



Heartflow Analysis Demonstrates Highest Diagnostic Performance for Detecting Heart Disease Compared to Other Non-Invasive Tests

May 22, 2018

Two New Studies Reinforce Value of the Heartflow Analysis in Providing Functional Evaluation of Coronary Blockages and Enabling Clinicians to Make Treatment Decisions

Paris, France – May 22, 2018 – [Heartflow, Inc.](#) today announced new data from the PACIFIC trial showed that the Heartflow Analysis had the highest diagnostic performance for detecting coronary artery disease (CAD), the most common form of heart disease, when compared to other commonly used non-invasive cardiac tests. Additionally, data from the SYNTAX III Revolution trial demonstrated the utility of the Heartflow Analysis combined with coronary computed tomography angiography (CTA) in helping clinicians make revascularization treatment decisions (stenting or coronary bypass surgery) for patients with multi-vessel disease. The non-invasive Heartflow Analysis is a personalized cardiac test that aids clinicians in identifying the right treatment pathway for each patient. The results of both trials were presented during the [EuroPCR Conference](#) in Paris, France.

The PACIFIC trial included 208 patients who each underwent a coronary computed tomography angiography (CTA), SPECT, PET and routine three-vessel invasive fractional flow reserve (FFR) measurements. The Heartflow Analyses were retrospectively obtained from the coronary CTA images. On a per vessel basis, Heartflow demonstrated significantly greater diagnostic performance (0.94 as measured by area under the receiver operating characteristic curve) compared to coronary CTA (0.83, $p < 0.001$), SPECT (0.70, $p < 0.001$) and PET (0.87, $p < 0.001$). The results of this head-to-head study were presented by Dr. Roel Driessen of the VU University Medical Center. Paul Knaapen, M.D., Ph.D. was the principal investigator of the PACIFIC trial.

In the SYNTAX III trial, two heart teams, each comprised of an interventional cardiologist, cardiac surgeon and radiologist, made treatment recommendations based on either data from a coronary CTA plus Heartflow Analysis or an invasive coronary angiogram. The study, which included more than 200 patients, showed almost perfect agreement in the treatment recommendations of the heart team using coronary CTA plus Heartflow Analysis and heart team using invasive angiography. SYNTAX III also demonstrated that the Heartflow Analysis provided supplemental information to a coronary CTA, allowing physicians to understand the functional significance of each lesion, and in some cases, changing the treatment recommendation. The data were presented today by Professor Patrick W. Serruys, M.D., Ph.D., FACC, FESC, chairman of the SYNTAX III trial.

“The new data presented at EuroPCR show that the Heartflow Analysis can hold great clinical value in real-world practice for the non-invasive evaluation of coronary artery disease as it provides both anatomic and functional evaluation of coronary lesions,” said Campbell Rogers, MD, FACC, chief medical officer, Heartflow. “A Heartflow-guided pathway provides physicians with functional information that was previously only available via invasive measures, and can reduce the need for patients to undergo additional tests. Additionally, by having non-invasive data available to them, physicians can develop a treatment plan ahead of time for a more efficient procedure.”

About the Heartflow FFR_{CT} Analysis

Clinicians diagnosing someone with suspected CAD want to know as definitively as possible if the individual has a significant blockage in their coronary arteries. They also want to know the impact of that blockage on blood flow so they can best determine which treatment pathway is appropriate (e.g., medical management, stenting or coronary artery bypass grafting).

Data from a patient's non-invasive coronary CTA are securely uploaded from the hospital's system to the cloud. Heartflow leverages deep learning to create a personalized, digital 3D model of the patient's coronary arteries. The Heartflow Analysis then uses powerful computer algorithms to solve millions of complex equations to simulate blood flow and assess the impact of blockages on coronary blood flow. The Heartflow Analysis is provided via a secure online interface to offer actionable information to enable clinicians to determine the optimal course of treatment. To date, clinicians around the world have used the Heartflow Analysis for more than 20,000 patients to aid in the diagnosis of heart disease.

This technology has been demonstrated to reduce unnecessary and invasive diagnostic coronary angiography procedures, which can be associated with bleeding, stroke, major blood vessel damage and other serious complications. It also significantly reduces healthcare costs for hospitals.¹

About Heartflow, Inc.

Heartflow, Inc. is a medical technology company transforming the way 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.

1. Douglas PS, DeBruyne B, Pontone G., Patel MR, et al. One-year outcomes of FFR_{CT}-guided care in patients with suspected coronary disease: The PLATFORM Study. J Am Coll Cardiol. 2016;68(5),435-45.