Heartflow Applauds Healthcare Stakeholders' Push for Change in How Coronary Artery Disease is First Diagnosed

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Use of coronary CTA instead of stress tests alone results in increased early initiation of preventative therapy and 41% reduction in cardiac death and myocardial infarction1

Publication in the Journal of the American College of Cardiology advocates coronary CTA to detect atherosclerosis and coronary artery blockages versus invasive imaging or stress tests in patients with stable chest pain

Adding the Heartflow Analysis to a CTA-first approach results in a significant reduction in unnecessary invasive cardiac testing, an increase in catheterization lab efficiency and a reduction in repeat non-invasive testing9

REDWOOD CITY, Calif. – October 29, 2020 — Heartflow, Inc. is highlighting a recent publication in the*Journal of the American College of Cardiology (JACC)* which advocates for the use of coronary computed tomography angiography (CTA) as the default diagnostic test for evaluating patients with stable chest pain. The article was authored by prominent healthcare stakeholders representing physician societies, provider institutions and government and commercial health plans.

Evidence from several clinical trials[1-3] has demonstrated the value of adopting a coronary "CTA-first" strategy. In the SCOT-HEART randomized controlled trial of more than 4,100 patients, the utilization of a CTA-first diagnostic approach led to a 41% reduction in cardiac death and myocardial infarction over five years and a significant increase in initiation of preventative therapy[1]. Citing results of these trials, the authors conclude that the diagnosis of stable chest pain in patients must change from detection of a perfusion abnormality to detection of atherosclerosis using a coronary CTA-first strategy.

"Transitioning to coronary CTA is essential in the U.S., and we need to remove the barriers that are impeding adoption," noted Michael Poon, M.D., Chief, Non-Invasive Cardiac Imaging, and System Director of Research, Cardiac Imaging and Clinical Transformation, Lenox Hill HospitalNorthwell Health and lead author of the *JACC* publication. "Among the barriers are the overwhelming use of SPECT myocardial perfusion imaging as compared to coronary CTA testing and 'perverse economic incentives' which underlie this pattern. Such incentives reward use of established, less effective practices as opposed to innovative technologies offering improved medical outcomes with long-term cost reduction. Despite these challenges, I remain strongly optimistic about widespread adoption, in light of the impressive clinical trial results showing the clear benefits of a CTA-first pathway for patients."

The Need for Improved Coronary Artery Disease Testing

In the U.S., cardiologists typically turn to established non-invasive tests such as stress echocardiography and nuclear single-photon emission computed tomography (SPECT) to detect perfusion abnormalities in the heart, seeking to determine which patients have coronary artery disease (CAD) and to identify who may benefit from revascularization – an invasive procedure.

As a result of the widespread use of these tools, several studies point to the need for a noninvasive test that more accurately determines who may benefit from invasive evaluation:

- About 60% of patients sent to invasive coronary angiography (ICA) do not have significant CAD.[4]
- Stress test results are not predictive of which patients had significant CAD and provided no predictive value beyond traditional cardiovascular risk factors such as high blood pressure or a history of smoking.[5]
- Patients with positive stress test results are less likely to undergo revascularization (35.2%) than patients with negative results (47.9%) or no stress test at all (40.3%).[6]

Overcoming Barriers to Adoption of Coronary CTA-first Strategy

Physicians and clinical societies in the UK, EU and Japan have already updated guidelines and implemented clinical programs, reimbursement and education to enable the switch to a coronary CTA-first strategy.

Heartflow has seen significant adoption of the CTA-first strategy in recent years, including at 75% of the top 50 heart hospitals in the U.S. as ranked by U.S. News and World Report.[8] The adoption of the CTA-Heartflow Analysis pathway has led to reduced waiting times and improved patient care, which are all critical factors especially during the pandemic when physicians and hospitals are doing everything they can to minimize the number of patients who are required to be in a hospital setting.

“We welcome this CTA-first approach which has broad support within the healthcare ecosystem globally,” said Campbell Rogers, M.D., FACC, Chief Medical Officer, Heartflow. “The benefits of coronary CTA are undeniable. Our PLATFORM trial comparing conventional strategies to coronary CTA paired with the Heartflow Analysis found that across 584 patients there was an 83% reduction in unnecessary invasive angiograms. More recently, results from the FORECAST trial show a significant reduction in unnecessary invasive cardiac testing, an increase in catheterization lab efficiency to higher levels than have been reported previously, and a large reduction in repeat non-invasive testing[9]. Combined with study results cited in the *JACC* publication, the evidence for adopting a coronary CTA-first treatment pathway, and for the added value of the Heartflow Analysis, is compelling.”

About the Heartflow FFR_{CT} Analysis

The Heartflow Analysis is a non-invasive, cardiac test for stable symptomatic patients with CAD, the leading cause of death worldwide. Starting with a standard coronary CTA, the Heartflow Analysis leverages deep learning and highly trained analysts to create a digital, personalized 3D model of the heart. The Heartflow Analysis then uses powerful computer algorithms to solve millions of complex equations to simulate blood flow and provides FFR_{CT} values along the coronary arteries. This information helps physicians evaluate the impact a blockage may be having on blood flow and determine the optimal course of treatment for each patient. A positive FFR_{CT} value (≤0.80) indicates that a coronary blockage is impeding blood flow to the heart muscle to a degree which may warrant invasive management.

Data demonstrating the safety, efficacy and cost-effectiveness of the Heartflow Analysis have been published in more than 400 peer-reviewed publications, including long-term data out to five years. The Heartflow Analysis offers the highest diagnostic performance available from a non-invasive test.[7] To date, clinicians around the world have used the Heartflow Analysis for more than 60,000 patients to aid in the diagnosis of heart disease.

About Heartflow, Inc.

Heartflow, Inc. is a digital health company uniquely positioned at the intersection of advanced artificial intelligence and healthcare to transform how heart disease is diagnosed and treated. Our non-invasive Heartflow FFR_{CT} Analysis leverages deep learning to create a personalized 3D model of the heart. By using this model, clinicians can better evaluate the impact a blockage has on blood flow and determine the best treatment for patients. Our technology is reflective of our Silicon Valley roots and incorporates decades of scientific evidence with the latest advances in artificial intelligence. The Heartflow FFR_{CT} Analysis is commercially available in the United States, Canada, Europe and Japan. For more information, visit www.Heartflow.com.

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