Rcadia COR Analyzer® System Demonstrates Potential for Coronary Artery Disease Patient Triage in Low to Moderate Risk Patients

Five Studies Presented at Society of Cardiovascular Computed Tomography Annual Scientific Meeting

Newton, MA - July 19, 2010 - Rcadia Medical Imaging today announced presentation of five studies demonstrating the potential of its COR Analyzer® System to assist in ruling out significant coronary artery stenosis (narrowing) in patients at low to intermediate risk of coronary artery disease (CAD) undergoing coronary computer tomography (cCTA). The ability to rule out disease and speed clinical decision making has great potential to reduce unneeded hospital costs, as well as improve patient care by allowing clinicians to focus on high priority patients. The studies were presented at the Annual Scientific Meeting of the Society of Cardiovascular Computed Tomography in Las Vegas.

"The growth of cCTA as a non-invasive method to evaluate suspected CAD patients has created a need to efficiently interpret the large volume cCTA images to better manage patient care in the Emergency Department (ED) and in radiology and cardiology departments," said Shai Levanon, President and CEO of Rcadia. "These data are part of a large and growing number of studies that support the use of the COR Analyzer as a powerful, complementary decision making tool for clinicians to prioritize cCTA studies, accelerate interpretation time, and provide confidence in ruling out suspected CAD patients as well as to improve interpretations by less experienced readers."

 Mr. Levanon noted that the high sensitivity and negative predictive values were consistent among these studies and previous trials, either in comparison with evaluations by "expert" clinician readers, or invasive angiography.

Triage of suspected CAD patients represents a major clinical and healthcare economic challenge in the U.S. An estimated six million patients enter the ED in the U.S. each year with chest pain. Because current diagnostic techniques are often equivocal, an estimated two million, primarily low risk patients, are admitted to the hospital for further testing at an annual cost of $10-$13 billion. In an estimated 85 percent of these patients, an acute coronary event is subsequently ruled out.

In these studies, the COR Analyzer demonstrated high negative predictive values, exceeding 97 percent in four, meaning that more than 97 percent of patients determined by the COR Analyzer System to not have significant stenosis were in agreement with a "gold standard" comparator. The COR Analyzer software interprets cCTA images in real time, with no human interaction to provide an immediate indication of whether a patient has significant (50 percent or more) stenosis.

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Key Study Details

In a multi-center study led by researchers at Stony Brook University Medical Center (Stony Brook, NY), researchers evaluated cCTA studies with the COR Analyzer from 341 patients from low, intermediate and high prevalence populations. The "results suggest that [the COR Analyzer] can be used in clinical practice to facilitate the accurate detection and exclusion of CAD on 64-slice and over CT scanners," said Michael Poon, MD, Director, Advanced Cardiac Imaging, Department of Radiology, at Stony Brook Medical Center. The COR Analyzer results "do not replace the expert analysis by the interpreting cardiologist, but rather work synergistically by combining the cardiologist's expertise with the software's capability," he said.

Using the consensus interpretations of two cardiologist expert readers as the gold standard, the COR Analyzer had a per patient sensitivity of 100 percent and a negative predictive value of 100 percent. The positive predictive value was 22 percent, 21 percent, and 38 percent for the low, moderate and high CAD prevalence groups, respectively.

Researchers at the Cardiac Study Center (Tacoma, WA), assessed the performance of the COR Analyzer in a retrospective study of 208 low risk and 75 intermediate risk patients. The COR Analyzer "exhibited very good sensitivity for significant lesions in both test groups, while maintaining the specificity at a clinically useful level," said Vinay Malhotra, MD, the study's lead investigator. The system "can add value by providing a wet read for fast triage, reading sequence prioritization, workflow optimization and boosting reader's confidence," he said.

Compared with invasive angiography, the COR Analyzer on a per patient basis showed a sensitivity and negative predictive values of 100 percent in the low risk group, and specificity and positive predictive values of 41.1 percent and 21.3 percent respectively. For the intermediate group, sensitivity and negative predictive value on a per patient basis was 97.8 percent and 90 percent, respectively, while specificity was 33.3 percent and positive predictive value was 71.4 percent.

Researchers at the Medical University of South Carolina compared evaluations of five observers with varying levels of experience. The COR Analyzer "improves reader performance for diagnosing coronary artery stenosis, especially for inexperienced readers at the per patient level," said Joseph Schoepf, MD, Professor of Radiology and Cardiology, Director of Cardiovascular Imaging at the university.

In the study, the readers of different experience levels evaluated cCTA studies in 50 patients and then revaluated the studies three months later with the COR Analyzer. The analyses were compared with quantitative catheter angiography.

Inexperienced readers' initial interpretations averaged 86 percent on a per-patient basis and improved to 100 percent with the COR Analyzer. For Intermediate and expert readers, the sensitivity remained at 93 percent and 96 percent, respectively.

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About the COR Analyzer® System

The COR Analyzer® System automatically provides - with no human interaction - an immediate indication of patients with suspected significant coronary artery disease. The COR Analyzer System processes cCTA images and generates comprehensive results and corresponding reports within minutes. The system's algorithm determines the presence of significant lesions (50 percent or more stenosis) in the coronary arteries and visualizes the results through the use of detection marks to indicate the location of candidate lesions. The COR Analyzer utilizes images from 64-slice or higher CT machines.

About Rcadia Medical Imaging

Rcadia Medical Imaging develops and markets automated image processing software products for blood vessel analysis in patients with suspected cardiovascular disease. The company's first FDA-cleared product, the COR Analyzer® System, provides fully automated, real-time analysis of Coronary CT angiography to enable the practical application of cCTA in detecting severe coronary artery disease. The COR Analyzer improves the utility of Coronary CTA studies in the emergency department to triage chest pain patients and optimizes work flow in cardiology and radiology departments. Learn more at www.rcadia.com.

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