New JAMA Network Open Publication Demonstrates the Coronary CT-Heartflow Analysis Pathway is 'Dominant' Compared to Stress Testing in Cost-Effectiveness Analysis

December 14, 2020

REDWOOD CITY, Calif. – December 14, 2020 — Heartflow, Inc., a leader in revolutionizing precision heartcare, announced that a new cost-effectiveness analysis found a diagnostic pathway which utilizes coronary computed tomography angiography (CTA) with the Heartflow FFR_{CT} Analysis to be "dominant" (less costly and more effective) as compared to stress testing for assessing patients with coronary artery disease (CAD), the leading cause of death. These new findings were published today in JAMA Network Open.

"In the United States, more than 8.7 million symptomatic patients undergo non-invasive diagnostic testing due to suspicion of obstructive CAD each year, at an expense of $15 billion annually to the US health system. In a major change as compared to 20 years ago, relatively few of these patients (10 to 20%) have obstructive CAD but about 50% have non-obstructive CAD, which has emerged as a new and important risk factor for cardiovascular events. Test characteristics of traditional stress testing, which are still used for 95% of patients in the US, for this new mix of CAD findings are much less accurate and may result in repeat testing and inefficient use of resources or will leave CAD unrecognized in many patients," said Udo Hoffmann, MD, MPH, senior author; Associate Chair of Imaging Sciences, Chief of the Division of Cardiovascular Imaging and Director of the Cardiovascular Imaging Research Center at Massachusetts General Hospital and Professor of Radiology, Harvard Medical School. "The main finding of our cost-effectiveness analysis is that anatomic-based strategies, including coronary CTA alone and coronary CTA with the addition of FFR_{CT}, are more effective at patient selection for invasive angiography and coronary revascularization and at identifying patients in whom statin therapy may prolong lives. These findings support the recent guideline changes by the European Society of Cardiology but most importantly support broader adoption of this approach in the US, which will hopefully be reflected in the upcoming US guidelines for stable chest pain."

For this cost-effectiveness analysis, the authors utilized a Markov microsimulation-model using individual patient data from the PROMISE trial to compare three diagnostic strategies: functional testing (nuclear stress testing, stress echocardiography, or exercise treadmill testing), coronary CTA alone, and coronary CTA coupled when appropriate with the Heartflow Analysis. One strategy was considered "dominant" compared to another strategy if it provided both cost-savings as well as better clinical outcomes.

To evaluate clinical effectiveness, the authors looked at lifetime rates of heart attack and death, as well as efficiency of patient selection for invasive diagnostic coronary angiography (ICA) and revascularization, such as a stent procedure or bypass surgery. The authors found that compared to stress testing, coronary CTA with the Heartflow Analysis improved by 50% the efficiency of selecting patients for invasive testing who then required coronary stenting or bypass procedures.

To measure cost-effectiveness, the authors looked at quality adjusted life years (QALY) and the incremental cost-effectiveness ratio (ICER) of the three strategies. For this analysis, the authors assumed a Medicare reimbursement rate of $1450 for the Heartflow Analysis. Patients who were diagnosed through the pathway of coronary CTA with the Heartflow Analysis gained an additional six months of life in perfect health compared to stress testing (QALYs: 25.14 for CTA+Heartflow, 25.15 for CTA alone, and 24.68 for stress testing) and cost $767 less compared to stress testing and $1,461 less compared to CTA alone. Over a lifetime, coronary CTA alone was cost-effective compared to stress testing (ICER $2743/QALY), and coronary CTA with the Heartflow Analysis was "dominant" as it cost less and was more effective.

The authors also compared the three strategies to a "do nothing" strategy, in which patients only received medication, using a cost-effectiveness threshold of $100,000 per QALY. Compared to a "do nothing" strategy, the coronary CTA with Heartflow Analysis strategy was the most cost effective, and stress testing was of borderline cost effectiveness (CTA + Heartflow vs do-nothing, $36,968/QALY; CTA alone vs do-nothing, $59,436/QALY; stress testing vs do-nothing, $99,678/QALY).

"The finding that coronary CTA with the Heartflow Analysis is 'dominant' compared to stress testing and more cost-effective than CTA alone reinforces what we have seen in clinical trials and clinical practice," said Campbell Rogers, MD, FACC, Chief Medical Officer, Heartflow. "These findings are incredibly impactful as it means the coronary CTA with Heartflow Analysis pathway can free up valuable resources for the patients who need invasive treatment, and keep those who do not at home, while delivering clear cost savings to the healthcare system."

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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.[1] To date, clinicians around the world have used the Heartflow Analysis for more than 70,000 patients to aid in the diagnosis of heart disease.

About Heartflow, Inc.

Heartflow, Inc. is a leader in revolutionizing precision heartcare, uniquely combining human ingenuity with advanced technology. Our non-invasive Heartflow FFR_{CT} Analysis leverages artificial intelligence 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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1. Driessen, R., et al. Comparison of Coronary Computed Tomography Angiography, Fractional Flow Reserve, and Perfusion Imaging for Ischemia Diagnosis. J Am Coll Cardiol. 2019;73(2),161-73.