt.com for more information (or 630-972-6220).

Sincerely,

Jerome L. Hines, M.D. President
Illinois Heart & Vascular

Cathleen Biga, President, CEO
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BATON ROUGE CARDIOLOGY CENTER

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Re: NCA Tracking Sheet for Cardiac Computed Tomographic Angiography (CAG-00385N)

Dear Ms. Norwalk:

Baton Rouge Cardiology Center appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Agency's analysis of Cardiac Computed Tomographic Angiography (CCTA).

Baton Rouge Cardiology Center represents 11 private practice cardiologists in the greater Baton Rouge area. Our physicians are using non-invasive CCTA as a valuable tool to diagnose and treat Coronary Artery Disease (CAD) and believe CCTA provides superior analysis of the coronary arteries. Several peer-reviewed studies support this finding and cardiologists and the patients they serve are eager to avail themselves of this potentially life-saving technology.

In 2006, all 50 states, including Louisiana, adopted Local Coverage Decisions (LCD) for CCTA that include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA. Our practice believes it is critical that CMS allow its current process of utilizing local experts to adopt LCDs and refrain from issuing National Coverage Decisions.

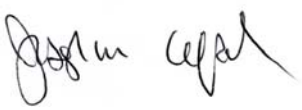
As a non-invasive procedure, CCTA costs less than the diagnostic alternative of interventional catheterization, and has improved patient diagnosis and outcomes with reduced morbidity/mortality. The accuracy and sensitivity of CCTA technology can reduce physicians' reliance on invasive catheterization to diagnose CAD, and thus may save Medicare costs associated with the more invasive procedure. This is borne out on review of the CCTA registries that several of our practices maintain. Peer reviewed abstracts and articles, utilizing these registry data points, conclude that CCTA is not an additive test and can exhibit cost savings from $489 to $1,454 per patient.

Baton Rouge Cardiology Center recognizes that inappropriate utilization of CT technology is a concern of the medical community, CMS, and Congress. Our physicians believe that **accreditation of CT labs, credentialing of physicians, and utilization of the published appropriateness criteria would significantly reduce the potential for inappropriate use of CCTA and support these endeavors.**

It is important to note the leading position of the cardiology specialty clinical and credentialing organizations, such as the American College of Cardiology, SCCT, ASNC, SCAI and the Intersocietal Accreditation Commission, which have completed clinical guidelines, physician credentialing criteria, and lab accreditation processes specific to CCTA. We encourage Medicare to continue looking to them for assistance.
In summary, Baton Rouge Cardiology Center requests that CMS:
1.Support the continued use of the states' Local Coverage Decisions on CCTA.
2.Use professionally accepted credentialing and appropriateness guidelines for CCTA, including those set forth by the American College of Cardiology. This will standardize appropriateness criteria and discourage inappropriate use of CCTA.
3.Support the model LCD proposed by the American College of Cardiology or the current National Government Services' LCD, which in particular identify clinically appropriate indications and diagnoses while addressing appropriate technical requirements.

Thank you for the opportunity to comment on the CCTA National Coverage Analysis. Please contact Martin "Bubby" Fischer at BubbyF@aol.com or (225) 769-0933 for more information.

Sincerely,



Joseph Cefalu, M.D., F.A.C.C.

Dear Ms. Baldwin,

There is nothing wrong with proceeding slowly on covering CTA of the coronary vessels. Coronary CTA may not yet warrant coverage, as it has not been proven effective. And though it likely is efficacious, approving reimbursement before the data is obtained will probably ensure that the data is not obtained. New and unproven procedures and imaging methods are often reimbursed quite well, to such an extent that practitioners tend to adopt them without adequate demonstration of superiority to established methods.

Much of the imaging and many of the expensive devices and techniques used in medicine today are unproven. Stents are routinely placed in iliac arteries, when there is no evidence of an advantage over primary balloon angioplasty alone (despite much greater cost)(1). Lasers, cutting balloons, and covered stents are used for the recanalization of superficial femoral arteries without evidence of advantage, and at great cost. Pass through of the costs of devices, and premium physician reimbursements for these procedures encourage their use. This is an unwise public policy for the unproven use of a device and particularly unneccessary in areas where there are ongoing turf battles to perform these procedures (between Cardiology, Vascular Surgery, and Interventional Radiology).

CMS should not reimburse for the use of devices that are not proven (in randomized prospective trials) to be superior to existant methods (ie, balloon angioplasty, medical therapy, or open surgical repair); further, the reimbursement should not be greater than for existant methods unless there is good evidence that the benefit (ie, decreased complication rate, increased QALYs) warrants through a decreased overall cost. The odd premium placed on procedures (versus an office visit and medical management) is a great disincentive to rational care. We will be paid thousands for the hour involved in placing a stent, while hours of office time managing an exercise program or medical regimen are paid a hundred. Even though the outcomes may be the same (2).

New procedures should only be reimbursed insofar as they are performed as part of large randomized trials that will provide efficacy and cost-benefit data. Cardiology has often done this, through control of a very large patient base. For many other procedures, single center populations are often inadequate. CMS has the opportunity to direct the rational, cost-effective application of new technology through its control of reimbursement.

Coronary CTA should be vetted through a CMS directed research plan. Most carotid stent placement is currently performed under some industry sponsored trial to win reimbursement. CMS could dictate the structure of a coronary CTA trial, to obtain the cost-benefit data needed. Control of the funding wins you great attention.

Sincerely, .

-- rick

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1. Klein WM, van der Graaf Y, Seegers J, Spithoven JH, Buskens E, van Baal JG, Buth J, Moll FL, Overtoom TT, van Sambeek MR, Mali WP. Dutch iliac stent trial: long-term results in patients randomized for primary or selective stent placement. Radiology. 2006 Feb;238(2):734-44.

2. Fowkes FG, Gillespie IN. Angioplasty (versus non surgical management) for intermittent claudication. Cochrane Database Syst Rev . 2000;(2):CD000017.

Cardiovascular Computed Tomography and A Positive-Sum Strategy in Cardiovascular Medicine

Recently the practice and politics of medicine have demonstrated a tendency towards a zero-sum strategy, one that is not focused on optimizing value and outcomes for our patients. Rather many of the cast members in healthcare (patients, doctors, hospitals, payors, employers, etc.) have a suspicious perception regarding the archetypal role each has in the growing healthcare crisis. Doctors perceive payors as gatekeepers that interfere with medical decision making by restricting care through the development of radiology management programs and prior authorization protocols. Their motivation is perceived to be the maximization of profit and salaries to their shareholders and management respectively. Hospitals perceive doctors to be shifting a growing amount of services to out-patient imaging facilities in which they may have a financial interest. Cardiologists perceive radiologists as individuals interested in protecting their turf by restricting clinical privileges in hospitals while giving the false impression of clinical superiority in image interpretation of cardiovascular pathophysiology. Government perceives new improvements in cardiovascular imaging as a potential contributor to increasing healthcare expenditures.

It is my belief that this zero-sum strategy in healthcare has created an inherently ineffective and self-defeating environment. In this environment healthcare costs remain high while quality of care remains suboptimal and sometimes low. Preventable conditions remain undetected until they become fully manifested and more costly to care for. Diagnostic tests are performed to allay fears of potential lawsuits rather than supplement clinical reasoning. Quality healthcare is rationed to those who can afford it, while the uninsured create an incentive to escalate charges so that costs can be recouped.

American medicine is at a flashpoint. Despite the dramatic advancements made in our field, cardiovascular disease remains a growing epidemic. More Americans will die from

cardiovascular disease than the next five causes of death combined. The war against this epidemic is waged through skirmishes in the catheterization lab and operating room, rather than through early detection and initiation of preventative therapies and lifestyle changes. It is within this environment that cardiovascular CT struggles to realize its potential as a cost-effective diagnostic tool. In order to realize its full potential, a positive-sum strategy will be required. Patients, providers, payors, and policy makers will need to cooperate and focus on optimizing healthcare outcomes for Americans.

Using the SHAPE Guidelines and calcium scoring CT, our group plans on transforming the cardiovascular care of our patients. We are taking a proactive rather than a reactive approach towards the identification of vulnerable patients. Our belief, supported by considerable published clinical evidence, will allow us to focus care on those who most require an aggressive therapeutic approach early in the timeline of their illness. If implemented on a national scale, this paradigm shift in care will result in an annual savings of $21.5 billion.

Current triage strategies within our hospitals for patients presenting with chest pain are highly inefficient. Annually more than 5 million Americans present to their local emergency rooms for the evaluation of acute chest pain. Current prediction algorithms used to estimate risk of acute coronary syndrome (ACS) are overshadowed by liability risks faced by the triaging physician for a missed diagnosis. Missed ACS occurs in 2% of patients and is associated with a twofold increased risk of mortality for the patient. This failure of diagnosis contributes to 20% of emergency room malpractice costs for physicians. As a consequence more than 3 million Americans are hospitalized annually from the emergency room for further evaluation. Most patients are never seen by cardiovascular specialists and are discharged without confirmed ACS. SPECT studies are commonly ordered by the inpatient physician on patients with negative serologic markers for ACS. Though capable of identifying flow-limiting stenosis (>70% luminal narrowing), perfusion studies fail to identify lesions less than 60% which cause more than two-thirds of most heart attacks. Patients with normal SPECT scans have a good prognosis, but leave the hospital without a clear understanding of the cause of their chest pain or a strategy to mitigate future risk. Although more sensitive and specific, invasive angiograms have their own limitations. In patients with ACS, invasive angiography identifies non-obstructive disease in 10-15% of patients which can be medically managed without an interventional approach. Another 5-10% of ACS patients have normal coronary angiograms. A growing number of studies have emerged demonstrating the cost-effectiveness of a strategy of using cardiovascular CT to optimize triage of patients presenting for the evaluation of acute chest pain. Such a strategy would save on length of stay, prioritize invasive care to those who require interventions, and identify vulnerable patients that would have been missed by other diagnostic strategies.

Our efficiency of evaluating chest pain in the outpatient setting is similarly limited. Cardiologists have been accused of contributing to the large rise in out-patient imaging. In truth, a substantial number of studies are ordered by primary care physicians without the counsel of specialists. Often a stress test with some form of imaging as well as an echocardiogram is ordered. Furthermore many diagnostic tests are ordered for symptoms other than chest pain: shortness of breath, palpitations, dizziness, chest wall pain, arm or shoulder pain, or syncope. Other indications which contribute to inappropriate imaging include: preoperative risk assessment prior to low risk surgery, part of a routine physical to impress patients that their

physician is being thorough, routine follow-up of patients with known coronary artery disease in the absence of symptoms, and many others that are even more tangential to the purpose for which testing is ideally suited. One would hope that the establishment of guideline documents would rectify the current state of affairs. Such guidelines, though well-constructed and evidence-based, are created by specialty organizations and are often not well adopted by community-based general practitioners. Specialists and hospitals who perform, supervise, or interpret many of these diagnostic tests rarely educate their referring physicians about appropriateness criteria due to fear of losing future referrals. Artifacts and abnormal findings on inappropriately ordered tests trigger additional testing and utilization that often does not contribute to a reduction in cardiovascular events. Our group, comprised of both specialists and primary care physicians, has developed a clinical algorithm in which cardiovascular CT, due to its very high negative predictive value, is used as an appropriate substitute for less sensitive and specific tests which were previously utilized. Such a strategy efficiently categorizes cardiovascular risk of our patients without the need for additional testing. The current reimbursement constructs in today's marketplace do not appropriately incentivize this model of care. Our aim is to more efficiently use noninvasive testing to selectively triage patients to an invasive approach only if an intervention is required. Currently 30% of angiograms performed in our country are normal. Additionally, a sizable percentage identifies disease which does not require an interventional approach to management.

CT angiography has numerous non-coronary applications. Peripheral and cerebrovascular arterial disease is beautifully represented by this technique and placed in context to its three-dimensional relationship to other vascular and non-vascular structures. It allows treatment strategies to be planned prior to catheter or surgical based interventions. Such planning increases both the safety and effectiveness of such procedures for patients. Electrophysiologic procedures such as the ablation of atrial fibrillation or ventricular tachycardia rely on an understanding of cardiac anatomy that is provided by multidetector CT. Cardiovascular CT is a unique tool to assess complex congenital heart disease, either in its native state or after surgical correction. CT also assists in the evaluation of patients with newly recognized cardiomyopathies, thereby avoiding invasive angiography. This technique also avoids invasive evaluation of young patients with valvular heart disease requiring surgery. Previously such patients routinely undergo coronary angiography prior to surgery. Cardiovascular CT continues to evolve and mature, and our approach to its use similarly continues to evolve. Although it is a relatively new addition to our diagnostic armamentarium, cardiovascular CT has matured to a level that justifies its current use and adoption by payors and policy makers.

I would urge CMS to join cardiovascular providers in a positive-sum strategy to strengthen the health of our patients and our economy. We must all continue to work together in our battle against cardiovascular disease. Old paradigms of care have proven to be ineffective, and new paradigms should not meet with unnecessary skepticism. National screening programs should be developed to identify cardiovascular disease early. Early prevention and treatment would optimally allocate health care dollars to augment the cardiovascular health of our citizens. Appropriateness criteria can be used as guidelines for use, while research and patient outcomes continue to add to our already substantial knowledgebase. Payors can monitor clinical practice patterns and incentivize cost-saving strategies. Hospitals should bring together the various clinical specialties that are now required to develop a multidisciplinary approach to

cardiovascular medicine. In such a collaborative environment all would benefit. Such a positive-sum strategy would embolden our commitment to reduce cardiovascular morbidity and mortality in America and bring vigor to our continued battle against this growing epidemic.

Tushar N. Shah, MD, FACC
Kettering, Ohio

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July 12, 2007

JoAnna Baldwin, MS

Lead Analyst

National Coverage Analysis for Coronary CTA

CMS

joanna.baldwin@cms.hhs.gov

Dear Ms. Baldwin:

We are writing to you as the steering committee of the MAGIC (Multicenter Assessment of AnGiographic Imaging by CT) study, a planned multicenter registry of coronary CTA. We have recently read with great interest about CMS's plans for a national coverage analysis of CTA. In view of the rapid developments occurring with this modality, the steering committee of the MAGIC study is in complete support of CMS's goals. To date, an increasing number of studies have established that CTA has high diagnostic accuracy for stenosis detection when compared to invasive angiography. However, given the large population potentially eligible for coronary CTA and thus major implications for payers, there is substantial interest to evaluate the clinical performance of CTA.

Randomized controlled trials and registries will play complementary roles in the assessment of this novel technology. While randomized trials will allow for a direct comparison of CTA to the current standard of care, registries will assess the impact of CTA on patient management when adopted as part of routine clinical practice. The MAGIC registry was initiated by academically based physicians and is a broad-

based data collection effort to correlate results of CT angiography and long-term clinical outcomes. The registry is in the advanced stages of development and the protocol, case-report forms and identification of participating hospitals has already been completed. The registry is supported by GE Health Care and additional industry support may be sought in the future. However, the study design, conduct and analysis are performed independently by McMaster University under the supervision of the study steering committee. Data will be collected on pre-CTA clinical risk assessment and stress testing (where applicable), CTA imaging findings, and post-CTA management. The incremental impact of CTA on prognostic assessment, and downstream diagnostic and therapeutic interventions will be evaluated.

The principle strengths of the registry include:
(1) long-term prospective follow-up after CTA imaging with patients evaluated for clinical outcomes, invasive angiography, revascularization, and further non-invasive testing out to 2 years after the index CTA study
(2) multicenter and multivendor design including representation of academic and private practice environments
(3) assessment of CTA within the appropriateness criteria framework with CT studies classified and evaluated by the proposed appropriateness level of the indication
(4) central blinded adjudication of outcome events
(5) real-life image quality, image interpretation and case mix
(6) study leadership from cardiology and radiology from institutions with an established reputation for excellence in cardiovascular outcomes studies and imaging research

A protocol synopsis is appended to this letter. Our team has been developing this registry over the past 12 months. The study will begin enrolling patients in October 2007, with an initial target sample size of 1100 patients. We believe this registry will contribute valuable data to the outcomes based evaluation of CTA. It may be complementary to other potential registries that could be developed as a consequence of a national coverage decision with evidence development by CMS. We are particularly sensitive to the fact that a potential initiative by CMS, independent of other on-going studies, may have consequences for recruitment into our registry. Since we have common goals in mind, the steering committee of MAGIC would be open to working with CMS to standardize data collection and outcome reporting to maximize the synergy of these efforts. We would be happy to discuss this potential collaboration with you at your convenience.

We look forward to your reply.

Yours sincerely,

MAGIC Steering Committee


Tej Sheth, MD
McMaster University


Pamela Douglas, MD
Duke University


Udo Hoffmann, MD
Massachusetts General Hospital


James Jollis, MD
Duke University


Shamir Mehta, MD
McMaster University


Manesh Patel, MD
Duke University

Madhu Natarajan, MD
McMaster University

July 13, 2007

Leslie V. Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

Re: NCA Tracking Sheet for Cardiac Computed Tomographic Angiography (CAG-00385N)

Dear Ms. Norwalk:

Cardiovascular Medicine P.C. (CVM) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Agency's analysis of Cardiac Computed Tomographic Angiography (CCTA).

CVM represents 28 private practice cardiologists in eastern Iowa and western Illinois. Our physicians are using non-invasive CCTA as a valuable tool to diagnose and treat Coronary Artery Disease (CAD) and believe CCTA provides superior analysis of the coronary arteries. Several peer-reviewed studies support this finding and cardiologists

and the patients they serve are eager to avail themselves of this potentially life-saving technology.

In 2006, all 50 states, including Iowa and Illinois, adopted Local Coverage Decisions (LCD) for CCTA that include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA. **Our practice believes it is critical that CMS allow its current process of utilizing local experts to adopt LCDs and refrain from issuing National Coverage Decisions.**

As a non-invasive procedure, CCTA costs less than the diagnostic alternative of interventional catheterization, and has improved patient diagnosis and outcomes with reduced morbidity/mortality. The accuracy and sensitivity of CCTA technology can reduce physicians' reliance on invasive catheterization to diagnose CAD, and thus may save Medicare costs associated with the more invasive procedure. This is borne out on review of the CCTA registries that several of our practices maintain. Peer reviewed abstracts and articles, utilizing these registry data points, conclude that CCTA is not an additive test and can exhibit cost savings from $489 to $1,454 per patient.

CVM recognizes that inappropriate utilization of CT technology is a concern of the medical community, CMS, and Congress. Our physicians believe that accreditation of CT labs, credentialing of physicians, and utilization of the published appropriateness criteria would significantly reduce the potential for inappropriate use of CCTA. It is important to note the leading position of the cardiology specialty clinical and credentialing organizations, such as the American College of Cardiology, SCCT, ASNC, SCAI and the Intersocietal Accreditation Commission, which have completed clinical guidelines, physician credentialing criteria, and lab accreditation processes specific to CCTA. We encourage Medicare to continue looking to them for assistance.

In summary, CVM requests that CMS:

1. Support the continued use of the states' Local Coverage Decisions on CCTA.
2. Use professionally accepted credentialing and appropriateness guidelines for CCTA, including those set forth by the American College of Cardiology. This will standardize appropriateness criteria and discourage inappropriate use of CCTA.
3. Support the model LCD proposed by the American College of Cardiology or the current National Government Services' LCD, which in particular identify clinically appropriate indications and diagnoses while addressing appropriate technical requirements.

Thank you for the opportunity to comment on the CCTA National Coverage Analysis. Please contact William Hauber at hauber@cvmedpc.com or (563) 324-2992 for more information.

Sincerely,

Edmund P. Coyne, MD
President

HEARTCARE MIDWEST

Dedicated to excellence in cardiovascular health

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July 13, 2007

Leslie V. Norwalk, Esquire
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P.O. Box 8015
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Re: NCA Tracking Sheet for Cardiac Computed Tomographic Angiography (CAG-00385N)

Dear Ms. Norwalk:

HeartCare Midwest, S.C. appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Agency's analysis of Cardiac Computed Tomographic Angiography (CCTA).

HeartCare Midwest represents 30 private practice cardiologists in the Central Illinois area. Our physicians are using non-invasive CCTA as a valuable tool to diagnose and treat Coronary Artery Disease (CAD) and believe CCTA provides superior analysis of the coronary arteries. Our analysis of the first one hundred cases showed a net saving of 65 cardiac catheterizations. Several peer-reviewed studies support this finding and cardiologists and the patients they serve are eager to avail themselves of this potentially life-saving technology.

In 2006, all 50 states, including Illinois, adopted Local Coverage Decisions (LCD) for CCTA that include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA. **Our practice believes it is critical that CMS allow its current process of utilizing local experts to adopt LCDs and refrain from issuing National Coverage Decisions.**

As a non-invasive procedure, CCTA costs less than the diagnostic alternative of interventional catheterization, and has improved patient diagnosis and outcomes with reduced morbidity/mortality. The accuracy and sensitivity of CCTA technology can reduce physicians' reliance on invasive catheterization to diagnose CAD, and thus may save Medicare costs associated with the more invasive procedure. This is borne out on review of the CCTA registries that

several of our practices maintain. Peer reviewed abstracts and articles, utilizing these registry data points, conclude that CCTA is not an additive test and can exhibit cost savings from $489 to $1,454 per patient.

HeartCare Midwest recognizes that inappropriate utilization of CT technology is a concern of the medical community, CMS, and Congress. Our physicians believe that **accreditation of CT labs, credentialing of physicians, and utilization of the published appropriateness criteria would significantly reduce the potential for inappropriate use of CCTA** and support these endeavors. It is important to note the leading position of the cardiology specialty clinical and credentialing organizations, such as the American College of Cardiology, SCCT, ASNC, SCAI and the Intersocietal Accreditation Commission, which have completed clinical guidelines, physician credentialing criteria, and lab accreditation processes specific to CCTA. We encourage Medicare to continue looking to them for assistance.

In summary, HeartCare Midwest requests that CMS:

1. Support the continued use of the states' Local Coverage Decisions on CCTA.
2. Use professionally accepted credentialing and appropriateness guidelines for CCTA, including those set forth by the American College of Cardiology. This will standardize appropriateness criteria and discourage inappropriate use of CCTA.
3. Support the model LCD proposed by the American College of Cardiology or the current National Government Services' LCD, which in particular identify clinically appropriate indications and diagnoses while addressing appropriate technical requirements.

Thank you for the opportunity to comment on the CCTA National Coverage Analysis. Please contact Jeffrey Shelton, CEO at jws@heartcaremw.com or 309-589-6501 for more information.

Sincerely,

Donald McElroy, M.D.
President

M. Fayaz Malik, M.D.
Director, Cardiac CT

Jeffrey Shelton
CEO

Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

Re: NCA Tracking Sheet for Cardiac Computed Tomographic Angiography (CAG-00385N)

Dear Ms. Norwalk

The Cardiology Group, P.A. appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Agency's analysis of Cardiac Computed Tomographic Angiography (CCTA).

The Cardiology Group, P.A. represents sixteen private practice cardiologists in the greater Southern New Jersey area. Our physicians are using non-invasive CCTA as a valuable tool to diagnose and treat Coronary Artery Disease (CAD) and believe CCTA provides superior analysis of the coronary arteries. Our experience is that CCTA reduces the number of invasive coronary catheterization procedures, lower overall healthcare costs, patient convenience, etc. As you know, several peer-reviewed studies support this finding and cardiologists and the patients they serve are eager to avail themselves of this potentially life-saving technology.

In 2006, all 50 states, including New Jersey, adopted Local Coverage Decisions (LCD) for CCTA that include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA. **Our practice believes it is critical that CMS allow its current process of utilizing local experts to adopt LCDs and refrain from issuing National Coverage Decisions.**

As a non-invasive procedure, CCTA costs less than the diagnostic alternative of interventional catheterization, and has improved patient diagnosis and outcomes with reduced morbidity/mortality. The accuracy and sensitivity of CCTA technology can reduce physicians' reliance on invasive catheterization to diagnose CAD, and thus may save Medicare costs associated with the more invasive procedure. This is borne out on review of the CCTA registries that several of our practices maintain. Peer reviewed abstracts and articles, utilizing these registry data points, conclude that CCTA is not an additive test and can exhibit cost savings from $489 to $1,454 per patient.

The Cardiology Group, P.A. recognizes that inappropriate utilization of CT technology is a concern of the medical community, CMS, and Congress. Our physicians believe that **accreditation of CT labs, credentialing of physicians, and utilization of the published appropriateness criteria would significantly reduce the potential for inappropriate use of CCTA** and support these endeavors. It is important to note the

leading position of the cardiology specialty clinical and credentialing organizations, such as the American College of Cardiology, SCCT, ASNC, SCAI and the Intersocietal Accreditation Commission, which have completed clinical guidelines, physician credentialing criteria, and lab accreditation processes specific to CCTA. We encourage Medicare to continue looking to them for assistance.

In summary, The Cardiology Group, P.A. requests that CMS:

4. Support the continued use of the states' Local Coverage Decisions on CCTA.
5. Use professionally accepted credentialing and appropriateness guidelines for CCTA, including those set forth by the American College of Cardiology. This will standardize appropriateness criteria and discourage inappropriate use of CCTA.
6. Support the model LCD proposed by the American College of Cardiology or the current National Government Services' LCD, which in particular identify clinically appropriate indications and diagnoses while addressing appropriate technical requirements.

Thank you for the opportunity to comment on the CCTA National Coverage Analysis. Please contact Thomas M. Galski, D.O., F.A.C.C. at *thomas.gmd@comcast.net* or 856-234-3332 for more information.

Sincerely,

Thomas M. Galski, D.O., F.A.C.C.
Heart Center
2051 Briggs Road
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July 13, 2007

Joseph Chin, M.D.,
JoAnna Baldwin, M.S.
Coverage and Analysis Group, CMS
7500 Security Blvd. (Mailstop C1-09-06)
Baltimore, MD 21244

Re: NCA for Computer Tomographic Angiography (CAG-00385N)

Dear Dr. Chin and Ms. Baldwin:

I am writing on behalf of Siemens Medical Solutions USA with respect to your internally-generated review of Coronary CT Angiography (CCTA). Siemens Medical Solutions is a manufacturer of advanced cardiac CT scanners. You have asked for comments on whether or not a national coverage determination on this technology is warranted at this time.

Clinicians treating Medicare beneficiaries throughout the country have identified CCTA as a promising technology that provides an extraordinary diagnostic ability to accurately and precisely diagnose coronary artery disease. Coronary artery disease is the leading killer of CMS beneficiaries and in fact all Americans. The most recent American Heart Association data shows 871,517 Americans were killed by cardiovascular disease in 2004 and that approximately 325,000 of these patients died suddenly.[1] Experts believe that the majority of these patient deaths had, as an underlying cause, treatable coronary artery disease.

As you know, the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) examined the literature surrounding this imaging technology in May of last year. As a result of the MedCAC review, CMS decided to continue to permit local contractors to make their own local coverage determinations on CCTA. Over the past year, varying local policies have been put into place, and many Medicare beneficiaries have had the benefit of this technology. Simultaneously, extensive data to document the clinical value of CCTA to Medicare beneficiaries continues to be collected.

We know of no studies that call into question the generally favorable views that were expressed by MedCAC on CCTA. The evidence remains quite promising for this technology, and local coverage has increased our knowledge base about the opportunities for its proper use. There is strong reason to believe that the potential overall costs of CCTA and treatment guided by a precise coronary diagnosis will compare very favorably to the sum of the current costs associated with diagnostic cardiac catheterization, for "after the event" medical care for heart attacks and congestive heart failure, as well as for the empiric treatment for patients with presumed coronary artery disease who don't actually have the disease.

We are concerned that CMS might view the national coverage process as a way to halt (or cut back) the increase in utilization of this technology. The tracking sheet notifying the public that CMS was considering a national coverage analysis of this topic stated that "CMS is concerned that…the procedure has been rapidly adopted by the clinical community." Rapid adoption should not be misinterpreted as an indication of inappropriate utilization. Rather, it should be interpreted as a possible indication of clinical superiority.

There has been no evidence generated in the past year since the MedCAC meeting to support a contraction in coverage. Although there are a number of other minimally-invasive diagnostic technologies that allow functional assessment for the presence of coronary artery disease, only CCTA provides consistent anatomic imaging of the coronary arteries and resultant very high sensitivity and negative predictive values.[2] Coronary CTA also has unique abilities to identify coronary artery plaque.[3] We believe these clinical advantages are precisely why clinicians choose to use CCTA, and why local Medicare contractors and many private insurers are providing coverage for it.

We think that those Medicare beneficiaries who currently enjoy access to CCTA through local coverage should not have this access restricted as a result of this national coverage review. If CMS chooses to develop a national coverage policy for CCTA, it should recognize the increasing number of indications for cardiac CTA. Clinicians from multiple specialties and

subspecialties have found CCTA pivotal in assessments of congenital cardiac anomalies, post-stent or post-CABG symptoms, the various classes of indeterminate stress tests, as well as various structural and functional analyses such as cardiac masses, pericardial disease, pulmonary vein anatomy with atrial fibrillation and aortic disease. For example, in emergency medicine, published literature points to large cost and time savings if the current clinical evaluation of chest pain colloquially known as "ruling out an MI" is replaced with a cardiac CTA.[4,5] There are roughly 6 million US emergency department visits annually for the complaint of chest pain.

Since CCTA is a groundbreaking technology, we expect significant further research to refine its indications and contraindications. The literature on the use of cardiac CTA for symptomatic heart disease is consistently positive. The one major area where there is strong epidemiologic data but not yet actual outcomes data to assess the use of cardiac CTA is in patients with high risk for coronary artery disease but no clearly cardiac symptoms. Invasive diagnosis with intravascular ultrasound suggests the power of plaque specific imaging data to improve outcomes here.[6]

At present, in view of the widespread morbidity and mortality of undiagnosed and under-diagnosed coronary artery disease throughout the Medicare population and the unique proven ability of CCTA to provide precise early diagnosis to prevent that morbidity and mortality, we urge CMS to retain the current local coverage that is in place and to cover the use of CCTA for these expanded indications—perhaps through coverage with evidence development. Any restrictions that are put into place on these indications should be based on evidence of actual misuse rather than on assumptions about potential misuse. Any CMS CCTA coverage decisions should also be time-limited to ensure that policies in place reflect current technology. Over the last decade, the major manufacturers of multi-detector CT scanners have released qualitatively (not just quantitatively) improved machines roughly every 24 to 36 months.

Thank you for your consideration.

Sincerely,

Donald W. Rucker, MD
Vice President and Chief Medical Officer
Siemens Medical Solutions USA

1. Rosamond W, Flegal K, Friday G, Furie K, Go A, Greenlund K, Haase N, Ho M, Howard V, Kissela B, Kittner S, Lloyd-Jones D, McDermott M, Meigs J, Moy C, Nichol G, O'Donnell CJ, Roger V, Rumsfeld J, Sorlie P, Steinberger J, Thom T, Wasserthiel-Smoller S, Hong Y. Heart

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2. Raff GL, Goldstein JA. Coronary angiography by computed tomography: coronary imaging evolves. *J Am Coll Cardiol* 2007;49:1830-3.
3. Schoenhagen P, White RD, Nissen SE, Tuzcu EM. Coronary imaging: angiography shows the stenosis, but IVUS, CT, and MRI show the plaque. *Cleve Clin J Med* 2003;70:713-9.
4. Gallagher MJ, Ross MA, Raff GL, Goldstein JA, O'Neill WW, O'Neil B. The diagnostic accuracy of 64-slice computed tomography coronary angiography compared with stress nuclear imaging in emergency department low-risk chest pain patients. *Ann Emerg Med* 2007;49:125-36.
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6. Nicholls SJ, Tuzcu EM, Crowe T, Sipahi I, Schoenhagen P, Kapadia S, Hazen SL, Wun CC, Norton M, Ntanios F, Nissen SE. Relationship between cardiovascular risk factors and atherosclerotic disease burden measured by intravascular ultrasound. *J Am Coll Cardiol* 2006;47:1967-75.

I urge CMS to consider Coverage with Evidence Development as the appropriate decision regarding reimbursement for coronary CTA. Coronary CTA has exploded onto the scene and there is little to no evidence-based appropriateness criteria governing its use. Cardiovascular imaging currently represents about one third of all imaging and is growing faster than other types of imaging. Thus, the potential for utilization and over-utilization of coronary CTA is huge. Coronary CTA needs to be considered in the context of all of the other cardiac imaging modalities available. The costs and benefits of coronary CTA need to be carefully weighed in terms of whether it answers the clinical question being asked in a way that another cardiac imaging study cannot, or in a more definitive manner that obviates the need for further testing. Or is coronary CTA just adding another layer of testing without really being necessary to make a management decision? A test such as coronary CTA which only gives anatomical information without corresponding functional information definitely has limitations. In light of the recent results of the COURAGE trial, patients with stable symptoms do not have any survival benefits or lower rate of subsequent cardiac events by being stented versus undergoing maximal medical treatment. Functional studies such as a treadmill stress test or stress echo can be used to diagnose whether coronary artery disease is present, and if it is present, can document subsequent progression of symptoms and disease. Since symptoms are the governing factor for the decision to perform an invasive procedure, the functional tests will be a better indication of need for an invasive procedure than static anatomical information seen on coronary CTA.

Coronary CTA is very useful in ruling out coronary disease in patients with equivocal functional stress tests, and can definitely help guide patient management in those patients.

In terms of use of coronary CTA in the Emergency Room, this is again a very unproven procedure in terms of whether it will decrease admissions for chest pain or result in better patient outcomes. There is a glaring lack of outcomes data for coronary CTA, and Coverage with Evidence Development would be a way to remedy this deficiency and try to standardize the way that the test is performed and the way that the images are read. Currently, there is no standardization in how to interpret the degree of coronary disease seen. This makes it very difficult to compare data across institutions or even among different providers.

Coronary CTA definitely has the potential to contribute greatly to the diagnosis and management of cardiac patients, but the benefits, costs, limitations, and appropriate use of this imaging modality must be understood in a systematic and evidence-based way.

Jennifer B. Meko, MD
Western Region Medical Director
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July 13, 2007

TO: Centers for Medicare and Medicaid Services (CMS)

FROM: Rita F. Redberg, MD, MSc, FACC, FAHA
UCSF School of Medicine, Division of Cardiology Professor of Medicine

RE: Comments on Cardiac Computed Tomographic Angiography (CCTA)
CAG-00385N

I fully support this national coverage analysis by CMS to assess the available evidence regarding CCTA and to consider the potential application of coverage with evidence development for studies to inform its use.

Currently, there are no outcomes data on use of CCTA in any clinical settings. The lack of outcomes data needs to be corrected. Each week I am seeing more and more patients in my Cardiology Faculty Practice, coming for evaluation after they have undergone CCTA for a variety of reasons with no clear benefit. In many of these patients, use of CCTA has led their referring doctors to recommend additional testing, such as , nuclear SPECT testing and/or invasive coronary angiography. These tests, as well as the CTA all carry significant radiation exposure.

CMS must all consider the importance of getting data on the accuracy and outcomes in of CTA in older patients, such as Medicare beneficiaries. There are many technical problems with CTA in the older population. Older subjects are: 1) more likely to be a higher calcium score, which prevents a good quality CTA, 2) it may be more dangerous to beta block the patient to get the heart rate slow enough for a good quality study, and 3) the older patient may have a harder time lying still again making a technically good quality study less likely in the Medicare population. It is essential to collect data, ideally in a randomized control trial, or a registry with clinical information, and 6 month follow up for clinical events and use of additional cardiac procedures.

I believe that CCTA represents a good topic for the CED approach, given the fact that this technology is being eagerly adopted and has potential clinical value, but there remain important gaps in knowledge about its risks, benefits and costs, particularly in patients at intermediate risk of CAD. The CED approach will allow the technology to be used while ensuring that the evidence required to apply the technology intelligently is being efficiently generated. It would also provide an opportunity to test the application of CED simultaneously by both public and private payers.

Dear Ms. Baldwin,

I have been a practicing radiologist in a large private practice in Phoenix, AZ for 20 years. For the past 8 years I have been at the forefront in our group in initiating and overseeing the revolutionary applications that have resulted from the marriage of Multi-detector CT (MDCT) scanning with 3D workstation technology. Without question, CT angiography (CTA) has been the most exciting and, in my opinion, medically useful application of the many uses of MDCT. I began instituting CTA of the pulmonary arteries,

aorta, renals, and carotids very early on and have expanded to include peripheral CTA as well. To a large degree, CTA has replaced traditional, invasive catheter based digital subtraction angiography (DSA) for diagnosis of vascular disease in our practice.

Having begun my career with an emphasis on MRI (I completed an MRI fellowship in 1987) and seen the implementation of a wide variety of new imaging technologies since beginning my radiology training in 1982, there is no question in my mind that performing high quality CTA is the most labor intensive endeavor I have experienced. It is my very strong belief, based largely on years of experience, that unless the physician interpreting CTA exams becomes highly skilled in interacting with the CT data sets on the 3D workstation (and takes the time to do so) the 'extraction' of medically relevant information that the technology presents will not be accomplished. I have accumulated innumerable examples of improperly interpreted scans due to the fact that the interpreter was not conversant with how to manipulate the enormous data sets on the 3D workstation. To become conversant with 3D technology takes an enormous amount of time if one wishes to do this well.

I have anxiously followed the evolution of CTA through numerous CME courses and have watched as the 'holy grail' of CTA, namely coronary/cardiac CTA (CCTA), moved from concept to application. About 14 months ago I headed up our practice's implementation of CCTA and continue to oversee its development utilizing our 64 slice CT scanner. While the institution and promise of this application is most exciting to me, it also in many, many instances has been the most disappointing. I have insisted on our practice properly utilizing the 8 category 3 cardiac CT codes and in so doing have spent incredible amounts of time fighting for authorization/verification and payment for work done that has often advanced patient care.

Coronary artery disease is so prevalent and affects so many people that to define the population at risk for acute coronary events and then aggressively managing their risk factors has the greatest potential in terms of secondary prevention of the life threatening sequela of the disease. Since the currently accepted pathophysiology of coronary artery disease (CAD) is that it is an inflammatory process in the vessel wall and that 'vulnerable' plaque rupture often begins a cascade of events leading to myocardial infarction or sudden death, it seems that any way of ***non-invasively*** discovering the presence of CAD (vessel wall disease) would offer the best opportunity at saving lives. Currently, the two methods of reliably imaging the vessel wall for plaque that may not be causing stenosis are intra-vascular ultrasound (IVUS) and CCTA. Of these two choices, only CCTA is non-invasive.

For a practice such as ours to make a commitment to providing quality CCTA is not a trivial pursuit; we have spent well beyond $1,400,000 to make this happen, not to mention an inordinate amount of professional time with little 'pay off' to date. Without appropriate reimbursement for the relative labor involved in doing this well, there is little incentive to offer this service. I have lamented for years the utter imbalance in relative reimbursement to relative labor intensity for non-cardiac CTA exams. In fact, I have documented my own reading times for a variety of exams (CTA, routine CT, MRI, US, NM, etc) and then compared that to the relative reimbursement of these various exams. This data accumulation has confirmed what I already knew….there is financial disincentive to perform high quality CTA compared to performing other imaging exams. In fact, I find it very troubling that in the hospital setting the financial incentives are such that it makes more 'business sense' to perform an invasive, higher risk carotid DSA on a patient as opposed to performing a risk free, more complete vessel assessment carotid CTA exam.

It is my strong hope, and even stronger recommendation, that CMS not only approve reimbursement for CCTA but also set reimbursement levels that incentivize physicians to spend the time to learn the proper methods of performing/interpreting these exams. Without proper alignment of relative labor to relative reimbursement, I believe physicians will take short cuts in the method of providing this service and quality will suffer (i.e. why should I spend 35 minutes reading a CCTA for 'X' dollars when I can read 5 MRI exams in that same time and collect 4-5 times the pay for my professional time?). A very glaring example I see all the time that illustrates this is the 'dependence' radiologists place on technologists' 3D models when interpreting CTA exams of all types. This is one way to save radiologist time since the time a radiologist spends 'interacting' with the MDCT data on 3D workstation, and 'problem-solving' areas of

potentially significant disease is not 'rewarded' or valued at current reimbursement levels compared to what one can generate in terms of revenue by avoiding the time intensive endeavor of using the 3D workstation.

I recently gave a presentation on CCTA to a group of physicians. In preparing for that talk, I accumulated numerous journal articles supporting the appropriate use of CCTA. I am attaching the reference list to this email for your review.

Sincerely,

Phillip Moeser, MD
Southwest Diagnostic Imaging
Phoenix, AZ

CARDIAC/CORONARY CT ANGIOGRAPHY

Since its development in the late 1990's, Multi-Detector Computed Tomography (MDCT) has revolutionized vascular imaging in many ways. MDCT has given us a non-invasive way of reliably imaging the degree of stenotic disease in many arterial distributions throughout the body (i.e. carotids, renals, and extremities). MDCT technology has now evolved to allow reliable non-invasive imaging of the coronary arteries. This presentation will attempt to summarize the current state-of-the-art in coronary/cardiac CT angiography (CTA).

The currently understood pathophysiology of coronary artery disease suggests it is an inflammatory process in the vessel wall that ultimately puts the patient at risk for acute coronary events due to vulnerable plaque rupture with resultant platelet aggregation and rapid vessel occlusion. Such acute coronary events often occur in segments of vessels that are less than 50% stenotic. Thus, a modality that can accurately image the vessel wall would seem better suited to identify and quantify the extent of disease and contribute to risk stratification/management when compared to a modality that images only the vessel lumen. The two modalities currently capable of imaging the vessel wall with reasonable spatial resolution are intravascular US and MDCT. Of these, MDCT is the non-invasive, less expensive choice for vessel wall as well as patent lumen imaging.

The technological challenge of reliably imaging rapidly moving small (1-5mm) vessels is enormous. It requires high temporal, spatial, and contrast resolution. With the advent of 64 slice CT scanners the challenge has been met. A sophisticated understanding of MDCT technology as well as of 3D post-processing of the acquired data is required to allow 'extraction' of the wealth of clinical information available on a typical CTA exam. Published studies on coronary/cardiac CTA are predominantly from 16 slice technology with a smattering of reports from 64 slice scanners. When compared with traditional cardiac catheterization, CTA has reported sensitivities of 82-99% and specificities of 95-98% for detection of stenosis of 50% or greater. The very high (96-100%) negative predictive value of CTA reported in numerous studies indicates the potential role for reliably excluding flow limiting coronary stenosis in symptomatic and asymptomatic patients.

There are numerous possible clinical uses for coronary/cardiac CTA including:

- Coronary calcium scoring – for risk assessment and risk management
- Assessment of the degree of coronary artery stenosis in low to intermediate risk patients with non-specific symptoms such as atypical chest pain (acute or chronic)
- Evaluating patients with equivocal treadmill stress or nuclear medicine stress/rest exams
- Identification and characterization of plaque as a contribution to risk assessment for CAD
- Evaluating patency and anatomy of coronary stents and CABG grafts
- Evaluating possible coronary artery anomalies
- Evaluating congenital abnormalities of the heart and great vessels (i.e. ASD, VSD, coarctation of the aorta)
- Detection/evaluation of suspected cardiac masses
- Evaluating pulmonary, left atrial, and coronary venous anatomy in consideration for EP studies (i.e. biventricular pacer and/or RF ablation procedures)
- Evaluation of cardiac wall motion/ejection fraction

Many of the above indications along with discussion of CAD risk assessment and technical aspects of exam performance will highlighted through presentation of clinical examples of cardiac/coronary CTA exams.

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July 13, 2007

Joseph Chin, M.D.,
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Re: NCA for Computer Tomographic Angiography (CAG-00385N)

Dear Dr. Chin and Ms. Baldwin:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) National Coverage Analysis (NCA) on Computed Tomographic Angiography (CAG-00385N).

As you know, ASNC is a greater than 5,000 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

ASNC is extremely concerned with CMS' decision to open a National Coverage Analysis of Computed Tomographic Angiography (CTA), and strongly recommends that the agency not adopt a NCD on CTA at this time. First, ASNC believes that the decision whether to cover CTA should be left to the local Medicare Carriers, who have more hands-on access to the results of its use on beneficiaries. Second, we feel that the NCA, as written, is setting an unachievable standard for a noninvasive diagnostic test in asking for data on CTA's impact on health care outcomes.

Coverage of CTA should first be evaluated at the local level:

ASNC questions why CMS has chosen to initiate the NCD process for CTA when the agency has only rarely used this approach in the past when establishing national coverage guidelines for diagnostic imaging procedures. Medical necessity for the vast majority of diagnostic imaging studies have been traditionally established by Local Coverage Determinations (LCDs). As you know, the LCD development process

integrates the views and perspective of all interested parties in the Medicare community such as the Medicare Contractor, Contractor Medical Directors and key members of the physician Contractor Advisory Committee – in this case, providers of CTA and the ordering physicians. As such, the Medicare Contractors are able to follow how CTA is being integrated into practice in their community and can change their LCDs as indications develop and new evidence become available.

By Seeking Data on Health Outcomes Related to CTA, the NCA Applies an Unachievable Standard for Non-Invasive Diagnostic Tests:

ASNC is also troubled that the questions raised by the NCA tracking sheet do not accurately identify the issues that a coverage policy for CTA could potentially address. Specifically, the statement: "CMS is concerned that despite the lack of clinical evidence to *demonstrate improved patient health outcomes with CTA*, the procedure has been rapidly adopted by the clinical community [emphasis added]" does not correctly articulate the purpose of CTA.

CTA is a highly useful tool for physicians to make better, more prompt diagnoses without employing invasive procedures (i.e. invasive coronary angiography) that may introduce risks of complications in all patients—especially for those whose overall physical condition may heighten any existing risks. While CTA may play an important role in the overall treatment of a patient (i.e. correct diagnosis), its use, alone, will not necessarily produce "better outcomes," since the subsequent course of treatment and other factors (e.g. co-morbidities, etc.) will have far greater influence in affecting a patient's health outcomes.

Applying the standard of "improved patient health outcomes" to diagnostic tests is problematic and totally ignores the value of a negative examination. For example, in studying a cohort of patients being treated for pneumonia, no one would question the value of a chest radiograph in excluding the disease, yet it is impossible to develop improved patient health outcome data for pneumonia from a negative chest radiograph as these patients never had the disease.

The overwhelming evidence from the literature is that CTA can accurately exclude obstructive coronary artery disease (CAD). In this regard CTA will replace nuclear cardiology imaging and invasive coronary angiography in numerous patients undergoing an evaluation for possible CAD. Since these patients do not have the disease, evaluating a long-term health outcome for these patients is problematic. Since coronary events would be extremely rare in the short-term, developing data proving that the patients benefited by having the study is impossible. The value of CTA for these patients has to be seen in terms of decreasing the downstream diagnostic interventions which would have otherwise been necessary based on the patient's clinical findings.

For example, the use of magnetic resonance angiography and CTA for diagnosis of carotid stenoses has significantly decreased the number of cerebral catheter arteriograms. As a diagnostic study, CTA must also be able to identify and characterize

disease. Studies comparing CTA to invasive coronary angiography are quite favorable and results are being used to triage patients into groups that have CAD but do not need invasive angiography. Finally, by its ability to detect CAD early, prior to the development of hemodynamically significant stenoses, CTA has the ability to detect CAD in patients that would have had a negative test for cardiac ischemia (nuclear cardiology and stress echocardiography). These patients are at substantial long term risk for future myocardial infarction (MI) and cardiac death. Given the impact of statin therapy and CAD progression, it can be confidently stated that initiation of medical therapy in these patients will delay or prevent MI and cardiac death. Studies to prove this point could take a decade or more.

In sum, CTA is not in and of itself a preventive or therapeutic procedure. It is designed to detect and characterize coronary artery, congenital and structural heart disease. The beneficial outcome for patients can best be expressed in terms of preventing downstream and sometimes invasive diagnostic examinations and in detecting the disease in patients who would have otherwise had a negative conventional workup.

Expand the Indications for CTA Use

There are several important indications for CT angiography that have not been listed among those outlined in the NCA.

> The American Heart Association (AHA) has recently published a Scientific Statement on Cardiac CT, and outlined two important indications that received Class IIa indications for use.1 These were:
>
> 1) For the assessment of obstructive disease in symptomatic patients (Class IIa)
> 2) Use of CT as one of the first choice imaging modalities in the workup of known and suspected coronary anomalies (Class IIa)

The cardiology community has also joined with the American College of Radiology in developing appropriateness criteria for CTA. [i]The methodology used for the appropriateness criteria was extremely rigorous and yielded the following appropriate indications for CTA:

- Un-interpretable or equivocal stress test (exercise, perfusion, or stress echo)
- Intermediate pre-test probability of CAD
- Initial evaluation of new onset or atypical chest pain or heart failure
- Evaluation of cardiac mass (suspected tumor or thrombus)
- Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, or complications of cardiac surgery)
- Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation

- Noninvasive coronary vein mapping prior to placement of biventricular pacemaker
- Noninvasive coronary arterial mapping, including internal mammary artery prior to repeat cardiac surgical revascularization
- Evaluation of congenital cardiac and coronary anomalies

Prognostic Data on Use of CTA Supports Continued Medicare Coverage:

Several recently published and ongoing studies[ii] indicate that CTA has substantial prognostic value, particularly when no abnormalities are found. In one study (in press), during a 15-month follow-up of 1,127 patients presenting with chest pain, MDCT coronary angiography identified individuals at increased risk for all-cause death, with increasing risk for more extensive CAD. Furthermore, normal MDCT coronary angiograms identified patients at extremely low risk for death[iii]. Two additional outcome studies have demonstrated 100% short term event-free survival after a normal or near normal CTA (i.e., no obstructive disease seen)[iv,v]. Thus, these patients can be managed medically without the need for invasive angiography. This results in a significant decrease in downstream costs from invasive testing[vi].

ASNC appreciates the opportunity to address issues raised by the agency's recent NCA on CTA. Given that cardiovascular disease is responsible for approximately one third of deaths occurring in the Medicare population, we hope that CMS does not stifle a rapidly evolving technique that has the opportunity to continue the improvement in cardiovascular care that has already seen an average annual 2.5% decrease in the coronary heart disease death rate for Americans experienced over the last thirty years.

Should you have any questions, please contact Christopher Gallagher, Director of Health Policy at 301-215-7575 or via email at Gallagher@asnc.org.

Sincerely,

Gregory S. Thomas, MD, MPH
President

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VIA ELECTRONIC MAIL

July 13, 2007

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RE: [CAG-00385N] Computer Tomographic Angiography

Dear Dr. Chin and Ms. Baldwin,

The Medical Imaging and Technology Alliance (MITA), a division of the National Electrical Manufacturer's Association (NEMA), is pleased to submit comments regarding the National Coverage Analysis (NCA) for Computer Tomographic Angiography (CTA). As the leading trade association representing companies whose sales comprise over ninety percent of the global market for medical imaging, we are pleased to provide the Centers for Medicare and Medicaid Services (CMS) with our reasoning why CTA is an intricate part of a patient's treatment plan, provides a less invasive measure for visualizing blood flow, and must be allowed to develop clinically. It is important for CMS to understand the genuinely adverse effects of restricted Medicare beneficiary access to the improved precision in disease detection and treatment decisions related to this imaging service, which provides exceptionally precise imaging of the heart, if a National Coverage Determination (NCD) is implemented and coverage is restricted or denied.

Imaging has made dramatic contributions over the past 30 years, and has a significant role in improving mortality and morbidity for Medicare beneficiaries. Advances in imaging have enhanced every aspect of health care, including screening, diagnosis, treatment, and follow-up monitoring—providing anatomical and biological details to clinicians that were unachievable even a decade ago.[vi]

As a recently developed modality, CTA is the first diagnostic test with the proven ability to precisely detect evidence of coronary heart disease, the single largest killer of Americans, as reported by the American Heart Association (AHA). This test provides cross-sectional images of the chest, including the heart and great vessels. In general, cardiac tomography is useful to evaluate aortic disease (such as aortic dissection), cardiac masses and pericardial disease. This technology has proven to effectively identify diseased, narrowed, enlarged, and blocked blood vessels, and pinpoint where internal bleeding may be occurring. This imaging innovation obviates much of the risk and discomfort associated with other invasive standards of care, such as catheterization. Regardless of how minimal, invasive surgical measures can be risky. Serious and life-threatening sequelae may occur, including arrythmia, stroke, coronary dissection, and access site bleeding. Furthermore, catheterization induces some discomfort, and mandates routine follow-up care.[vi] It is the opinion of some health care providers that it is important to limit invasive exploratory surgery. Technological advances, such as CTA, allow physicians to perform reliable non-invasive clinical studies. To limit the scope of this test may force Medicare beneficiaries to undergo lengthy, less-reliable, and more expensive diagnostic testing that may lead to missed diagnoses or unnecessary surgical procedures ultimately resulting in increased morbidity and medical expenditures.

MITA respects the importance and necessity of implementing a sound, reasonable coverage analysis of CTA, but asks CMS to consider the following concerns and recommendations to ensure continued proper access for this nascent technology.

In brief:

- MITA is concerned that CMS is proposing an anomalous policy for a non-invasive diagnostic test that has proven its worth in clinical practice for certain indications, thereby restricting its use on selected Medicare beneficiaries who benefit from such non-invasive methods of detection;
- MITA asks that CTA continue to be evaluated by and decisions for coverage be decided by local carrier medical directors through the well-established local coverage determination process (LCD);
- MITA suggests CMS consider referring to the medical consensus policies regarding appropriate CTA indications created by the American College of Cardiology (ACC) and the American College of Radiology (ACR), if CMS determines an NCD to be justified rather than the recommended LCD process; and

- MITA urges CMS to not incorporate specific equipment standards for CTA devices within a coverage determination, due to the potential for impeding physician medical decision making, and due to the rapid evolution occurring in the equipment.

Improved Health Outcomes

With inflated health care costs and stressed budgets, health outcomes research can identify potentially effective strategies, that when properly implemented, can improve the quality and value of care. MITA agrees with CMS that sound outcomes research should be provided to support coverage of certain technologies; however, we disagree with CMS's statements rationalizing the need for this NCA. Specifically, CMS stated that, "CMS is concerned that despite the lack of clinical evidence to demonstrate improved patient health outcomes with CTA, the procedure has been rapidly adopted by the clinical community."[vi] The impact of diagnostic tests on patient outcomes is not as directly evident and measurable as specific therapeutic interventions (which also present challenges), because a diagnostic test does not directly improve a patient's condition but rather serves to guide the physician's clinical decision-making which takes many factors into account. Nonetheless, diagnostic tests are a critical part of delivering appropriate clinical care and improving patient quality of life. For example, CTA is utilized to support subsequent decisions on selection of, starting, stopping, or modifying patient treatment. The measurable impact on the patient is demonstrated by the specific treatment that slows disease progression, promotes clinical stability, and prolongs survival. These are the components of improving quality of life. A diagnostic test should be measured by its ability to enhance efficiency of patient care and prevent additional, unnecessary, or outdated testing on patients. Hence, improved patient outcomes are difficult to quantify on a patient-by-patient basis and may not be the best proxy by which to evaluate overall quality of care.

According to CMS's guidance regarding Coverage with Evidence Development (CED), CMS states that, "An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary (emphasis added)."[vi] To limit or deny coverage for CTA solely based on "improved health outcomes" is not appropriate justification. Assessing the therapeutic value of a diagnostic test may be addressed in several ways, such as delivering accurate prognostic information, or eliminating the need for further testing thereby reducing overall cost of care. With healthcare budgets under continuous pressure, cost-effective treatment is paramount to payers, providers and patients. Indeed, MITA takes pride in the fact that our members' products provide cost-effective, high quality studies with clinically-proven results. MITA asks that CMS consider other measurements for determining improved quality of care when deciding whether limiting coverage for CTA is warranted.

Coverage of CTA Should Be Decided at the Local Carrier Level

MITA believes that implementing an NCD to restrict coverage of CTA is premature and unwarranted. The current LCD process facilitates the appropriate diffusion of beneficial technologies. Because CTA is an emerging technology, a nationally uniform and potentially restrictive coverage decision across all regions and all sites of service may hinder patient access and impede proper utilization.

Currently, medical specialty organizations such as the ACC and the ACR continue to work with local Medicare carrier medical directors to ensure consensus guidelines are in place to address over-utilization of certain diagnostics and to educate ordering physicians regarding appropriate clinical use. In particular, the ACC and ACR collaborated and produced a medical policy that addresses the appropriate coverage pathway for CTA and its indications. Clinical experts and payers were involved in this process and reviewed available peer-reviewed literature and data resulting in this comprehensive coverage document. In fact, Medicare contractors have incorporated portions of this medical policy into their own coverage determinations.

Separately, CMS states that there is concern because, "…the procedure [CTA] has been rapidly adopted by the clinical community."[vi] This should not be the "per se" basis for CMS's consideration of adopting a restrictive coverage policy. Simply put, imaging provides the best care possible for diagnosing and treating a wide range of medical conditions. Rapid adoption of a particular technology may not, in fact, lead to higher overall health care costs. This service may provide superior clinical efficacy over other existing diagnostic tests. In fact, CTA is less expensive than conventional angiography and promotes lower morbidity and mortality rates.

In closing, MITA feels strongly that coverage decisions regarding CTA should be decided upon at the local carrier level and recommends that CMS allow that process to continue.

Equipment Standards

MITA urges CMS to not incorporate specific equipment standards for CTA devices within an NCD, if CMS determines an NCD is necessary. There are numerous types of devices that are currently on the market and each of them have specific equipment characteristics that are unrelated to the overall value of the technology. It has come to our attention that some local contractors have implemented LCDs that include such equipment specifications, based on the number of detectors, gantry speed and collimation size. This is not sound policy.

For CTA to be clinically effective as a diagnostic tool, temporal resolution or the ability to deliver image detail within a short timeframe is the critical component that drives CTA's value. While temporal resolution may be achieved through multiple combinations of features, such as gantry speed, differentiation in features across equipment does not reflect an appropriate proxy for inclusion or exclusion in a

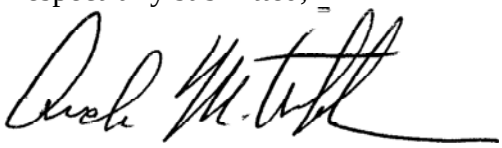
coverage determination. Further, as CTA technology continues to rapidly develop, MITA believes that naming specific requirements outlining preferred equipment in a coverage determination may become quickly outdated hindering Medicare beneficiaries' access to this innovative technology.

Conclusion

Cardiac CTA is the first and only diagnostic non-invasive tool to provide precise and comprehensive anatomic information about the heart and as such offers extraordinary promise for revolutionizing cardiac care. The rapidly increasing scientific literature is quite positive about its impact in removing physician (educated) guess work in diagnosing the correct and precise sources, among many possibilities, of heart ailments. We are concerned that by applying extremely high downstream clinical trial standards to the use of cardiac CTA, CMS policies may delay the ability to provide precise early cardiac diagnoses to Medicare beneficiaries, and thereby lose a significant opportunity to address the current large burden of heart attacks, congestive heart failure, arrhythmias and sudden death.

As CMS gathers and reviews all relevant medical and scientific information regarding CTA, and to ensure transparency, MITA asks that these reviewed studies be made available for public review. MITA hopes that these comments will be useful to CMS in determining that a national coverage determination is not needed at this time. We look forward to further dialogue on this issue and encourage CMS to contact us with any questions, comments, or requests for additional information.

Respectfully submitted,



Andrew Whitman
Vice President

[vi] Lewin Report, p. ii. Also see Alexanderson E, Granados N, Gomez-Martin D, Ricalde A, Meave A. [Evaluation of coronary artery disease by myocardial perfusion imaging in women] *Arch Cardiol Mex*. 2005 Jan-Mar;75(1):35-41. Also see Mowatt G, Brazzelli M, Murray A, Fraser C, Vale L. "Systematic Review of Single Photon Emission Computed Tomography (SPECT) Myocardial Perfusion Scintigraphy for the Diagnosis and Management of Angina and Myocardial Infarction." *Nucl Med Commun*. 2005;26(3):217-29.

[vi] Hoffman M, Shi H, Schmitz B, et al. NonInvasive Coronary Angiography With Multislice Computed Tomgraphy. *JAMA*. 2005;293:2471-2478.

[vi] Guidance can be found on the CMS web site: http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=206, accessed on July 10, 2007.

[vi] Guidance can be found on the CMS web site: http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8, *accessed July 10, 2007*.

[vi] Guidance can be found on the CMS web site: http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=206, accessed on July 10, 2007.

July 13, 2007

Joseph Chin, M.D.,
JoAnna Baldwin, M.S.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

Re: NCA for Computer Tomographic Angiography (CAG-00385N)

Dear Dr. Chin and Ms. Baldwin:

The American College of Cardiology (ACC) and the American College of Radiology (ACR) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) National Coverage Analysis (NCA) on Computed Tomographic Angiography (CAG-00385N).

The ACC is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy.

The ACR, representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists is also a non-profit professional medical specialty society with a mission to serve patients by improving the quality of patient care, through advancing the science of radiology, providing continuing education, conducting research for the future of radiology, and shaping health care coverage and policy.

We are submitting a joint comment letter at this time because both of our respective organizations share the same general concerns with CMS' decision to open an NCA of Computed Tomographic Angiography (CTA). The ACC and ACR strongly recommend the agency not adopt a National Coverage Decision (NCD) on CTA at this time.

While we intend to submit more detailed comments upon review of CMS' subsequent draft NCD memo, at present our general concerns and recommendations are as follows:

1. The decision whether to cover CTA should be left to the local Carriers, who have more hands-on access to the results of its use on beneficiaries at this time;

2. The NCA, as written, is mistakenly setting an inaccurate standard for a non-invasive diagnostic test in asking for data on CTA's impact on health care outcomes. However, this field is progressing rapidly and outcomes studies documenting the diagnostic value, prognostic value and cost effectiveness are being published; and
3. The NHIC California Medicare Local Coverage Decision (LCD) is an excellent example of the model policy process. This policy is a strong adaptation of the model LCD created by the ACC and ACR discussed below, and could serve as a basis for a national policy should CMS determine a NCD to be more appropriate than the recommended LCD process.

Coverage of CTA should be Left to Local Carriers:

The ACC and the ACR consider implementation of an NCD for CTA unnecessary at this time. Historically, the NCD process has only rarely been used to establish national coverage guidelines for diagnostic imaging procedures. Medical necessity for the vast majority of diagnostic imaging studies has been established by the LCD process. We feel strongly that CTA should continue to be covered at the local level via the model policy and LCD processes.

For two years, our societies have been working with the local Medicare contractors to develop appropriate coverage policies for coronary CTA, and the majority of Medicare contractors have developed local policies for coverage. The Contractor Medical Directors are able to work closely with the physician Contractor Advisory Committee members from both the providers of CTA and the ordering physicians. Thus they are able to follow how CTA is being integrated into practice in their community and can change their LCDs either as indications develop or on the basis of inappropriate volume.

In addition to the local Carrier process, the ACC and ACR developed a model LCD for CTA with broad input from Carrier Medical Directors as well as the private payor community—resulting in a comprehensive tool that has proven to be influential on current LCDs for CTA. Because NCDs are "one-size-fits-all" policies and are difficult to modify quickly in unanticipated situations, we believe the authority to make such coverage determinations for CTA is best exercised at the local level.

By Seeking Data on Health Outcomes Related to CTA, the NCA Mistakenly Applies an Inaccurate Standard for Non-Invasive Diagnostic Tests:

If, however, CMS determines that some degree of national consistency in coverage for cardiac CTA is in the best interests of Medicare patients, the ACC and ACR believe that sufficient evidence exists to provide guidance about indications that should be included in a national coverage determination. Prior to discussing this evidence, however, we must note that the questions raised by the NCA tracking sheet do not accurately identify the issues that a coverage policy for CTA could potentially address. Specifically, the statement: "CMS is concerned that despite the lack of clinical evidence to *demonstrate improved patient health outcomes with CTA*, the procedure has been rapidly adopted by

the clinical community [emphasis added]" does not properly articulate the purpose of CTA.

CTA is a highly useful tool for physicians to make better, more prompt diagnoses without employing invasive procedures (i.e. catheter deployment) that may introduce risks of complications in all patients—especially for those whose overall physical condition may heighten any existing risks. While CTA may play an important role in the overall treatment of a patient (i.e. correct diagnosis), its use, alone, will not necessarily produce "better outcomes (*sic*)," since the subsequent course of treatment and other factors (e.g. co-morbidities, etc.) will have far greater influence in affecting a patient's health outcomes.

Applying the standard of "improved patient health outcomes" to diagnostic tests is problematic and totally ignores the value of a negative examination. For example, in studying a cohort of patients being treated for pneumonia, no one would question the value of a chest radiograph in excluding the disease, yet it is impossible to develop improved patient health outcome data for pneumonia from a negative chest radiograph as these patients never had the disease. Similarly, CTA as a diagnostic test must be effective at excluding the coronary artery disease.

The overwhelming evidence from the literature is that CTA can accurately exclude coronary artery disease. In this regard, CTA will replace nuclear medicine imaging and catheter angiography in numerous patients undergoing a chest pain workup. Because these patients do not have the disease, evaluating a long-term health outcome for these patients is problematic. Since coronary events would be extremely rare in the short-term, developing data proving that the patients benefited by having the study is impossible. The value of CTA for these patients has to be seen in terms of decreasing the downstream diagnostic interventions which would have otherwise been necessary based on the patient's clinical findings.

For example, the use of CTA for diagnosis of carotid stenosis has significantly decreased the number of cerebral catheter arteriograms. As a diagnostic study, CTA must also be able to identify and characterize disease. Studies comparing CTA to catheter coronary angiography are quite favorable and results are being used to triage patients into groups that have coronary artery disease (CAD) but do not need catheter angiography. Finally, by its ability to detect non-stenotic soft plaque, CTA has the ability to detect CAD in patients that would have had a negative nuclear medicine and catheter angiography. These patients are at risk for future adverse coronary events and initiation of medical therapy in these patients may decrease the number of future myocardial infarctions.

In sum, CTA is not a preventive or therapeutic procedure. It is designed to detect and characterize coronary artery disease and other vascular diseases of the heart. The beneficial outcome for patients can only be expressed in terms of preventing downstream and sometimes invasive diagnostic examinations and in detecting the disease in patients who would have otherwise had a negative conventional workup. The value of a negative examination cannot be over emphasized.

NHIC's LCD for CTA is an Excellent Example of the Model LCD Process' Effectiveness:

A number of local Medicare carriers have used a model LCD in developing their own policies. In particular, NHIC's (Medicare's Part B Carrier for California) LCD for Multislice or Multidetecter Computed Tomography Angiography of the Heart and Great Vessels (L22517) is an excellent example of how the collaborative efforts between ACC and ACR, as well as Contractor Medical Directors and other stakeholders to develop a model LCD demonstrate the effectiveness of a local approach to CTA coverage decisions (*See Attachment A*). It is our understanding that this LCD enjoys strong endorsement from Contractor Medical Directors in general beyond only NHIC's, particularly since numerous clinical experts consulted during its development formed a subgroup for looking critically at literature and indications. Additionally, it should be noted that the vast majority of CMDs cover the Category III codes for coronary CTA and most of these approvals are based on the model LCD.

Further, this model LCD also covers indications for CTA use that are not addressed in the NCA, but are supported by current research data. While the data on efficacy of CTA is still forming, it exists in sufficient amounts to support its continuing, or even expanded, coverage under Medicare. The ACC and ACR recommend the following be considered for inclusion in any NCD on CTA:

A. Expand the Indications for CTA Use:

There are several important indications for CT angiography that have not been listed among those in the current model LCD developed by ACC and ACR.

The American Heart Association (AHA) has recently published a Scientific Statement on Cardiac CT, and outlined two important indications that received Class IIa indications for use[1]. These were:

1) For the assessment of obstructive disease in symptomatic patients (Class IIa)
2) Use CT as one of the first choice imaging modalities in the workup of known and suspected coronary anomalies (Class IIa)

The societies have also assessed CTA and developed appropriateness criteria. The methodology used for the appropriateness criteria was rigorous and the results are

[1] Budoff MJ, Achenbach S, Blumenthal RS, Carr JJ, Goldin JG, Greenland P, Guerci AD, Lima JAC, Rader DJ, Rubin GD, Shaw LJ, Wiegers SE. Assessment of Coronary Artery Disease by Cardiac Computed Tomography, A Scientific Statement From the American Heart Association Committee on Cardiovascular Imaging and Intervention, Council on Cardiovascular Radiology and Intervention, and Committee on Cardiac Imaging, Council on Clinical Cardiology. Circulation 2006; 114 (16): 1761-91.

attached, along with a description of the approach used to reach conclusions[2]. These appropriate indications (scores 7-9) include:

- Un-interpretable or equivocal stress test (exercise, perfusion, or stress echo)
- Intermediate pre-test probability of CAD
- Initial evaluation of new onset or atypical chest pain or heart failure
- Evaluation of cardiac mass (suspected tumor or thrombus)
- Evaluation of pericardial conditions (pericardial mass, constrictive pericarditis, or complications of cardiac surgery)
- Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation
- Noninvasive coronary vein mapping prior to placement of biventricular pacemaker
- Noninvasive coronary arterial mapping, including internal mammary artery prior to repeat cardiac surgical revascularization
- Evaluation of congenital cardiac and coronary anomalies

B. <u>Current Data Demonstrates Accuracy of CTA – i.e. Negative studies avoids invasive testing risk and trauma – (From AHA Statement)</u>:

A negative test (normal coronaries or non-obstructive disease) on CTA makes the presence of significant luminal obstructive disease highly unlikely (negative predictive power on the order of 95-99%). Over the last two years, 16- and 64-row Computed Tomography has been validated to have a very high negative predictive power to 'rule out' obstructive disease in symptomatic persons in an outpatient chest pain environment, in congestive heart failure of unknown etiology and emergency department evaluation of chest pain syndromes.

A recent study[3], in concordance with prior studies, demonstrates a very high negative predictive power for the presence of obstructive CAD (100% in this study). Thus, the strength of CTA remains in the ability to rule out disease (negative tests), so that further evaluation (including stress testing, functional tests and angiograms) can be avoided safely in these patients, remains a primary use of CTA in recently published Appropriateness Criteria and American Heart Association Guidelines[4]. Other studies have demonstrated this high negative

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[2] Hendel RC, Patel MR, Kramer CM, et al. ACCF/ACR/SCCT/SCMR/ASNC/NASCI/SCAI/SIR Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging. J Am Coll. Cardiol: 2006: 48; 1606 –13.

[3] James K. Min , Leslee J Shaw, Richard B Devereux, Peter M. Okin, Jonathan W. Weinsaft, Donald J. Russo, Nicholas J. Lippolis, Daniel S. Berman, Tracy Q. Callister. Prognostic Value of Multidetector Coronary CT Angiography for Prediction of All-cause Mortality. Journal of the American College of Cardiology (in press).

[4] Leslee J. Shaw, Daniel S. Berman, James K. Min, Donna Polk, Tracy Q. Callister, Prognosis by coronary computed tomographic angiography: a comparison with myocardial perfusion SPECT. American Heart Association, Chicago, IL 2006. (Circulation, October 2006) (Abstract).

predictive power, giving clinicians confidence that a negative CTA (no obstructive disease seen), will result in a normal or near normal CATH.

These studies suggest that CTA would allow reliable triage of patients with suspected coronary artery disease, with decreased utilization of downstream testing after a normal or near-normal CTA. The study by Raff et al. demonstrated that over 67% of patients presenting to the emergency room had normal or near normal CTA studies and those with negative studies demonstrated freedom from major adverse events over 6 months (100% safety)[5].

C. Prognostic and Cost Data on Use of CTA Supports Continued Medicare Coverage:

Several recently published ongoing studies[6] indicate that CTA has prognostic value, particularly when no abnormalities are found. In one study (in press), during a 15-month follow-up of 1,127 patients presenting with chest pain, CTA identified individuals at increased risk for all-cause death, with increasing risk for more severe or proximal (left main) disease. Furthermore, normal CT angiograms identified patients at extremely low risk for death[7]. Two additional outcome studies have demonstrated 100% short term event-free survival after a normal or near normal CTA (i.e., no obstructive disease seen)[8]. Thus, these patients can be managed medically without the need for coronary angiography. This results in a significant decrease in downstream costs from invasive testing[9]. A sensitivity analysis recently examined cost implications if CTA was performed prior to invasive coronary angiography for patients with mildly abnormal or equivocal SPECT perfusion

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[5] James K. Min, Fay Lin, Antonio Legorreta, Ning Kang, Amanda Gilmore. Differences in Episode Based Costs for Coronary Computed Tomographic Angiography vs. Myocardial Perfusion Imaging for the Diagnosis of Coronary Artery Disease. AHA: Cardiovascular Disease, Epidemiology and Prevention March 2007.

[6] James K. Min, Fay Lin, Antonio Legorreta, Ning Kang, Amanda Gilmore. Hospitalization Outcomes in Individuals Undergoing Coronary Computed Tomographic Angiography, Myocardial Perfusion Imaging or Cardiac Angiogram Catheterization for the Diagnosis of Coronary Artery Disease. AHA: Cardiovascular Disease, Epidemiology and Prevention March 2007. See also footnotes: 3, 4, 5, 7 and 8.

[7] See 3 above.

[8] Gopal A, Ahmadi N, Young E, Weinberg N, Tiano J, Amelia Y, Flores M, Witteman AM, Holland TC, Mao SS, Fischer H, Budoff MJ. Cardiac computed tomographic angiography in an outpatient setting: an analysis of Patient Outcomes over a 30 month period. J Am Coll. Cardiol 2007; 49:114A; and

Lesser JR, Flygenring B, Knickelbine T, et al. Clinical utility of coronary CT angiography: coronary stenosis detection and prognosis in ambulatory patients. Catheter Cardiovasc Interv. 2007 Jan; 69(1): 64-72.

[9] Cole JH, Chunn VM, Morrow JA, et al., Cost implications of initial computed tomography angiography as opposed to catheterization in patients with mildly abnormal or equivocal myocardial perfusion scans. Journal of Cardiac Computed Tomography July 2007; 1(1):21-26.

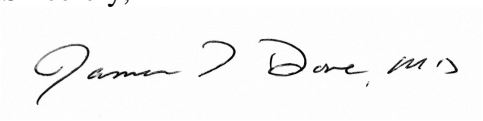
images. This study demonstrated an average savings of $1454/patient when using coronary CTA as the "gatekeeper" for invasive coronary angiography[10].

*****

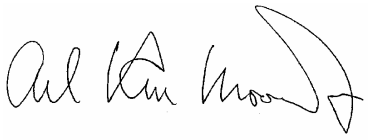
The ACC and ACR reiterate their appreciation to CMS for the opportunity to comment on the NCA for Computed Tomographic Angiography. Our organizations are eager to assist CMS in developing any further changes to this policy, and would welcome such an opportunity. If you have any questions, please contact:

- Sergio Santiviago, Senior Specialist, Regulatory Affairs, at ssantivi@acc.org or Rebecca Kelly, Director of Regulatory Affairs, at rkelly@acc.org;
- Anita Pennington, Economics and Health Policy Analyst, at apennington@acr.org or Maurine Dennis, Senior Director of Economics and Health Policy, at msdennis@acr.org.

Sincerely,



James T. Dove, M.D., F.AC.C.
President



Arl Van Moore, Jr., M.D.
Chairman ACR Board of Chancellors
President Charlotte Radiology

cc: Jack Lewin, M.D., CEO
Harvey L. Neiman, M.D., FACR, Executive Director

[10] See 9 above.

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July 13, 2007

Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

Re: NCA Tracking Sheet for Cardiac Computed Tomographic Angiography (CAG-00385N)

Dear Ms. Norwalk:

Midatlantic Cardiovascular Associates, P.A. appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Agency's analysis of Cardiac Computed Tomographic Angiography (CCTA).

Midatlantic represents 75 private practice cardiologists in the greater Baltimore area. Our physicians are using non-invasive CCTA as a valuable tool to diagnose and treat Coronary Artery Disease (CAD) and believe CCTA provides superior analysis of the coronary arteries. We have been using CCTA activity for over 1 year, and have found it quite beneficial. Recently we performed a scan on a gentleman for multiple CAD risk factors and no symptoms. It was found that he had severe triple vessel disease requiring emergent bypass surgery. In the opposite vain I recently had a patient with a positive nuclear stress test suggestive of severe disease. The patient was begun on multiple medications and told she needed a cardiac catherization. She refused as she had a family member who had horrific complications following this catherization (a stroke), because of this we performed a CCTA which revealed no evidence of coronary artery disease. Based on this case we have saved a hug amount of money by saving the cost of this cath. She was taken off all her cardiac medications, again a major cost savings. We no longer label this patient with CAD (what a mental relief) and saved any potential complications which can occur from cardiac catherization. The patients we have done had nothing but positive comments. It only takes 1 hour to perform with minimal risk and a wealth of knowledge is acquired. By using this test we are individualizing care not treating patients just based on risk factors and cholesterol levels. We are treating if they have heart disease. We have taken many people off medications that did not need it (saving cost and side effects). We have also found many patients who had a very low Framington Risk and would not be usually treated but were found to have severe disease thus saving lives. Several peer-reviewed studies support this finding and cardiologists and the patients they serve are eager to avail themselves of this potentially life-saving technology.

In 2006, all 50 states, including Maryland, adopted Local Coverage Decisions (LCD) for CCTA that include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA. **Our practice believes it is critical that CMS allow its current process of utilizing local experts to adopt LCDs and refrain from issuing National Coverage Decisions.**

As a non-invasive procedure, CCTA costs less than the diagnostic alternative of interventional catheterization, and has improved patient diagnosis and outcomes with reduced morbidity/mortality. The accuracy and sensitivity of CCTA technology can reduce physicians' reliance on invasive catheterization to diagnose CAD, and thus may save Medicare costs associated with the more invasive procedure. This is borne out on review of the CCTA registries that several of our practices maintain. Peer reviewed abstracts and articles, utilizing these registry data points, conclude that CCTA is not an additive test and can exhibit cost savings from $489 to $1,454 per patient.

Midatlantic recognizes that inappropriate utilization of CT technology is a concern of the medical community, CMS, and Congress. Our physicians believe that **accreditation of CT labs,**

credentialing of physicians, and utilization of the published appropriateness criteria would significantly reduce the potential for inappropriate use of CCTA and support these endeavors. It is important to note the leading position of the cardiology specialty clinical and credentialing organizations, such as the American College of Cardiology, SCCT, ASNC, SCAI and the Intersocietal Accreditation Commission, which have completed clinical guidelines, physician credentialing criteria, and lab accreditation processes specific to CCTA. We encourage Medicare to continue looking to them for assistance.

In summary, Midatlantic Cardiovascular Associates, P.A. requests that CMS:

1. Support the continued use of the states' Local Coverage Decisions on CCTA.
2. Use professionally accepted credentialing and appropriateness guidelines for CCTA, including those set forth by the American College of Cardiology. This will standardize appropriateness criteria and discourage inappropriate use of CCTA.
3. Support the model LCD proposed by the American College of Cardiology or the current National Government Services' LCD, which in particular identify clinically appropriate indications and diagnoses while addressing appropriate technical requirements.

Thank you for the opportunity to comment on the CCTA National Coverage Analysis. Please contact me at 410-876-7772 or at sjerome@midatlanticcardio.com for more information.

Sincerely,

Scott Jerome, D.O.
CCTA Program Director

CARDIOLOGY ADVOCACY ALLIANCE

National leadership on issues that affect cardiovascular patients and their physicians 734.878.2108 ▪ cardiologycaa.com

July 13, 2007

Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

Re: NCA Tracking Sheet for Cardiac Computed Tomographic Angiography (CAG-00385N)

Dear Ms. Norwalk:

On behalf of our 4,500 members, the Cardiology Advocacy Alliance (CAA) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Agency's analysis of Cardiac Computed Tomographic Angiography (CCTA).

The CAA represents private practice cardiologists nationwide. Many of our members are using non-invasive CCTA as a valuable tool to diagnose and treat Coronary Artery Disease (CAD) and believe CCTA provides superior analysis of the coronary arteries. Several peer-reviewed studies support this finding and cardiologists and the patients they serve are eager to avail themselves of this potentially life-saving technology.

In 2006, all 50 states adopted Local Coverage Decisions (LCD) for CCTA that include appropriate clinical indications, diagnoses, and technical requirements for the performance of CCTA. **CAA believes it is critical that CMS allow its current process of utilizing local experts to adopt LCDs and refrain from issuing National Coverage Decisions.**

As a non-invasive procedure, CCTA costs less than the diagnostic alternative of interventional catheterization, and has improved patient diagnosis and outcomes with reduced morbidity/mortality. The accuracy and sensitivity of CCTA technology can reduce physicians' reliance on invasive catheterization to diagnose CAD, and thus may save Medicare costs associated with the more invasive procedure. This is borne out on

review of the CCTA registries that several of our practices maintain. Peer reviewed abstracts and articles, utilizing these registry data points, conclude that CCTA is not an additive test and can exhibit cost savings from $489 to $1,454 per patient.

CAA recognizes that inappropriate utilization of CT technology is a concern of the medical community, CMS, and Congress. Our members believe that **accreditation of CT labs, credentialing of physicians, and utilization of the published appropriateness criteria would significantly reduce the potential for inappropriate use of CCTA** and support these endeavors. It is important to note the leading position of the cardiology specialty clinical and credentialing organizations, such as the American College of Cardiology, SCCT, ASNC, SCAI and the Intersocietal Accreditation Commission, which have completed clinical guidelines, physician credentialing criteria, and lab accreditation processes specific to CCTA. We encourage Medicare to continue looking to them for assistance.

In summary, CAA requests that CMS:

1. Support the continued use of the states' Local Coverage Decisions on CCTA.
2. Use professionally accepted credentialing and appropriateness guidelines for CCTA, including those set forth by the American College of Cardiology. This will standardize appropriateness criteria and discourage inappropriate use of CCTA.
3. Support the model LCD proposed by the American College of Cardiology or the current National Government Services' LCD, which in particular identify clinically appropriate indications and diagnoses while addressing appropriate technical requirements.

Thank you for the opportunity to comment on the CCTA National Coverage Analysis. Please contact CAA Executive Director Margo Burrage at mburrage@cardiologycaa.com or 734.878.2108 for more information.

Sincerely,

Ann E. Honeycutt
CAA President

Stuart A. Winston, DO
CAA Vice President of Medical Affairs

July 11, 2007

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mailstop C1-09-06
Baltimore, MD 21244-1850

RE: National Coverage Analysis for Computer Tomographic Angiography
CAG-00385N

VIA: Electronic Submission

Dear Doctor Phurrough:

Thank you for providing Bracco Diagnostics Inc. with this opportunity to submit comments on the National Coverage Analysis (NCA) for Computed Tomographic Angiography (CTA). Bracco Diagnostics Inc. is a global manufacturer of contrast imaging agents and radiopharmaceuticals used in medical imaging procedures. The products that we offer are used in outpatient hospital procedures performed in radiology departments, cardiac catheterization laboratories, and nuclear medicine departments across the United States.

The Centers for Medicare and Medicaid Services (CMS) opened the NCA on CTA on June 13, 2007 and indicated that it sought evidence to validate CTA as a noninvasive method, using intravenous contrast, to visualize the coronary arteries (or other vessels) using high resolution, high speed computed tomography (CT) for the following potential uses:

1) A substitute for invasive coronary angiography and

2) Evaluation of chest pain in the emergency room.

We believe that existing and developing clinical evidence increasingly demonstrates that CTA is a useful complement to invasive coronary angiography and a valuable tool for evaluating chest pain evaluation in the Emergency Department (ED).

CTA Substitute for Invasive Coronary Angiography

While coronary angiogram is currently the gold standard for detecting coronary artery stenosis, CTA has consistently shown its ability to rule out significant narrowing of the major coronary arteries and can non-invasively detect soft plaque in the walls that has not yet hardened but might otherwise lead to future cardiac problems.

CTA has been demonstrated to provide quantitative measures of coronary artery calcified plaque (CACP) and non-calcified plaque (NCP). CACP, as determined by cardiac CT, documents the presence of coronary atherosclerosis, identifies individuals at elevated risk for myocardial infarction (MI) and Cardiovascular Disease (CVD) death, and adds significant predictive ability to the Framingham Score (an index of traditional CVD risk factors). Data suggest that cardiac CT may improve risk prediction, especially in individuals determined to be at intermediate risk according to the NCEP ATP III criteria and for whom decisions concerning prevention strategies may be altered based on the test results. The use of cardiac CT angiography for noninvasive assessment of lumen stenosis in symptomatic individuals has the potential to significantly alter the management of CAD and current diagnostic testing patterns[1].

Chest Pain in the ED

The American Heart Association (AHA) continues to report that coronary heart disease is the single leading cause of death in United States and that an estimated 325,000 people a year die of coronary attack in an ED or without being hospitalized[2].

In March 2007, the AHA published clinical literature which demonstrated that the use of sixty four (64) slice cardiac Multi-Detector Computed Tomography (MDCT) is a potentially valuable diagnostic tool in ED patients with chest pain of uncertain origin that provides early direct noninvasive visualization of coronary anatomy. In summary, 58 patients were prospectively studied (56+/-10 years of age, 36% female) with chest pain possibly ischemic in origin and no new ECG changes or elevated biomarkers. The patients underwent 64-slice contrast-enhanced MDCT, which showed normal coronary vessels (no or trivial atheroma) in 15 patients, nonobstructive plaque in 20 (MDCT-negative patients), and obstructive coronary disease (>=50% luminal narrowing) in 23 (MDCT-positive group). By further investigation (new elevation of cardiac biomarkers, abnormal myocardial perfusion scintigraphy and/or invasive angiography), acute coronary syndrome was diagnosed in 20 of the 23 MDCT-positive patients (ED MDCT sensitivity 100% [20/20], specificity 92% [35/38], positive predictive value 87% [20/23], negative predictive value 100% [35/35]). During a 15-month follow-up period, no deaths or myocardial infarctions occurred in the 35 patients discharged from the ED after initial

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[1] Budoff, Matthew J. et al., Assessment of Coronary Artery Disease by Cardiac Computed Tomography: A Scientific Statement from the American Heart Association Committee on Cardiology and Intervention, and Committee on Cardiac Imaging, Council on Clinical Cardiovascular Imaging and Intervention, Council on Cardiovascular Radiology. Publication:Circulation114;1761-1791 October 2, 2006; http://circ.ahajournals.org/cgi/reprint/114/16/1761?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=Cardiac+Computed+Tomography+&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT

[2] Rosamond, et al, February 6, 2007, Heart Disease and Stroke Statistics Update 2007, American Heart Association Circulation, http://circ.ahajournals.org/cgi/reprint/115/5/e69

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triage and MDCT findings. One patient underwent late percutaneous coronary intervention (late major adverse cardiovascular events rate, 2.8%). Overall, ED MDCT sensitivity for predicting major adverse cardiovascular events (death, myocardial infarction, or revascularization) during hospitalization and follow-up was 92% (12/13), specificity was 76% (34/45), positive predictive value was 52% (12/23), and negative predictive value was 97% (34/35). This study found that use of CTA in the ED resulted in a high positive predictive value for diagnosing acute coronary syndrome, whereas a negative MDCT study predicted a low rate of major adverse cardiovascular events and favorable outcome during follow up[3].

While there are an ample number of initiatives underway (clinical trials, publications, and data registry information) that will demonstrate the value and clinical utility of CTA, it is highly unlikely that all of the evidence needed to validate this technology would be available on or before CMS' NCA decision date of December 31, 2007. For these reasons, **we believe that CMS should implement Coverage with Evidence Development (CED) and should work with the medical specialty societies and key opinion leaders (KOL) in the field to arrive at a practical policy that brings benefit to the Medicare beneficiaries by allowing appropriate access to this revolutionary technology.**

Bracco recognizes the challenges that CMS faces in developing new coverage determinations and would welcome the opportunity to meet with CMS to expand upon our recommendations in greater detail. Thank you for the opportunity to comment on this coverage analysis. Should you have any questions, please do not hesitate to contact me via telephone at 609-514-2274 or email tamar.thompson@diag.bracco.com.

Respectfully,

Tamar Thompson, RMA, CCS, CCS-P
Manager, Health Economics

cc: Scott Hollander, Sr. Vice President, Sales and Marketing, Bracco
Cosmo DePinto, Marketing Director, X-Ray
Lynne Giglio, Product Manager, X-ray, CT Marketing
Joseph Chin, MD, CMS Coverage and Analysis Group
JoAnna Baldwin, MS, CMS Coverage and Analysis Group

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[3] *Rubinshtein, Ronen MD; et al.,* Usefulness of 64-Slice Cardiac Computed Tomographic Angiography for Diagnosing Acute Coronary Syndromes and Predicting Clinical Outcome in Emergency Department Patients With Chest Pain of Uncertain Origin., Publication: Circulation. 115(13):1762-1768, March 19, 2007. http://circ.ahajournals.org/cgi/reprint/115/13/1762?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=Cardiac+Computed+Tomography+&searchid=1&FIRSTINDEX=10&resourcetype=HWCIT

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Society of Cardiovascular Computed Tomography

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July 12, 2007

Joseph Chin, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
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ELECTRONICALLY SUBMITTED

Subject: Proposed National Coverage Analysis for Computer Tomographic Angiography (CAG-00385N)

Dear Dr. Chin:

The Society for Cardiovascular Computed Tomography (SCCT) is a professional medical membership organization that addresses all issues pertaining to the field of cardiovascular computed tomography. SCCT works to foster optimal clinical effectiveness of cardiovascular CT (CCT) through professional education, establishment of standards for quality assurance and professional training, and the development of evidence-based guidelines to enhance patient care and improve the quality of cardiovascular medical practice.

In two years of existence, SCCT has grown to more than 3,900 members, consisting of CCT experts throughout the world and has already published the first issue of its journal—The Journal of Cardiovascular CT. This unparallel growth of a new medical society is related to the unrivaled power of the new modality—centered in its ability to provide high quality noninvasive coronary angiography.

SCCT members have been responsible for the vast majority of the key published scientific and peer-reviewed literature in the field of CCT. These publications in turn form the basis of all of the practice guidelines and position statements that have been developed. In the past few years, SCCT has worked along with other physician societies to develop standards for the coverage of cardiovascular CTA including the model Local Coverage Determination (LCD), ACC Competency Statement on Cardiac CT and MR as well as the ACC/ACR Appropriateness Criteria for Cardiac CT and MR.

Based on careful consideration of the potential clinical impact on CCT imaging, we have the following concerns regarding the proposal of a NCD for CTA:

1. The negative impact of a NCD on the current LCDs already in place at the Medicare carrier level.
2. The limited indications presented as appropriate for CTA usage in a NCD.
3. CMS concern of a lack of level I clinical evidence to demonstrate improved patient health outcomes with CTA.

1. The negative impact of a NCD on the current LCDs already in place at the Medicare carrier level

From the development of the model LCD for Cardiovascular Computed Tomography and Cardiovascular Computed Tomographic Angiography in 2005 to the subsequent introduction of the Category III codes for CCTA (0144T-0151T) in January 2006, SCCT has been working with the Medicare carriers and representatives of each Carrier Advisory Committee to develop clinical indications that are most appropriate for the clinical use of this non-invasive imaging modality. A major goal of such category III codes is to allow data collection in order to explore and validate the true clinical utility of this imaging technology.

In May of 2006, SCCT provided testimony before the Medicare Coverage Advisory Committee as they reviewed the current state of evidence on noninvasive imaging techniques for diagnosing coronary artery disease. The data presented by SCCT and other societies outlined the current and emerging applications for cardiovascular CTA. The results of the meeting concluded that CT was not ready for a national coverage policy due to lack of outcome data.

During the last year, data collection and publication of clinical trials has continued regarding appropriate usage of CCT. While more data for CCT exists (*comprehensive references attached),* it is still premature to cast a national coverage policy.

If CMS were to implement a NCD with limited clinical indications, the consequences would result in a substantial reduction in the amount of clinical data being collected at the local level to assess longitudinally the benefits of CTA services in specific patient populations, and would stifle local Medicare carrier efforts to collect data. The opportunity to develop the data needed to understand the ability of the new CTA method to provide cost-effective diagnosis in a variety of clinical settings could be lost. It is untimely and potentially disruptive to the process of data gathering to implement a NCD now, while important clinical evidence is being and will be collected.

2. The limited indications presented as appropriate for CTA usage in a NCD

The current potential indications for cardiovascular CTA as suggested by the CMS are too limited. Based on the recently published consensus statements on the Appropriateness Criteria for Cardiac Computed Tomography and Cardiac Magnetic Resonance Imaging, the panel of expects, after careful evaluation of the current published evidence and practice of cardiovascular medicine, concluded that 13 clinical scenarios are appropriateness indications for performing CCT.

1. Evaluation of chest pain syndrome in patients with intermediate pre-test probability of CAD.
2. Evaluation of acute chest pain in patients with intermediate pre-test probability of CAD.
3. Evaluation of suspected coronary anomalies
4. Evaluation of chest pain syndrome in patients with uninterpretable or equivocal stress test.
5. Assessment of complex congenital heart disease including anomalies of coronaries, great vessels, and cardiac chambers and valves.
6. Evaluation of coronary arteries in patients with new onset heart failure to assess etiology.
7. Evaluation of cardiac mass
8. Evaluation of pericardial conditions
9. Evaluation of pulmonary vein anatomy prior to invasive radiofrequency ablation for atrial fibrillation.
10. Non-invasive coronary vein mapping prior to placement of biventricular pacemaker
11. Noninvasive coronary arterial mapping, including internal mammary artery, prior to repeat cardiac surgical revascularization.
12. Evaluation of suspected aortic dissection or thoracic aortic aneurysm.
13. Evaluation of suspected pulmonary embolism.

Furthermore, The American Heart Association (AHA) has recently published a Scientific Statement on Cardiac CT, and outlined two important indications that received Class IIa indications for use.[1] These were a broad application--assessment of obstructive disease in symptomatic patients (Class IIa)—and a narrow application as one of the first choice imaging modalities in the workup of known and suspected coronary anomalies (Class IIa).

The description provided by CMS in the NCA states that there are only two narrow potential uses of CTA: 1) a substitute for invasive coronary angiography and 2) evaluation of chest pain in the emergency room. By limiting the consideration to these two indications, SCCT is concerned that CMS beneficiaries will be subjected to a far more layered, expensive, and less effective diagnostic work-up than can be achieved by broader appropriate use of the powerful new modality..

3. CMS concern of a lack of level I clinical evidence to demonstrate improved patient health outcomes with CTA.

Current clinical evidence demonstrates and validates the excellent diagnostic accuracy of CTA – there is no other noninvasive test that rivals this accuracy. Negative studies avoid the risk, trauma, and expense of invasive testing.[1]

A negative test (normal coronaries or non-obstructive disease) on CTA makes the presence of significant luminal obstructive disease highly unlikely (negative predictive power on the order of 95-99%). Over the last two years, 16- and 64-row CT have been validated to have a very high negative predictive power to 'rule out' obstructive coronary artery disease in symptomatic persons in an outpatient chest pain environment, in congestive heart failure of unknown etiology and emergency department evaluation of chest pain syndromes. Currently, a multi-center trial that is designed to evaluate the usefulness of CCTA in the acute evaluation of chest pain is underway and is based on favorable preliminary data from well-designed clinical trials.[3,4]

A recent study,[2] in concordance with prior studies, demonstrates a very high negative predictive power for the presence of obstructive CAD (100% in this study). Thus, the strength of CT angiography remains in the ability to rule out disease (negative tests), so that further evaluation (including stress testing, functional tests and angiograms) can be avoided safely in these patients. Furthermore, a recent investigation has delineated the role of plaque extent, severity, composition and location as it relates to stress-induced myocardial ischemia, which now enables CTA to identify accurately not only those who no longer need further evaluation but also those that require therapeutic intervention (1). These studies suggest that coronary CTA would allow reliable triage of patients with suspected coronary artery disease, with decreased utilization of downstream testing after a normal or near normal CTA.

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[1] Budoff MJ, Achenbach S, Blumenthal RS, et al. A Scientific Statement from the American Heart Association Committee on Cardiovascular Imaging and Intervention, Council on Cardiovascular Radiology and Intervention, and Committee on Cardiac Imaging, Council on Clinical Cardiology. AHA Scientific Statement: Assessment of Coronary Artery Disease by Cardiac Computed Tomography. Circulation. 2006; 114:1761-1791

[2] Hoffmann H, Dübel HP, Laube H, et al. Triage of Patients with Suspected Coronary Artery Disease Using Multislice Computed Tomography. Acad Rad 2007:in press

3. Goldstein JA, Gallagher MJ, O'Neill William, et al. A Randomized Controlled Trial of Multi-Slice Coronary Computed Tomography for Evaluation of Acute Chest pain. A randomized controlled trial of multi-slice coronary computed tomography for evaluation of acute chest pain. J Am Coll Cardiol. 2007 Feb 27;49(8):863-71. Epub 2007 Feb 12.;

4. Hoffmann U, Nagurney JT, Moselewski F. et al. Coronary multidetector computed tomography in the assessment of patients with acute chest pain. Circulation. 2006 Nov 21;114(21):2251-60.

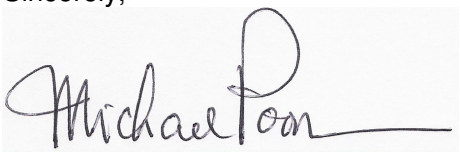
Emerging Outcome data in support of the Prognostic Value of CTA in the Outpatient Setting

While the proposed NCD considers possible application of coronary CTA in the emergency room, it does not provide for one of the most important applications of coronary CTA-its use in suspected coronary artery disease. Several published studies, studies in press, and ongoing studies, see *Attachment A*, indicate that CTA has prognostic value in outpatients with chest pain or other manifestations of suspected coronary artery disease particularly when no abnormalities are found. In one study (in press), during a 15-month follow-up of 1,127 patients presenting with chest pain, coronary CTA identified individuals at increased risk for all-cause death, with increasing risk for more severe or proximal (left main) disease. Furthermore, normal coronary CTAs identified patients at extremely low risk for death (2). Two additional outcome studies have demonstrated 100% short term event-free survival after a normal or near normal CTA (i.e., no obstructive disease seen) (7,8). Thus, these patients can be managed medically without the need for coronary angiography. This results in a significant decrease in downstream costs from invasive testing. In several preliminary analyses, coronary CTA has demonstrated substantial cost-reductions with similar health outcomes in a strategy that employed coronary CTA at the initial test compared to a traditional (approved) nuclear stress testing strategy in patients with suspected coronary artery disease (4-7). Application of the limited NCD at this time, would exclude this important, effective, cost-saving approach in the patient with symptoms that do not rise to the level of going to the emergency room.

If cardiac CTA is allowed to develop, evidence will emerge that will ultimately allow the development of an evidence-based NCD for its effective applications. Limiting the coverage applications only to those in which this evidence base is currently complete would have the effect of severely slowing the emergence of this evidence.

SCCT continues to strive for higher standards of care by supporting coordinated research efforts to promote further development and applications of CCT, and to investigate accuracy, effectiveness, and cost-effectiveness in cardiovascular diagnosis. SCCT appreciates the opportunity to share our comments on the recently proposed NCA for CTA and hopes that our expertise will provide assistance in the final decision. If you have any questions for SCCT, we are happy to assist, please feel free to contact Mia Rosenberg at (202) 375-6418.

Sincerely,



Michael Poon, MD
President, Society of Cardiovascular Computed Tomography

Attachment A: Prognostic Studies

1. Fay Lin, Leslee J. Shaw, Daniel S. Berman, Tracy Q. Callister, Jonathan W. Weinsaft, Franklin J. Wong, Massimiliano Szulc, Vishal Tandon, Peter M. Okin, Richard B. Devereux, James K. Min. Multidetector Computed Tomography Coronary Artery Plaque Predictors of Stress-Induced Myocardial Ischemia by SPECT. **Atherosclerosis (in press).**

2. James K. Min , Leslee J Shaw, Richard B Devereux, Peter M. Okin, Jonathan W. Weinsaft, Donald J. Russo, Nicholas J. Lippolis, Daniel S. Berman, Tracy Q. Callister. Prognostic Value of Multidetector Coronary CT Angiography for Prediction of All-cause Mortality. **Journal of the American College of Cardiology (in press).**

3. Leslee J. Shaw, Daniel S. Berman, James K. Min, Donna Polk, Tracy Q. Callister, Prognosis by coronary computed tomographic angiography: a comparison with myocardial perfusion SPECT. American Heart Association, Chicago, IL 2006. **(Circulation, October 2006)** (abstract).

4. James K. Min, Fay Lin, Leslee J. Shaw, Antonio Legorreta, Ning Kang, Amanda Gilmore. Costs and Clinical Outcomes Following Coronary Computed Tomography Angiography: A Matched Comparison to Myocardial Perfusion SPECT. Journal of Cardiovascular Computed Tomography, 2007 (abstract).

5. James K. Min, Fay Lin, Antonio Legorreta, Ning Kang, Amanda Gilmore. Differences in Episode Based Costs for Coronary Computed Tomographic Angiography vs. Myocardial Perfusion Imaging for the Diagnosis of Coronary Artery Disease. AHA: Cardiovascular Disease, Epidemiology and Prevention March 2007. **Circulation 115;8:e143.**

6. James K. Min, Fay Lin, Antonio Legorreta, Ning Kang, Amanda Gilmore. Hospitalization Outcomes in Individuals Undergoing Coronary Computed Tomographic Angiography, Myocardial Perfusion Imaging or Cardiac Angiogram Catheterization for the Diagnosis of Coronary Artery Disease. AHA: Cardiovascular Disease, Epidemiology and Prevention March 2007. **Circulation;115;8:e275**

7. James Min, Fay Lin, Antonio Legorreta, Ning Kang, Amanda Gilmore. Cost-Effectiveness and Clinical Outcomes of Coronary Computed Tomography Compared to Myocardial Perfusion Imaging for the Diagnosis of Coronary Artery Disease. **J Am Coll Cardiol 2007;49:107A.**

8. Gopal A, Ahmadi N, Young E, Weinberg N, Tiano J, Amelia Y, Flores M, Witteman AM, Holland TC, Mao SS, Fischer H, Budoff MJ. Cardiac computed tomographic angiography in an outpatient setting: an analysis of Patient Outcomes over a 30 month period. **J Am Coll Cardiol 2007;49:114A**

9. Lesser JR, Flygenring B, Knickelbine T, et al. Clinical utility of coronary CT angiography: coronary stenosis detection and prognosis in ambulatory patients. **Catheter Cardiovasc Interv. 2007 Jan;69(1):64-72.**

10. Sola S, Fu ZA, Obuchowski NA, Garcia MJ. Cost savings of a strategy using coronary CT angiography versus coronary angiography to evaluate patients with an abnormal stress test. Journal of Cardiovascular Computed Tomography, Washington, DC, 2007: 1: S1 (abstract)

Coding Article for Local Coverage Determination (LCD)	
Contractor Name	Wheatlands Administrative Services
Contractor Number	00650
Contractor Type	Carrier
Primary Geographic Jurisdiction	Kansas, Nebraska, N.W. Missouri
Article Database ID number	A40784
Article Title	Coding Article for Coronary Computed Tomographic Angiography (CCTA)
AMA CPT /ADA CDT Copyright Statement	CPT codes, descriptions and other data only are copyright 2006 American Medical Association (or such other data of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. CDT-4 codes and descriptions are © 2002 American Dental Association. All rights reserved.
Article Publication Date	08/18/2006
Article Beginning Effective Date	08/18/2006
Article Text	**Corresponding LCD:** Coronary Computed Tomographic Angiography (CCTA) **LCD database ID number:** L23458 Medicare does not cover screening services in the absence of signs, symptoms, or complaints under section 1862 (a)(7) of the Social Security Act. Screening used to demonstrate the presence of coronary calcification in patients and the presence of atherosclerosis is not a Medicare benefit.[3] ICD-9-CM codes V70.0-V70.9 or V82.9 should be billed in the absence of a sign, symptom, or complaint. **Unstable Angina and Acute Chest Pain Syndromes** Unstable angina: angina characterized by dissimilar or prolonged attacks or which is recent or new in onset. In hospital death rate is lower for patients <75 as well as ≥75 with unstable angina when all the following are provided:[14] 1) catheterization within 48 hours of admission 2) early aspirin 3) early beta blockers 4) early heparin 5) early glycoprotein IIb/IIIa inhibition and catheterization The test CCTA/MDCT may be reimbursed as part of the evaluation of unstable angina if percutaneous coronary intervention (PCI) or coronary angiography (CA) cannot be performed or is equivocal. The test CCTA/MDCT may also be reimbursed if one or more of the test(s) below is performed and every test(s) performed fulfills the following criteria: • Troponin T ≤ 0.01ng/ml • Troponin 1 ≤ 1.0 ng/ml • A score on the following risk formula is < 0.2. [8, 18] The calculation may be executed by clicking on the following link: Predictive Instrument for Acute Ischemic Heart Disease **Chronic Stable Angina and Chest Pain Syndromes of Uncertain Etiology** Chronic stable angina: angina characterized as completely reversible and similar attacks, which have occurred over months. There are many permutations of different diagnostic tests to evaluate chronic stable angina and coronary artery disease (CAD). Adults with typical and atypical chest pain should undergo stress testing. Standard treadmill or bicycle exercise test should be undertaken unless the patient cannot physically perform stress electrocardiogram (EKG) testing, has

left bundle branch block (LBBB), an electronic pacemaker, or the angina is unstable. Other noninvasive test(s) (NIT) provide additional information like the extent of myocardial ischemia. These other NIT(s) have equal or better likelihood ratios and expose the patient to less radiation and contrast medium.

Coronary computed tomographic angiography CCTA and MDCT may be medically necessary when all of the following conditions are fulfilled.[9,10]

1. Percutaneous coronary intervention (PCI) or coronary angiography (CA) is not planned, unable to be performed, or is equivocal
2. Exercise treadmill or bicycle electrocardiogram is equivocal or is unable to be performed, for example; because of LBBB
3. PLUS at least one of the following NIT has been attempted and the results could not be interpreted or were equivocal or none of the following tests could be performed:
    - exercise stress echocardiography
    - exercise stress echocardiography (dobutamine)
    - exercise myocardial perfusion (SPECT)
    - pharmacologic myocardial perfusion (SPECT)

Asymptomatic Coronary Artery Disease

The elective evaluation of patients with objective risks identified by the National Cholesterol Education Program (NCEP) and The Centers for Medicare and Medicaid Services change request #3411 may be reimbursed.[22]

The National Cholesterol Education Project uses the Framingham Risk Score (FRS) Calculation tool to predict a patient's 10-year risk of suffering a major cardiac event. When pre-test probability is low, a positive result from NIT is not sufficient to reclassify the patient as high risk; when the risk is high, a negative NIT is not sufficient evidence to withhold preventative intervention. Determination of the usefulness or necessity of NIT in asymptomatic patients with risk factors for coronary artery disease depends upon pre-test probability of disease[3] and the likelihood ratio (LR).

Exercise treadmill or bicycle electrocardiogram	Likelihood ratio 4.4
Electron beam CT coronary calcium score	Likelihood ratio 3.4

[3]

NIT including CCTA/MDCT is only medically necessary when the risk is 10 to 20 percent, intermediate.[1]

Computed tomography coronary calcium scoring may be medically necessary when both of the following conditions are fulfilled:

1. The patient is not diabetic – there is no medical necessity to use NIT to test asymptomatic diabetics because there is no reason to withhold recommendations for lifestyle changes and other long-term preventative measures in patients who are known to be diabetic and asymptomatic.
2. The FRS/NCEP risk is 10 to 20 percent and standard treadmill electrocardiogram or bicycle exercise EKG is not possible, safe, or the results are equivocal. The 10 year risk calculation may be performed by clicking on the following link: Framingham Scoring System - Predictive Instrument for 10 Year Risk of Heart Problems

Other uses

When CCTA/MDCT can replace CA, can avoid PCI or can significantly enhance the probability of PCI or other intervention success, it may be reimbursed. Examples of other services include the following, but the list is not a complete list:

- Evaluation of bypass grafts and graft stenosis
- Evaluation of stent restenosis. However stents cause artifacts on CCTA/MDCT. Stents should be ≥ 3.0mm to qualify for evaluation by this technology.

Cardiologists and radiologists sometimes will collaborate to provide the professional and/or technical components of CCTA/MDCT. The reason is the significant number of times incidental findings occur when CCTA/MDCT is performed.

Incidental Findings
10-50%

Examples:

- Pulmonary emboli
- Lung cancer
- Esophageal cancer
- Pseudoaneurysm left ventricle
- Hodgkin's lymphoma

3,12

Incidental findings may lead to additional testing; for example, complete chest computed tomography (CT). Additional tests may result in additional contrast medium and radiation. If the glomerular filtration rate is < 50ml/minute/1.73m^2 or the volume of contrast used in a few days is > 5ml/kg divided by the serum creatinine, the risk of acute renal failure is significantly increased. These facts contribute to the manufacturer's recommendation that physicians with training in chest CT imaging review incidental findings in CCTA/MDCT.

Acceptable Levels of Competence for Performance and Interpretation

While it is not the Carrier's intention to credential providers, Medicare does expect a satisfactory level of competence from providers who submit claims for services rendered. It is well known that substandard studies often lead to preventable repetition of studies and overutilization of services.

The acceptable levels of competence, as defined by the American College of Cardiology (ACC)/American Heart Association (AHA) Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the American College of Radiology (ACR) Clinical Statement on Noninvasive Cardiac Imaging (2005), are outlined as follows:

For the technical portion, a recommended level of competence is fulfilled when the image acquisition is obtained under all of the following conditions:

a. The service is performed by a radiologic technologist who is credentialed by a nationally recognized credentialing body (American Registry of Radiologic Technologists or equivalent) and meets state licensure requirements where applicable.
b. If intravenous beta blockers or nitrates are to be given prior to a CT coronary angiogram or calcium score, the test must be under the *direct supervision* of a certified registered nurse and physician (familiar with the administration of cardiac medications) who are available to respond to medical emergencies and it is strongly recommended that the certified register nurse and physician be ACLS certified.
c. When contrast studies are performed, the physician must provide *direct supervision* and the radiologic technologist or registered nurse administering the contrast must have appropriate training on the use and administration of contrast media.

For the professional portion, a recommended level of competence is fulfilled when the interpretation is performed by a physician meeting the following requirements:

a. The physician has appropriate additional training in CT Coronary Angiography and cardiac CT imaging equivalent to the guidelines set forth by the ACC or ACR (for example: the ACCF/AHA Clinical Competence Statement on Cardiac Imaging with Computed Tomography and Magnetic Resonance (2005) and the ACR Clinical Statement on Noninvasive Cardiac Imaging (2005)), or

b. The physician has appropriate medical staff privileges to interpret CT Coronary Angiograms at a hospital that participates in the Medicare program, and is actively training in cardiac CT (as in paragraph a). A grace period of 24 months should be allowed to acquire the necessary training beginning with the final approval activation date of this policy (October 2, 2006).

Over read

Modifiers 90 and 91 are not recognized with category III codes, "T" codes. Therefore, the physician, cardiologist, or radiologist who over reads the CCTA/MDCT will use modifier 26 for the professional component plus modifier 77 repeat procedure by another physician. The ordering physician's UPIN (NPI) must appear in box 17 and 17A of the CMS-1500 claim form.

Additional Coding Instructions

- The guidelines of the Correct Coding Initiative supersede all coding instructions in this policy.
- The diagnosis code(s) must best describe the patient's condition for which the service was performed.
- Billed services for which the provider expects a medical necessity denial should have either the GA (with signed ABN) or GZ (without signed ABN) modifier attached to the code. If the service is statutorily non-covered or without benefit category, use the GY modifier instead.
- When a CT scan without contrast is reported on the same day as a CT scan with contrast, on the same anatomical site, use the code for "without contrast followed by contrast," if there is one. Otherwise code the CT with contrast only.
- When billing for the use of low osmolar contrast material (LOCM) with contrast CT scans, both the CT scan and the contrast code should be submitted on the same claim. The line reporting the LOCM should point to the appropriate ICD-9-CM code.
- There should be no separate charge for the injection to administer the contrast. IV injection of the contrast is considered part of the CT scan.
- ICD-9-CM code V82.9 or V70.0-V70.9 should be used to indicate screening tests performed in the absence of a specific sign, symptom, or complaint.
- Hospitals, hospital-associated radiologists, ambulatory health care facilities, and physician owner/operators of mobile units may bill for mobile scans as they would for scans performed on stationary equipment.
- The name and UPIN or NPI of the referring/ordering physician or qualified nonphysician practitioner are required in Items 17 and 17a of the CMS-1500 form, or the electronic equivalent.
- CT Scans are payable in the following places of service:
  For the global and the technical component (modifier TC) - office (11), assisted living facility (13), mobile unit* (15), nursing facility (32), custodial care facility (33), independent clinic (49), community mental health center (53), and state or local public health clinics (71).
  For the professional component (modifier 26) - office (11), assisted living facility (13), mobile unit* (15), inpatient hospital (21), outpatient hospital (22), hospital emergency room (23), ambulatory surgical center (24), nursing facility (32- for Medicare patient not in a Part A stay), custodial care facility (33), independent clinic (49), community mental health center (53), and state or local public health clinics (71).
  Note: Place of service mobile unit (15) should be used for mobile units performing diagnostic or therapeutic services. Mobile units going to other sites such as SNF, adult homes, physician offices etc., should be using the site of service of the place that they are going to be performing the service, e.g. 31, 32, 33, 11, and not mobile. However, if the mobile unit is not serving an entity which could be described by an existing POS code, place of service mobile unit (15) should be used.

	• Qualifying criteria should be placed in box 19 (or narrative section). For example, Troponin T is ≤ 0.01, risk formula score is less than 0.2 or FRS risk = 16%.
Other Comments	This coding article is to be used in conjunction with the corresponding LCD. The following link will provide the Coronary Computed Tomographic Angiography (CCTA) coding guideline flowsheet. **The following are comments/responses concerning the draft LCD during the comment period June 21, 2006 - August 5, 2006:** **Comment:** Physicians commented that calcium scoring should not be excluded under all circumstances by the policy. The reason is the following. Before the complete test is performed with contrast, a calcium score is generated. If the calcium score is low, less than 80, the remainder of the test is unnecessary. The more comprehensive test, the use of contrast and additional radiation can be avoided. **Response:** The contractor did agree. Calcium scoring will be allowed when the test is indicated according to a framework outlined in the policy. Calcium scoring will be denied when it is used as a screening tool to detect risk of coronary disease according to the following: *Medicare does not cover screening services in the absence of signs, symptoms, or complaints under section 1862 (a)(7) of the Social Security Act. "Screening" used to demonstrate the presence of coronary calcification in patients and the presence of atherosclerosis is not a Medicare benefit.* **Comment:** One request was made to allow asymptomatic patients with low probability of a future coronary event and equivocal stress studies to undergo CCTA/MDCT. The policy allows asymptomatic patients with intermediate risk and equivocal stress test. **Response:** The contractor cites the study by Philip Greenland, MD. The review states: in patients with low probability of an event according to an assessment of multiple risk factors, noninvasive tests will typically not be helpful, since a positive test will not yield a probability that is high enough to justify reclassification of the risk as high.[3] Therefore, in this regard, the policy will continue to allow reimbursement for CCTA/MDCT based upon The Framingham Risk Score patients who have intermediate risks and equivocal stress tests. **Comment:** The predictive instrument for acute ischemic heart disease on page 2 of the policy initially set a value of less than 0.5 as a criteria to consider reimbursement for CCTA/MDCT. Cardiologists pointed out that a patient with acute chest pain plus ECG ST segment elevation of 1mm or more or depression of 1mm or more should undergo coronary angioplasty. Therefore, when at least these two components are present, CCTA/MDCT is not medically necessary. Coronary angiography should be undertaken. **Response:** The contractor changed the qualifying criteria based upon the predictive instrument for acute ischemic heart disease. The new qualifying value is less than 0.20. The value 0.20 is the probability of the following: • Does the patient have pain in their chest or left arm? • Does the patient exhibit an ECG ST segment with elevation of 1mm or more, or depression of 1mm or more? **Comment:** Physicians requested more clarity in the statements in the "Other Uses" section on page 6 of the policy.

Response:
The contractor edited this section. The purpose was to clarify the request that physicians consider the effects of contrast and radiation before ordering CCTA/MDCT in these cases.

Comment:
Several physicians stated in more than once locations in the policy "percutaneous coronary intervention" was used. The correct term should have been "coronary angiography".

Response:
The comments are helpful. The policy will be corrected. Throughout the policy when coronary angiography or percutaneous coronary intervention is used, the policy will state: coronary angiography (CA) and/or percutaneous coronary intervention (PCI) (CA/PCI)

Comment:
Likelihood ratios have been calculated for electron-beam computed tomography (EBCT), calcium scoring, and coronary computed tomographic angiography CCTA/MDCT. These are different tests. A commenter stated the two tests seemed to be used interchangeably. The likelihood ratio of EBCT would usually be lower than CCTA/MDCT. Therefore, the impression of the utility of CCTA/MDCT might be reduced.

Response:
Category III codes, "T" codes, use both EBCT calcium scoring and CCTA/MDCT within the narrative description of some codes; for example:

0147T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image post processing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium

On page 3 within the Likelihood ratio chart, Electron beam computed tomography will be separated from CCTA/MDCT. The positive likelihood ratio of EBCT will be 1.08-6.55.[24] The positive likelihood ratio of CCTA/MDCT is between 1.9-4.2.[25]

These results are based on the Coronary Assessment by Computed Tomographic Scanning and Catheter Angiography (CATSCAN) study. Within the study, the statement that enthusiasm should be tempered because it is uncertain these impressive findings can be replicated in centers with variable expertise. A study using a 64-slice scanner on 73 patients and which excluded 6 patients for safety and technical reasons made a similar statement. This study said different patient populations and imaging protocols comparing this small study to others is not permitted.[26]

Also in the CATSCAN study, the number of false-positive and unevaluable segments among patients with a high prevalence of coronary artery disease was greater than previously reported. This was a multicenter and multinational study. This means following CCTA/MDCT many patients would still need to proceed to conventional angiography or additional noninvasive testing in clinical practice. This is a reason CCTA/MDCT is not medically necessary unless other noninvasive tests are ambiguous or cannot be successfully performed.

The likelihood ratios of EBCT and CCTA/MDCT will be separated. The commentator's suggestion was a good one.

Concepts these ratios support are: first, other noninvasive tests already in use may provide equal or greater information about heart muscle viability. Second, some of these other noninvasive tests can be performed without using additional radiation or contrast medium. And third, if the pretest probability of myocardial ischemia is high, for example, a symptomatic patient with a calcium score > 600, the test is not medically necessary; coronary angiography should be performed.[25]

Comment:
A commentator agreed a positive EBCT would not be sufficient to reclassify an asymptomatic patient from a low risk as a high-risk patient. However, the commentator suggested a positive CCTA/MDCT would reclassify the patient as a high-risk patient.
Response:
The statement by the commentator is understandable. However, it is unproven. There are no published multicenter large population studies available to evaluate if a positive coronary computed tomographic angiography study would effectively change clinical decisions plus reduce the number of major cardiac events. Even among symptomatic patients, the large multinational Coronary Assessment by Computed Angiography (CATSCAN) study concluded: coronary angiography performed with 16 row scanners is limited by a high number of nonevaluable cases and false positives. The study found its routine use in clinical practice is not justified.[25]

The use of 64 slice technology has been studied and published using 73 consecutive patient referred because of suspected coronary artery disease (CAD) or prior to coronary artery by-pass surgery. The findings suggested improvement in diagnostic accuracy. Nevertheless, because different patient populations were evaluated, a direct comparison between 16 and 64 slice MDCT is not allowed. Published large population prospective multicenter studies will be necessary in order to demonstrate it is medically necessary to use CCTA/MDCT to test low risk patients.[26]

Comment:
Both the predictive instrument and the scoring of the Framingham risk of death or myocardial infarction were cumbersome. One suggestion was just to reference the predictive instrument for unstable angina. A second suggestion was to have Medicare claims processors add up the risk score based upon the Framingham model.
Response:
The predictive instrument as well as the Framingham risk score can be calculated within seconds. The policy contains links to each of these tools. The physician, provider, clicks on the link within the policy. The link opens the calculation tool. The provider clicks in the appropriate boxes within the tool. The calculation automatically appears for the provider. The provider may use the number as outlined in the coding article to meet some coverage criteria.

Comment:
The CCTA/MDCT should be used prior to coronary angiography (CA).
Response:
The practice guidelines for unstable angina require CA within 48 hours. In order to limit the morbidity of additional contrast, CCTA/MDCT should not precede CA in this scenario.

Comment:
For clarification, suggestions to change section titles from the following:

- Acute or Unstable Angina
- Chronic Stable Angina

	• Asymptomatic Coronary Artery Disease were made. The suggested titles were the following: • Unstable Angina and Acute Chest Pain Syndromes • Chronic Stable Angina and Chest Pain Syndromes of Uncertain Etiology • Suspected Coronary Artery Disease in Asymptomatic Individuals **Response:** The only suggestion not accepted was "Suspected Coronary Artery Disease in Asymptomatic Individuals". This was not accepted because it could be more easily misinterpreted as a screening test. Screening tests are prohibited by law in Section 1862(a)(7) of the Social Security Act. **Comment:** In the section "Asymptomatic coronary artery disease" a suggestion was made to change "CCTA/MDCT" to "computed tomography coronary calcium scoring". The appropriate test to add to the Framingham Risk Score to increase accuracy when predicting a future major coronary event is the computed tomographic coronary calcium score. The language in the policy implied the coronary computed tomographic angiography was indicated or necessary. The implication was incorrect. **Response:** The comment is correct and helpful. The change was made. **Added Sources to LCD:** 24. Schmermund A, Bailey KR, Rumberger JA et.al An algorithm for non invasive identification of angiographic three-vessel and or left main coronary artery disease in symptomatic patients on the basis of cardiac risk and electron-beam computed tomographic calcium scores J Am Coll Cardiology 1999; 33: 444-52 25. Garcia MJ, Lessick J, Hoffman MHK Accuracy of 16-Row Multidetector Computed Tomography for the Assessment of Coronary Artery Stenosis JAMA 2006; 296: 403-411 26. Leschka S, Alkadhi H, Plass A, Desbiolles L, Grüenfelder J, Marincek B, Wildermuth S, Accuracy of MSCT coronary angiography with 64 slice technology: first experience European Heart Journal; 2005: 1482-1487 27. Medicare Program Integrity Manual, Pub.100-8, Chapter 13, §13.5.4 for alternative services be tried first
Revision History for Coding Article	

Contractor Name	Wheatlands Administrative Services
Contractor Number	00650
Contractor Type	Carrier
LCD Database ID Number	L23458
LCD Title	Coronary Computed Tomographic Angiography (CCTA)
Contractor's Determination Number	200602PP
AMA CPT / ADA CDT Copyright Statement	CPT codes, descriptions and other data only are copyright 2006 American Medical Association (or such other data of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. CDT-4 codes and descriptions are © 2002 American Dental Association. All rights reserved.
CMS National Coverage Policy	• Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations. • Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary. • Title XVIII of the Social Security Act, section 1833(e). This section prohibits Medicare payment for any claim, which lacks the necessary information to process the claim. • Medicare National Coverage Determination Manual, Pub.100-3, Chapter 1, Part 4, §220.1. This section references diagnostic testing with CT scan. • Medicare Claims Processing Manual, Pub.100-4, Chapter 13, §20. This section establishes payment conditions for radiological services • Medicare Claims Processing Manual, Pub.100-4, Chapter 13, §20.1, 20.2 for payment conditions on professional components (PC) and technical components (TC) • Medicare Claims Processing Manual, Pub.100-4, Chapter 18, §100-100.7 for Cardiovascular Disease Screening • Medicare Program Integrity Manual, Pub.100-8, Chapter 13, §13.5.4 for alternative services be tried first • Medicare Contractor Beneficiary and Provider Communication Manual, Pub.100-9, Chapter 5, §20. This section addresses standards of medical/surgical practice and correct coding initiatives
Primary Geographic Jurisdiction	Kansas, Nebraska, N.W. Missouri
Oversight Region	Region VII
CMS Consortium	Midwest
Original Policy Effective Date	10/02/2006
Original Policy Ending Date	
Revision Effective Date	01/09/2007
Revision Ending Date	
Indications and Limitations of Coverage and/or Medical Necessity	Medical necessity includes directives to reduce the risk of harm to the patient. Medical necessity also incorporates with the former, a ranking or ordering of services according to their likelihood ratio as it relates to subsequent clinical decision-making. A likelihood ratio (LR) is a statistical expression of the odds that a given test result will occur in a patient with the disease compared to one without the pathologic condition.[1] Rankings of tests which evaluate coronary arteries can be found in the coding article which accompanies this policy. If the probability of the presence or absence of a disease is high, additional testing is not medically necessary to establish a diagnosis nor a treatment plan regardless of the LR.

Coronary computed tomographic angiography (CCTA) or multidetector row computed tomography (MDCT), which are the same, employ radiation, contrast medium and usually beta blockers. [2] Therefore, the medical necessity of avoiding risk of harm to the patient is based on three conditions. The conditions are the following:

- the test should not be considered medically necessary if evidence-based practice guides exist and their use would involve less exposure to radiation, contrast medium or other potential side effects of CCTA/MDCT [3, 4, 5]
- the test is not medically necessary when the pre-test knowledge is sufficient to make a reasoned clinical decision.[3] A test is not medically necessary when there is little incremental gain by performing the test and risks are associated with the test
- the test is not medically necessary when weighing factors such as likelihood ratios, the risk associated with the test, and the body of information supplied in peer reviewed journals demonstrates other tests supply more or equal information at equal or less risk respectively [3, 4, 5, 6]

Evaluation of coronary arteries using CCTA/MDCT will be divided into four areas for clarity in the policy. The division will be as follows:[3]

- Unstable angina: angina which is new, prolonged, or dissimilar to prior attacks
- Chronic stable angina: angina which is similar to previous attacks over months and completely reversible
- Asymptomatic: patients with an increased probability of coronary events based upon documented risk factors and a possibility of preventing morbidity exists
- Other: preprocedural tests to provide anatomic information and thereby increase the probability of successfully accomplishing the procedure

Unstable Angina and Acute Chest Pain Syndromes

Coronary angiography (CA) or Percutaneous coronary intervention (PCI), aggressive strategy is associated with lower morbidity and mortality in patients with unstable angina and is a recommended clinical practice guideline. [7, 18] At least one of the following assessments should be undertaken if unstable angina is suspected. Furthermore, treatment and evaluation of unstable angina should use PCI or CA, not CCTA/MDCT, when any of the following are true:

- Troponin T > 0.01ng/ml
- Troponin 1 > 1.0 ng/ml
- A score on the following risk formula is ≥ 0.2. [8, 18] The calculation may be executed by using the following formula ***or*** clicking on the following link: Predictive Instrument for Acute Ischemic Heart Disease

$$P = [1 + \exp(b_0 + \sum_{i=1}^{7} b_i X_i)]^{-1}$$

Where,

P = probability that acute ischemic heart disease is present (0 to 1)

Exp = e the base of the natural log

b_0 = a constant = –7.5698

b_i = regression coefficient

X_i = X = 1 if clinical condition$_i$ is present OR X = 2 if condition$_i$ not present

where i = 1 to 7 corresponding to the 7 conditions as follows:

1 = b_1 = 0.9988 Pain in chest or left arm.

2 = b_2 = 0.7145 Patient report of pressure, pain, or discomfort in chest as most important symptom.

3 = b_3 = 0.4187 History of a heart attack.

4 = b_4 = 0.5091 History of nitroglycerin use for chest pain.

5 = b_5 = 0.7682 Electrocardiographc ST segment with elevation of 1 mm or more or depression of 1 mm or more.

6 = b_6 = 0.8321 Electrocardiographic ST segment with elevation of 1mm or more, straightening, or depression of 1 mm or more.

7 = b_7 = 1.1278 Electrocardiographic T waves with peaking or inversion of 1 mm or more.

The test CCTA/MDCT may be performed as part of the evaluation of unstable angina if CA or PCI cannot be performed or is equivocal. Any of the following tests performed must fulfill the criteria below in order to justify coverage for CCTA/MDCT:

- Troponin T ≤ 0.01ng/ml
- Troponin 1 ≤ 1.0 ng/ml
- A score on the risk formula is < 0.2. The link to the formula is above.

Chronic Stable Angina and Chest Pain Syndromes of Uncertain Etiology

There are many permutations of different diagnostic tests to evaluate chronic stable angina and coronary artery disease (CAD). Adults with typical and atypical chest pain should undergo stress testing. Standard treadmill or bicycle exercise test should be undertaken unless the patient has left bundle branch block (LBBB), an electronic pacemaker, cannot physically perform the exercise, or the angina is unstable. As many as 30 percent of these tests may have false positive or false negative results. Noninvasive testing, NIT, may provide useful additional prognostic information compared to CCTA/MDCT. Examples of the additional information provided by NIT, and not provided by CCTA/MDCT include exercise time, inducible left ventricular dysfunction, heart rate response and most important, the extent of myocardial ischemia.

The L.R. of several NIT procedures to assess symptomatic chronic stable angina are listed as follows:

Procedure	Likelihood ratio
Exercise treadmill or bicycle electrocardiogram	2.8
Stress echocardiography	5.7
Stress echocardiography (dobutamine)	8.5
Exercise myocardial perfusion (SPECT)	9.0
Pharmacologic myocardial perfusion (SPECT)	9.0
Electron-beam computed tomography	1.08-6.55
CCTA/MDCT	1.9-4.2

[9,24,25]

Noninvasive tests, NIT for coronary artery disease including those listed above compared to CCTA/MDCT have equal or superior LR rankings, do not expose the patient to as much radiation or contrast medium and provide more information.

Coronary computed tomographic angiography CCTA and MDCT may be medically necessary when all of the following conditions are fulfilled.

1. Coronary angiography (CA) or percutaneous coronary intervention (PCI) is not planned, unable to be performed, or is equivocal
2. Exercise treadmill or bicycle electrocardiogram is equivocal or is unable to be performed, for example; because of LBBB
3. At least one of the following NIT has been attempted and the results could not be interpreted or were equivocal or none of the following tests could be performed:
    - exercise stress echocardiography
    - exercise stress echocardiography (dobutamine)
    - exercise myocardial perfusion (SPECT)
    - pharmacologic myocardial perfusion (SPECT)

Asymptomatic Coronary Artery Disease

Elective evaluation of asymptomatic patients is not to direct treatments but long-term risk and secondary prevention. Factors like family history, tobacco use, diabetes, gender, age, and the levels of cholesterol, weight and blood pressure are associated with increased long-

term risk for developing coronary artery disease.[22] Office base tools like the National Cholesterol Education Program (NECP) for non-diabetics provide estimated risk of coronary disease. The 10 year risk calculation may be performed by clicking on the following link: Framingham Scoring System - Predictive Instrument for 10 Year Risk of Heart Problems

N Engl J Med 349:5 www.nejm.org July 31, 2003

Estimate of 10-Year Risk for Men (Framingham Point Scores)

Age (yr)	Points
20-34	-9
35-39	-4
40-44	0
45-49	3
50-54	6
55-59	8
60-64	10
65-69	11
70-74	12
75-79	13

Estimate of 10-Year Risk for Women (Framingham Point Scores)

Age (yr)	Points
20-34	-7
35-39	-3
40-44	0
45-49	3
50-54	6
55-59	8
60-64	10
65-69	12
70-74	14
75-79	16

Total Cholesterol (mg/ dl)	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
<160	0	0	0	0	0
160-199	4	3	2	1	0
200-239	7	5	3	1	0
240-279	9	9	4	2	1
≥280	11	8	5	3	1

Total Cholesterol (mg/ dl)	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
<160	0	0	0	0	0
160-199	4	3	2	1	1
200-239	8	6	4	2	1
240-279	11	8	5	5	2
≥280	13	10	7	4	2

	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
Non-smoker	0	0	0	0	0
Smoker	8	5	3	1	1

	Points				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
Non-smoker	0	0	0	0	0
Smoker	9	7	7	2	1

HDL (mg/dl)	Points
≥60	-1
50-59	0
40-49	1
<40	2

HDL (mg/dl)	Points
≥60	-1
50-59	0
40-49	1
<40	2

Systolic BP (mm Hg)	Points	
	if untreated	If treated
<120	0	0
120-129	0	1
130-139	1	2
140-159	1	2
≥160	2	3

Systolic BP (mm Hg)	Points	
	if untreated	If treated
<120	0	0
120-129	1	3
130-139	2	4
140-159	3	5
≥160	4	6

	Point Total	10-Year Risk %

	Point Total	10-Year Risk %

<0	<1
0	1
1	1
2	1
3	1
4	1
5	2
6	2
7	3
8	4
9	5
10	6
11	8
12	10
13	12
14	16
15	20
16	25
≥17	≥30

10-year risk____%

<9	<1
	1
10	1
	1
12	1
13	2
14	2
15	3
16	4
17	5
18	6
19	8
20	11
21	14
22	17
23	22
24	27
≥25	≥30

10-year risk____%

Figure 1 **Framingham Scoring System for Calculating the 10-Year Risk of Major Coronary Events in Adults without Diabetes.**
HDL denotes high-density lipoprotein cholesterol, and BP blood pressure. All age ranges are given in years. To convert values for cholesterol to millimoles per liter, multiply by 0.02586. Reprinted from the National Heart, Lung, and Blood Institute.[5] [3]

When pre-test probability is low, a positive result from NIT is not sufficient to reclassify the patient as high risk; when the risk is high, a negative NIT is not sufficient evidence to withhold preventative intervention. Determination of the usefulness or necessity of NIT in asymptomatic patients with risk factors for coronary artery disease depends upon pre-test probability of disease[3] and the likelihood ratio.

Exercise treadmill or bicycle electrocardiogram	Likelihood ratio 4.4
Electron beam CT coronary calcium score	Likelihood ratio 3.4

[3]

Computed tomography coronary calcium scoring may be medically necessary when both of the following conditions are fulfilled:

1. The patient is not diabetic – there is no medical necessity to use NIT to test asymptomatic diabetics because there is no reason to withhold recommendations for lifestyle changes and other long-term preventative measures in patients who are known to be diabetic. This applies to asymptomatic diabetic patients. Symptomatic diabetic patients may be categorized as unstable angina or chronic angina.
2. The FRS/NCEP risk is 10 to 20 percent and standard treadmill electrocardiogram or bicycle exercise EKG is not possible, safe, or the results are equivocal.

Medicare does not cover screening services in the absence of signs, symptoms, or complaints under section 1862 (a)(7) of the Social Security Act. “Screening” used to demonstrate the presence of coronary calcification in patients and the presence of atherosclerosis is not a Medicare benefit.

	A published study directly assessed the additive value of coronary calcium scores with respect to the predictive value of measurements of conventional risk factors. The computed tomography coronary calcium scoring result provided little incremental predictive information.[3] Furthermore, a study of military recruits demonstrated a positive coronary computed tomography screening failed to change their lifestyle.[3] Finally, coronary calcium scoring and/or CCTA used as a screening test is not a Medicare benefit.[21,23] **Other Uses** Clinical conditions in which CCTA/MDCT may add useful incremental information include the following: • Evaluation of bypass grafts and graft stenosis with atypical symptoms and/or equivocal stress studies • Evaluation of stent restenosis. However, stents cause artifacts on CCTA/MDCT. Stents should be ≥ 3.0mm to qualify for evaluation by this technology. • Evaluation of complex congenital anomaly • Presurgical evaluation prior to biventricular pacemaker placement • Presurgical evaluation prior to non-coronary artery surgery, for example, an electrophysiologic procedure to isolate pulmonary veins for radiofrequency ablation of an a focus of arrhythmia which cannot be successfully treated by other means. • Presurgical cardiovascular analysis in patients with equivocal stress studies prior to renal or liver or kidney pancreas transplants. A published review of the risks of nephropathy associated with NIT found exceeding a volume of contrast medium of 5ml per Kg body weight divided by serum creatinine is a good predictor of nephropathy. And if glomerular filtration rate is less than 50ml per minute per 1.73m^2 alternative imaging that does not use contrast medium should be considered. Finally, multiple infusions of contrast medium over a short period of time; for example, four days, should be avoided.[4] When CCTA/MDCT and CA or PCI are used together, additional contrast is used. The physician ordering the CCTA/MDCT must document in the physician's notes and patient record the reason(s) both types of studies are medically necessary. For example, the cardiologist may be unable to complete all the desired views during PCI or CA.[11] Otherwise the CCTA/MDCT will be considered not medically necessary.
Coverage Topic	Diagnostic Tests and X-Rays, Lab Services
CPT/HCPCS Codes	0144T Computed tomography, heart, without contrast material, including image postprocessing and quantitative evaluation of coronary calcium 0145T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology 0146T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium 0147T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium 0148T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium

	0149T	Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium
	0150T	Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology in congenital heart disease
	0151T	Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing, function evaluation (left and right ventricular function, ejection-fraction and segmental wall motion) (list separately in addition to code for primary procedure)
ICD-9 Codes that Support Medical Necessity	***TRUNCATED DIAGNOSIS CODES ARE NOT ACCEPTABLE.*** ***ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM book appropriate to the year in which the service was performed.*** ***It is not enough to link the procedure code to a correct, payable ICD-9-CM code. The diagnosis or clinical signs/symptoms must be present for the procedure to be paid. Further, these ICD-9-CM codes can be used only with the conditions listed in the Indications and Limitations sections of this policy.*** 411.1 Intermediate coronary syndrome 412 Old myocardial infarction 413.0 Angina decubitus 413.1 Prinzmetal angina 413.9 Other and unspecified angina pectoris 414.00 Coronary atherosclerosis of unspecified type of vessel, native or graft 414.01 Coronary atherosclerosis of native coronary artery 414.02 Coronary atherosclerosis of autologous vein bypass graft 414.03 Coronary atherosclerosis of nonautologous biological bypass graft 414.04 Coronary atherosclerosis of artery bypass graft 414.05 Coronary atherosclerosis of unspecified type of bypass graft 414.06 Coronary atherosclerosis, of native coronary artery of transplanted heart 414.07 Coronary atherosclerosis, of bypass graft (artery) (vein) of transplanted heart 414.11 Aneurysm of coronary vessels 414.12 Dissection of coronary artery 414.8 Other specified forms of chronic ischemic heart disease 414.9 Unspecified chronic ischemic heart disease 427.31 Atrial fibrillation 427.32 Atrial flutter 427.41 Ventricular fibrillation 427.42 Ventricular flutter 745.10 Complete transposition of great vessels 745.11 Transposition of great vessels, double outlet right ventricle 745.12 Corrected transposition of great vessels 745.19 Other transposition of great vessels 745.2 Tetralogy of Fallot 745.3 Bulbus cordis anomalies and anomalies of cardiac septal closure, common ventricle 745.4 Ventricular septal defect

	745.5	Ostium secundum type atrial septal defect
	745.60	Unspecified type congenital endocardial cushion defect
	745.61	Ostium primum defect
	745.69	Other congenital endocardial cushion defect
	745.7	Cor biloculare
	745.8	Other bulbus cordis anomalies and anomalies of cardiac septal closure
	745.9	Unspecified congenital defect of septal closure
	746.00	Unspecified congenital pulmonary valve anomaly
	746.01	Congenital atresia of pulmonary valve
	746.02	Congenital stenosis of pulmonary valve
	746.09	Other congenital anomalies of pulmonary valve
	746.1	Congenital tricuspid atresia and stenosis
	746.2	Ebstein's anomaly
	746.3	Congenital stenosis of aortic valve
	746.4	Congenital insufficiency of aortic valve
	746.5	Congenital mitral stenosis
	746.6	Congenital mitral insufficiency
	746.7	Hypoplastic left heart syndrome
	746.81	Congenital subaortic stenosis
	746.82	Cor triatriatum
	746.83	Congenital infundibular pulmonic stenosis
	746.84	Congenital obstructive anomalies of heart, not elsewhere classified
	746.85	Congenital coronary artery anomaly
	746.86	Congenital heart block
	746.87	Congenital malposition of heart and cardiac apex
	746.89	Other specified congenital anomaly of heart
	746.9	Unspecified congenital anomaly of heart
	747.0	Patent ductus arteriosus
	747.41	Total congenital anomalous pulmonary venous connection
	747.42	Partial congenital anomalous pulmonary venous connection
	747.49	Other congenital anomalies of great veins
	786.05	Shortness of breath
	786.50	Unspecified chest pain
	786.51	Precordial pain
	786.59	Other chest pain
	794.30	Nonspecific abnormal unspecified cardiovascular function study
	794.31	Nonspecific abnormal electrocardiogram (ecg) (ekg)
Diagnoses that Support Medical Necessity	Not applicable	
ICD-9 Codes that DO NOT Support Medical Necessity		
ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation		
Diagnoses that DO NOT Support Medical Necessity	All ICD-9-CM codes not listed in section: ICD-9 Codes that Support Medical Necessity	
Documentation Requirements	1. ICD-9-CM diagnosis codes supporting the medical necessity must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.	

	2. Providers performing CT scans on a mobile unit must maintain a record of the attending physician's order. 3. Coronal sagittal, multiplanar, oblique, 3-Dimensional and/or Holographic reconstruction of computerized tomography, magnetic resonance imaging, or other tomographic modality (CPT codes 76376 and 76377 are effective January 1, 2006), may be considered medically unnecessary and denied if equivalent information to that obtained from the test has already been provided by another procedure (magnetic resonance imaging, ultrasound, angiography, etc.), or could be provided the CCTA/MDCT scan. 4. Each claim must be submitted with ICD-9-CM codes that reflect the condition of the patient, and indicate the reason(s) for which the service was performed. Claims submitted without ICD-9-CM codes will be returned. 5. The documentation of the study requires a formal written report, with clear identifying demographics, the name of the interpreting provider, reason for the test, an interpretive report, and copies of images. The computerized data with image reconstruction should also be maintained. 6. Documentation must be available to Medicare upon request.
Appendices	
Utilization Guidelines	
Sources of Information and Basis for Decision	1. Bielak LF, Rumberger JA, Sheedy PF et al. Probabilistic model for the prediction of angiographically defined obstructive coronary artery disease using electron beam computed tomography calcium score strata 2. Thompson RC, Thomas GS, Yasuda T et al. Potential indications for coronary angiography by computed tomography 3. Greenland P, Gaziano JM Selecting asymptomatic patients for coronary computed tomography or electrophysiologic exercise testing N Engl J Med 2003; 349: 465-73 4. Barrett BJ, Parfrey PS Preventing nephropathy induced by contrast medium N Engl J Med 2006; 354: 379-86 5. Thompson RC, Cullom SJ Issues regarding radiation dosage of cardiac nuclear and radiography procedures J Nucl Cardiol 2006; 13: 19-23 6. Morin RL, Gerber TC, McCollough CH Radiation dose in computed tomography of the heart Circulation 2003; 107: 917-922 7. Braunwald E, Antman EM, Beasley JW et al. ACC/AHA Guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction-2002 Summary article: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on the Management of Patients with Unstable Angina) Circulation 2002; 106: 1893-900 8. Pozen MW, D'Agustino RB, Selker HP et al. A predictive instrument to improve coronary care unit admission practices in acute ischemic heart diseases (a prospective multicenter trial) N Engl J Med 1984; 310: 1273-8 9. Abrams J Chronic stable angina N Engl J Med 2005; 352: 2524-33 10. Clouse ME Noninvasive screening for coronary artery disease with computed tomography is useful Circulation 2006; 113: 125-146 11. Earls J Consultations in computed tomography How to use CT in clinical practice: solving problems cardiologists face www.gemedical.com www.mhsource.com/mru release Jan 2005/expiration Jan 2008 12. Dowe DA Consultations in computed tomography The current status and future of coronary CT angiography www.gemedical.com www.mhsource.com/mru release Dec 2004/expiration Dec 2007 13. Shavelle DM, Budoff MJ, LaMont DH et al. Exercise testing and electron beam computed tomography in the evaluation of coronary artery disease J Am Coll Cardiol 200; 36: 32-8

	14. Alexander KP, Roe MT, Chen AY et al. Evolution in cardiovascular care for elderly patients with non-ST-segment elevation acute coronary syndromes: Results from the CRUSADE National Quality Improvement Initiative J Am Coll Cardiol 2005; 46: 1479-87 15. United States Agency for Health Care Research and Quality Non-Invasive Imaging for coronary artery disease (draft) April 28, 2006 16. Hoffman MH, Shi H, Schmidtz BL Noninvasive Coronary Angiography with Multislice Computed Tomography JAMA 2005; 293: 2471-78 17. Garcia MJ Noninvasive Coronary Angiography JAMA 2005; 293: 2531-32 18. Gibler WB, Cannon CP, Blomkalns AL et al. Practical Implimentation of the Guidelines for Unstable Angina/Non-ST-Segment Elevation Myocardial Infarction in the Emergency Department Circulation 2005; 111: 2699-2710 19. Local Coverage Determination (LCD) L3662 from Contractor #00803 Empire, NY 20. Local Coverage Determination (LCD) L21374 from Contractor #05130 CIGNA 21. Local Coverage Determination (LCD) L15394 from Contractor #00803 Empire 22. Transmittal 408, CR#3411, dated December 17, 2004, for Cardiovascular Disease Screening 23. Local Coding Article, A22381, and Local Coverage Determination (LCD) L3679 from Contractor #00801 HealthNow 24. Schmermund A, Bailey KR, Rumberger JA et.al An algorithm for non invasive identification of angiographic three-vessel and or left main coronary artery disease in symptomatic patients on the basis of cardiac risk and electron-beam computed tomographic calcium scores J Am Coll Cardiology 1999; 33: 444-52 25. Garcia MJ, Lessick J, Hoffman MHK Accuracy of 16-Row Multidetector Computed Tomography for the Assessment of Coronary Artery Stenosis JAMA 2006; 296: 403-411 26. Leschka S, Alkadhi H, Plass A, Desbiolles L, Grüenfelder J, Marincek B, Wildermuth S, Accuracy of MSCT coronary angiography with 64 slice technology: first experience European Heart Journal; 2005: 1482-1487 27. Medicare Program Integrity Manual, Pub.100-8, Chapter 13, §13.5.4 for alternative services be tried first 28. **Policy Rationale:** This policy was written within guidelines in the Medicare Program Integrity Manual, Pub.100-8, Chapter 13, §13.4.B to assure beneficiary access to care.
Advisory Committee Notes	This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from Radiology, Vascular Medicine, and Cardiology. Advisory Committee meeting date: July 13, 2006 Public Comment Forum meeting date: June 29, 2006
Start Date of Comment Period	06/21/2006
End Date of Comment Period	08/05/2006
Start Date of Notice Period	08/18/2006
Related Documents	This policy is to be used in conjunction with the corresponding coding article titled “Coding article for Coronary Computed Tomographic Angiography (CCTA)” Medicare Coverage Database # A40784.
LCD Attachments	

Revision History for Coronary Computed Tomographic Angiography (CCTA) – L23458	
Update Number Date	**Changes**
#1 01/09/2007	**CPT/HCPCS Codes** **Change description of codes 0144T-0151T to be compliant with the YR2007 approved definitions:** 0144T Computed tomography, heart, without contrast material, including image postprocessing and quantitative evaluation of coronary calcium 0145T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology 0146T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium 0147T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium 0148T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), without quantitative evaluation of coronary calcium 0149T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium 0150T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing; cardiac structure and morphology in congenital heart disease 0151T Computed tomography, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image postprocessing, function evaluation (left and right ventricular function, ejection-fraction and segmental wall motion) (list separately in addition to code for primary procedure)

Coronary Computed Tomographic Angiography (CCTA)

Unstable Angina and Acute Chest Pain Syndromes:
At least one of the following must be performed
- Troponin T
- Tropinin 1
- Predictive instrument for unstable angina

Each of the following tests performed must fulfill the criteria:
- Troponin T less than or equal to 0.01ng/ml
- Troponin 1 less than or equal to 1.0 ng/ml
- A score on the risk formula is < 0.2. The calculation may be executed by using the Predictive Instrument for Acute Ischemic Heart Disease. The link is available within the coding article and LCD.

If any are false, service is not allowed

If test meets criteria or when PCI or CA cannot be performed, the service is allowable

Chronic Stable Angina and Chest Pain Syndromes of Uncertain Etiology:
Stress EKG has been attempted and results are equivocal or the test cannot be performed and the reason is documented by the physician in the patient's record
PLUS
At least one of the following NIT has been attempted and the results could not be interpreted, were equivocal, or none of the following tests could be performed for reasons the physician documented in the patient's record.
- exercise stress echocardiography
- exercise stress echocardiography (dobutamine)
- exercise myocardial perfusion (SPECT)
- pharmacologic myocardial perfusion (SPECT)

If either are false, service is not allowed

If any of the above factors are true, the service is allowable

Asymptomatic Coronary Artery Disease for Non Diabetic Patients:
The FRS/NCEP risk is 10 to 20 percent and standard treadmill electrocardiogram or bicycle exercise EKG is not possible, is unsafe, or the results are equivocal. The 10 year risk calculation may be executed with the Framingham Scoring System. The link is available within the coding article and LCD.

If BOTH factors are false, service is NOT payable

If BOTH of the above factors are true, the service is payable

I have been using CTA-Coronaries since 2006 and the local hospital acquired a 64-slice MSCT scanner in March of 2007. It has been very helpful in the intermediate cardiovascular risk patients with equivocal to positive stress tests. The calcium scoring have provided important prognostic informations and the CTA-C itself have helped to delay or eliminate some potential catheterization. The unique ability to clearly define the course of anomalous coronies vessel is also very helpful in the management of these patients since some of these anomaly has a potential to cause sudden cardiac death. Thank you for your consideration.

James B. Lam,M.D.

I am a general (noninvasive) cardiologist and our group provides CTA as a diagnostic test. I am seeing things of importance I never would have seen before. A 40 yo fire fighter with chest pain and normal ekg was found to have an aortic intramural hematoma. I have been more likely to assess the aortic root in patients with bicuspid aortic valves and have uncovered important (surgical) pathology. Occult heart failure may have cad excluded without a cath and lower risk valve surgery patients can have valve surgery without coronary angiography. The technology is wonderful -- it is our responsibility to use it judiciously.

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Agree with many of the points amde by prior respondents. However data to support improved outcomes is only just beginning to appear and it will be quite a while until large multicenter studies are available that fully address the issue. However, both clinical experience at many centers and early reports such as that by Goldstein et al: A randomized controlled trial of multi-slice coronary computed tomography for evaluation of acute chest pain.J Am Coll Cardiol. 2007 Feb 27;49(8):863-71. strongly point to lowering of costs, shortening of patient hospital visits for chest pain and reduced utilization of radionuclide stress testing, which is currently reimbursed at a higher level than CTA. Our own experience at St. Francis Hospital, Roslyn, NY, a high volume cardiac center, certainly supports the findings of Goldstein et al. However, meticulous attention to appropriateness of testing, use of appropriate technology and the qualifications and training of physicians and technologists performing these studies is certainly needed.

Nathaniel Reichek MD, FACC, FAHA
Director, Research and Education, St. Francis Hospital
Professor of Medicine and Biomedical Engineering, Stony Brook University, SUNY

At our institution, the benefits coronary CTA have incontrovertibly significantly impacted the care of many patients. There is no doubt that many patients are spared diagnostic catheter angiography and prolonged hospital stays, morbidity related to catheterization, and the uncertainty accompanying chest pain in the presence of negative nuclear medicine and EKG studies. There is no other test that offers such a huge benefit for patients, hospitals, and insurers alike. Our patients and doctors recognize ccta's huge potential benefit, and are very frustrated and confused about insurer's reimbursement (or lack thereof).
The literature has confirmed the diagnostic accuracy of ccta compared to cardiac catheterization for 16-detector scanning, and even better results have been reported for 64-detector scans. There is no doubt that this is a cheaper, safer, faster alternative to catheterization, at no significant decrease in accuracy. It will only improve with time, provided that institutions can anticipate a reasonable monetery reimbursement to fund the technology investment.

Sincerely,
Juliet Fallah
CTA director at Good Samaritan Hospital, Downers Grove

We have experience with Coronary CTA for over 3 years. I have seen many people who would not have been taken to cardiac cath because of their "lack of symptoms" or results of stress test (-)

I feel that we have saved their lives and prevented untimely death as well as cost for treatment for a massive coronary.

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I personally feel that Cardiac CT with 64 slice, though not perfect is a great emerging technology which has uses in the Emergency Department to rule out CAD as a cause of chest pains. This is already a cost effective methodology. Its role in ruling out CAD in the high risk patient especially after Stents or CABG is yet to be defined. However it has also been found to be useful pre-ablation, and in making a road map pre cath in patients who have had multiple Bypasses.
The technology is ready clinical use, and would be cost effective.
Rajiv Chandra MD FACC
Alpha Medical.
Melbourne Florida.

06/28/2007

Cardiac CTA has been around in one form or another for 20 years; only the emergence of better spatial resolution by 64-slice has afforded the reality of reliable coronary assessment. CTA has a NPV of nearly 100% and has been shown to provide quantitative details of heart/vascular anatomy. To this end, the most appropriate use is to rule out obstructive disease while still providing also quantitatinve information on plaque burden itself (calcified and non-calcified plaque) AND in defining cardiac/vascular anatomy in which other tests may not be as valuable. These appropriateness criteria have been published and are supported by all active imaging organizations in the US.

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07/02

CT angiogram is a very good noninvasive technology fo diagnosis of coronary artery disease. It has made a significant impact in our group of 20 cardiologists. We perform Cath correlation quality control conferences and so far have had very good correlation.It has a great potential in managing our patients reducing the unnecessary risk of invasive strtegy. This is a diagnostic and not a therapeutic modality. Thus the outcome data should not even be a factor in using this amazing technology.

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I have personally used CT Angiography over the past 3 years. My experience has been positive.
This is based on the following:
1. The recognition of remodeling in coronary arteries and the 40% stenotic plaque which is missed by all the other modalities of cardiac testing and which is known to be a major factor in plaque rupture. This group of patients has been treated by me with pleotrophic drugs with the result that we have had no acute myocardial infarctions over this period of time in our Medicare patients.
2. I have found that the technique is extremely useful in post interventional patients to study venous and arterial bypasses, the pathology of stents and of native vessels, proximal and distal to stents.
3. While I have not been particularly impresses in the utility of calcium scans especially in the elderly, CT angiograms have been most useful in the diagnosis and management of patients, particularly in diabetics, females and patients with the Metabolic Syndrome. The recent work published in JAMA in women highlighting C-Reactive protein and family history has also been an important clue in detecting unsuspected coronary artery disease.
4. Finally, if one accepts the premises of the COURAGE Trail, the exclusion of anatomy that indicates surgery such as left main disease or extensive triple vessel disease or post interventional pathology cannot be effectively done by invasive intervention which costs financially, approximately 10 times, that of CTA and, in addition, is unacceptable to patients bearing in mind, the inconveinence and risks involved.

T.Anthony Don Michael, MD
FACC,FACP
Clinical Professor of Medicine, UCLA
President, Advanced Heart and Medical Center

07/06/2007

Robert M Steiner MD Prof of Radiology and Dir of Pulmonary and Cardiac Radiology Temple Univ Philadelphia
We have been using CTA of the coronary arteries for the last 2 years for a variety of indications including post-operative congenital heart disease, unexplained chest pain from the ED as well as physicians offices and for preparation for LA ablation and biventricular pacing . We believe this test is extremely efficatious,less time consuming ,less invasive and less expensive than invasive studies.Certainly its greatest value at this time is its high negative predictive value in the workup of the patient for chest pain .

07/11/2007

I AM THE PRESIDENT OF THE CARDIOVASCULAR SPECIALISTS, A 20 PLUS PHYSICIAN GROUP OF CADIOLOGISTS (INVASIVE, ELECTROPHYSIOLOGY, AND NONINVASIVE), VASCULAR SURGEONS, AND INTERVENTIONAL RADIOLOGY. WE ARE ACTIVELY UTILIZING CVCTA IN ALL PHASES OF OUR PRACTICE. IT IS AN IMAGING MODALITY THAT HAS CLINICALLY DEMONSTRATED ITS IMPORTANCE TIME AND TIME AGAIN. IT WILL BE A PERMANENT PART OF OUR EVALUATION AND TREATMENT OF PATIENTS AND SHOULD BE RECOGNIZEDAS SUCH BY CMS.

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