Heartflow Analysis Enables Physicians to Confidently and Safely Differentiate Patients in Need of Invasive Treatment and Patients Who Can be Managed Medically for Coronary Artery Disease

August 25, 2018

Global Studies of Over 8,500 Patients Demonstrate Marked Improvement in Outcomes When Physicians Utilize the Heartflow Analysis in Diagnosis and Treatment

MUNICH, GERMANY, August 25, 2018 – Late-breaking data published and presented today confirm that the non-invasive Heartflow® FFR_{CT} Analysis enables physicians to effectively differentiate patients in need of coronary stenting or bypass surgery from those who can be managed with medications alone.

The ADVANCE Registry was published in the European Heart Journal (EHJ) and the Aarhus University Hospital experience was published in the Journal of the American College of Cardiology (JACC). Both studies were presented during the late-breaking science session today at the European Society of Cardiology (ESC) conference.

In these studies, the Heartflow Analysis changed physician management of patients and enabled physicians to determine more efficiently which patients required invasive management and which did not. The Heartflow Analysis identified a set of patients at very low risk of adverse outcomes when undergoing medical therapy, and a set whose risk was reduced when undergoing invasive management.

The ADVANCE Registry included more than 5,000 patients in the U.S., Japan, Europe and Canada. The Aarhus University Hospital experience included more than 3,600 patients in Denmark who were followed for an average of two years.

“These studies confirm the role of the Heartflow Analysis in identifying disease that other tests may miss, and in providing reassurance to patients and doctors that some blockages are not in need of invasive management,” said Campbell Rogers, MD, FACC, chief medical officer, Heartflow.

Identifying the Right Treatment for Each Patient

The Heartflow Analysis provides FFR_{CT} values along the coronary arteries, helping physicians to assess the impact of a blockage on blood flow. A positive FFR_{CT} value (≤ 0.80) indicates that a coronary blockage is impeding blood flow to the heart muscle. In both studies, patients underwent a coronary computed tomography angiogram (CTA), and when additional information was needed, a Heartflow Analysis 3D digital model was then used to help determine optimal management.

In the ADVANCE Registry, the added information contained in the Heartflow Analysis led physicians to reconsider and change management plans for two-thirds of their patients. Some who were originally scheduled to receive a coronary stent or bypass operation were safely able to avoid the procedure and be treated with medications alone, while others who would have received medications were redirected to stenting or bypass surgery.

In the Aarhus University Hospital experience, physicians were able confidently and safely to differentiate higher risk patients who required additional testing, stenting or bypass surgery from patients whose treatment required only medications.

In both studies, coronary narrowings associated with negative FFR_{CT} values (>0.80) were predominantly managed with medications alone and were associated with excellent outcomes, similar to those outcomes in patients who had no or minimal narrowings.

Enabling Treatment Decisions that Lead to Safer Outcomes

In both studies, the Heartflow Analysis helped physicians identify patients who could be treated safely without invasive testing or treatment. In the ADVANCE Registry, among more than 1,500 patients with a negative FFR_{CT} value, the vast majority received medical therapy without invasive testing or treatment, and none experienced adverse events. In contrast, when the Heartflow Analysis showed a positive FFR_{CT} value, it helped physicians identify patients who were at higher risk for death, heart attack or emergency stenting or bypass, and who would likely benefit from invasive management. In the Aarhus University Hospital experience, patients with a positive FFR_{CT} value who received medical therapy alone suffered heart attacks at a rate six times higher than that seen among patients who received a stent or underwent bypass surgery. In the ADVANCE study, patients with positive FFR_{CT} values were at 20-fold higher risk compared to those with negative FFR_{CT} values.

“The Heartflow Analysis is a tool that helps me more effectively develop treatment plans with greater confidence for my CAD patients,” said Timothy Fairbairn, MBChB, FRCP, PhD, consultant cardiologist, Liverpool Heart and Chest Hospital and first author of the ADVANCE registry paper. “Being able to use a non-invasive cardiac test to clearly differentiate which of my patients need invasive procedures or are most at-risk for adverse events is instrumental in my ability to provide them with the best care.”

About the Heartflow FFR_{CT} Analysis

Clinicians diagnosing someone with suspected coronary artery disease (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 Heartflow’s software application running in the AWS 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.

The Heartflow Analysis provides the highest diagnostic performance compared to other commonly available tests[1] and is able to help physicians identify CAD often missed by other tests. The technology also has demonstrated a reduction in unnecessary tests, such as an invasive diagnostic coronary angiogram[2], which can be associated with bleeding, stroke, major blood vessel damage and other serious complications. It also significantly reduces healthcare costs for hospitals.[3]

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. Driessen, et al. Presented at EuroPCR 2018. Nørgaard et al, Euro Radiology 2015; 25(8):2282-90
2. Douglas et al. PLATFORM Trial. Eur Heart J. 2015;36(47):3359-67
3. 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.