CADScor®System
Coronary Artery Disease (CAD) Diagnostic Aid

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Unmet Need

Predictive Risk Stratification New onset stable chest pain is a common problem. Distinguishing between serious and benign chest pain is imperative, however the risk status in suspected significant coronary artery disease (CAD) is not well defined.[1]
There are many diagnostic testing options to evaluate the presence of significant coronary artery disease.[1] Many of these involve complex or invasive procedures (e.g. invasive coronary angiography), additional patient visits, the potential for increased or unnecessary healthcare system costs, and radiation exposure.[2] Nine out of ten patients assessed with stable chest pain in clinical studies do not have significant coronary artery disease.[3-5]
Using the CAD-score to risk stratify patients prior to further testing reduces unnecessary evaluation and risks. The CAD-score can thus aid the decision to initiate additional evaluations or not, or to observe the patient further prior to additional evaluations. The presence of other patient risk factors or conditions may influence this decision.[6]

Patient Access to Care Risk stratification can be especially challenging in care settings with limited cardiology resources or lack of access to diagnostic testing (i.e. rural settings, Medicaid and Medicare populations). Primary care risk stratification mitigates potential cardiology referrals access issues (i.e. lack of transportation, scheduling backlog), which may impact cardiac patient's follow up cardiac care compliance.

Technology

FDA Clearance The CADScor®System is an FDA De Novo cleared device (DEN190047) class II device, indicated for use as a diagnostic aid in symptomatic patients suspected of stable coronary artery disease (CAD) without a previous diagnosis of CAD.[7]

First-line Coronary Diagnostic Aid The CADScor®System can rapidly and accurately rule out significant coronary artery disease early in the diagnostic pathway, thus providing physicians, healthcare providers and healthcare systems with a non-invasive, first-line diagnostic aid for point-of-care risk stratification for patients who are experiencing stable chest pain to assess if additional invasive testing is indicated.[6]
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The CADScor®System Manufactured by Acarix, the CADScor®System is a point-of-care sensitive acoustics and advanced AI diagnostic aid to analyze coronary blood flow to rule out significant coronary artery disease (CAD) in patients experiencing stable chest pain.
The CADScor® System records heart sounds, murmurs, and vibration for calculation of a patient-specific score, indicating the risk of coronary stenosis, as an aid in cardiac analysis and diagnosis.[7]
The CAD-score is a patient specific heart murmur score indicative of Coronary Artery Disease (CAD)/Chronic Coronary Syndrome (CCS) for immediate risk stratification. The CAD-score can thus aid the decision to initiate additional evaluations, or to observe the patient further prior to additional evaluations.[6]

Mechanism of Action The CADScore®System uses highly sensitive acoustics and advanced AI to analyze coronary blood flow to rule out significant coronary artery disease (CAD) in patients experiencing stable chest pain.[6]

The CADScor®System is indicated as follows:
The intended use of the CADScor®System is to record heart sounds, murmurs and vibration for calculation of a patient specific score, indicating the risk of presence of coronary stenosis, as an aid in cardiac analysis and diagnosis.[7]

Published Clinical Data Several published clinical studies demonstrate the efficacy of the CADScor®System. Of note, are two peer reviewed published studies with independent patient populations (n=3977) demonstrating that a score of 20 or less indicates no significant CAD, with a negative predictive value (NPV) of 95.4%-97.2%.[8,9] The FDA labeling for the CADScor®System is an NPV of 96.2%.[6]

American College of Cardiology (ACC) Clinical Workflow Acarix collaborated with the American College of Cardiology (ACC) Innovation Program (www.acc.org/about-acc/innovation) to develop a proposed use of the CADScor®System as a first line diagnostic aid in patients with stable chest pain. (www.acarix.com/resources/downloads/us)

National Institute For Health and Care Excellence (NICE) NICE MIB defines CADScor®System as a as a stable coronary artery disease rule-out method after first clinical evaluation (clinical history, physical examination, 12-lead ECG) and before CT coronary angiography (CTCA). (www.nice.org.uk/advice/mib174/chapter/summary)

References

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