

Clinical Trials Expected to Provide CT Cardiac Insights

By Sholom Ackelsberg, General Manager, Research, Global Molecular Imaging and CT Business, GE Healthcare

Although cardiac catheterization is considered the gold standard for diagnosing coronary artery disease (CAD), it is an invasive procedure and therefore carries a slight mortality risk. Clinicians have been exploring non-invasive coronary imaging alternatives with technologically advanced equipment like 16 and 64 detector row CT with an imaging technique known as coronary CT angiography (CCTA). Systems like the GE LightSpeed® VCT have made CCTA a readily available diagnostic tool for use in helping physicians to identify people with coronary artery disease.

Acceptance of CCTA as a new standard-of-care will largely depend upon clinical proof that the new imaging modality is as good as or better than the existing gold standard and/or that it provides health outcomes benefits. Additionally, there must be sufficient reimbursement to facilitate widespread clinical use of CCTA. Reimbursement is heavily dependent upon clinical and health-economic evidence. With the guidance of medical advisors, GE is funding several multi-center clinical trials with clearly defined endpoints.

VCT 001

The aim of this study is to evaluate the accuracy and efficacy of contrast-enhanced coronary artery visualization using a state-of-the-art, 64 multidetector row CT scanner compared to conventional X-ray coronary angiography and gather the necessary clinical and financial data to model the potential impact of this technology on cardiovascular care.

ACCURACY

ACCURACY, (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography), also known as VCT002, is an open-label, prospective multi-center study designed to evaluate diagnostic performance of intravenous contrast-enhanced CCTA using the GE LightSpeed VCT scanner. This study aims to detect coronary luminal obstruction in patients with typical or atypical chest pain suspected of CAD in comparison to cardiac catheterization.

The targeted population for ACCURACY are patients with typical or atypical chest pain suspected of having CAD who have been referred for elective coronary angiography. The primary endpoint is to determine sensitivity and specificity of CCTA using the LightSpeed VCT to detect the presence or absence of at least one significant coronary luminal obstruction in the major epicardial arteries and branches.

PICTURE

The PICTURE (Perfusion Imaging and CT - Understanding Relative Efficacy) trial, also known as VCT003, is a prospective multi-center study using a contrast-enhanced cardiac computed tomography (CT) for the detection of coronary artery disease.

The primary endpoint of the study is to determine if intravenous (IV) contrast-enhanced coronary CT angiography using a 64 channel GE LightSpeed VCT scanner is non-inferior to myocardial perfusion scintigraphy (MPS) for diagnosis of CAD in symptomatic subjects at an intermediate risk of ischemic heart disease.

Approximately 300 patients at between 9 and 14 different sites (Figure 2) are being evaluated; each patient will receive a SPECT and CCTA on the GE LightSpeed VCT. If both scans are negative, the patient will be followed. If either is positive, the patient will receive cardiac catheterization as the gold standard for diagnosing CAD.

SPARC

The SPARC (Study of Myocardial Perfusion and Coronary Anatomy Imaging Roles in CAD) trial has dual components. The first study is being conducted to determine the impact of stress perfusion, CCTA, and combined perfusion-anatomy imaging on post-test resource utilization.

The primary hypothesis is that the use of combined perfusion-anatomy studies will result in reduced post-test referral to cardiac catheterization as compared to the use of stress perfusion or anatomy alone.

The second study is designed to look at the comparative incremental prognostic value and risk stratification of stress perfusion, CCTA, and combined imaging approaches. The primary hypothesis is looking at patients with known or suspected CAD and the use of a combined myocardial perfusion-coronary anatomy imaging approach as being superior to using either approach alone with respect to its incremental prognostic value. This will also determine successful risk stratification for cardiac death or nonfatal myocardial infarction.

Acute Chest Pain Study

This study, being performed at the University of Washington, looks at patients with low to intermediate risk for CAD who present to the Emergency Department with acute chest pain. Using 64 slice CCTA, the investigators are evaluating whether they can exclude obstructive CAD as a cause for cardiac chest pain. They will be looking to determine if obstructive coronary artery disease can be diagnosed nearly as accurately and with lower overall cost using 64 slice CCTA, when compared to routine methods of evaluation. The study is designed to see if multi-slice CT provides additional diagnostic and prognostic information, as well as to determine other etiologies for chest pain.

GE Healthcare is committed to further understanding the role of MDCT in clinical care. The five trials presented here, with their pivotal clinical endpoints, will hopefully set the stage for the future direction of the use of cardiac CT angiography. ■

Figure 1

ACCURACY Sites	
Site	Location
Appleton Cardiology	Appleton, WI
Arizona Heart	Phoenix, AZ
Baylor University Heart & Vascular	Dallas, TX
Capital Cardiology	Troy, NY
CardioVascular Institute of North Colorado	Greeley, CO
Columbia University	New York, NY
Fairfax Radiological Consultants	Fairfax, VA
Geisinger Medical Center	Danville, PA
Heart Center for Excellence	Kalamazoo, MI
Henry Ford Hospital	Detroit, MI
The Indiana Heart Hospital	Indianapolis, IN
Morristown Memorial	Morristown, NJ
Northeast Medical Center	Concord, NC
North Shore University Hospital	Manhasset, NY
Sacramento Heart & Vascular	Sacramento, CA
Southern Heart Center	Hattiesburg, MS
St Luke's Medical Center	Milwaukee, WI
Boston Medical Center	Boston, MA
University of Michigan	Ann Arbor, MI



Sholom Ackelsberg is General Manager, Research, Global Molecular Imaging and CT Business for GE Healthcare.

Figure 2

PICTURE Sites (as of Sep 7, 2007)	
Site	Location
Access Clinical Trials	Beverly Hills, CA
Capital Cardiology	Albany, NY
Cardiology Associates	Mobile, AL
Harbor UCLA Medical Center	Torrance, CA
Pacific Cardiology	Honolulu, HI
Sacramento Heart & Vascular	Sacramento, CA
South Denver Cardiology	Littleton, CO
Southern Heart Center	Hattiesburg, MS
The Indiana Heart Hospital	Indianapolis, IN