FFRCT RIPCORD Study: Availability of Heartflow FFRCT Analysis Changes the Management of Patients with Coronary Artery Disease

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PARIS — May 19, 2015— Adding the Heartflow® FFR_{CT} Analysis to a standard coronary CT angiogram (cCTA) may change the course of treatment in more than one third of patients with coronary artery disease, according to a study presented today at the EuroPCR 2015 conference. Results of the FFR_{CT} RIPCORD study, presented by Prof. Nick Curzen of the University Hospital Southampton, United Kingdom, further reinforces the ability of the Heartflow Analysis to aid in patient management.

The Heartflow Analysis is the first and only non-invasive imaging technology for coronary artery disease to offer physicians insight on both the extent of any arterial blockage, as well as whether it is impacting blood flow, two vital pieces of information physicians need to develop a treatment plan that is right for a patient. Using standard cCTA images, Heartflow's technology solves millions of complex equations simulating blood flow in the coronary arteries to provide mathematically computed fractional flow reserve (FFR_{CT}) values.

In the study, three experienced cardiologists reviewed cCTAs of 200 consecutive cases of patients with stable chest pain. The physicians agreed upon a plan to manage each patient: optimal medical therapy, a percutaneous coronary intervention (PCI) such as a stent, or coronary bypass surgery. In some cases, the physicians agreed that they were unable to make a decision and needed more information, such as an invasive diagnostic angiogram with associated invasive fractional flow reserve (FFR).

Next, the physicians were shown the results of the Heartflow FFR_{CT} Analysis for each case and made a second management decision incorporating these data. Adding the Heartflow Analysis changed the decision to medical therapy in 26 of the 87 cases (30 percent) that were originally recommended for a PCI. Of cases originally recommended for medical therapy, 7 of 67 (9 percent) were changed to PCI and one was changed to bypass surgery. Without the Heartflow Analysis, the physicians needed more information in 38 cases (19 percent), but with the Heartflow Analysis, there were no cases in which the physicians needed additional information.

Overall, the management plan was changed in 72 of the 200 patients (36 percent). In 16 of the 87 cases considered candidates for PCI based on the angiogram (18 percent), one or more of the target lesions was changed using the FFR_{CT} Analysis.

"It is well established that invasive FFR can refine management decisions based solely upon the angiogram for patients with chest pain," said Prof. Curzen. "This study demonstrates that the non-invasive Heartflow FFR_{CT} Analysis has the potential to become the default method for the initial assessment of many patients with cardiac-sounding chest pain by assessing both the coronary anatomy and physiology simultaneously. This could have important implications for our clinical practice and would challenge conventional care pathways."

Invasive fractional flow reserve (FFR) is seen as the gold standard in diagnosing functionally significant coronary artery disease. In patients with multi-vessel disease, an FFR-directed PCI strategy is associated with better clinical outcomes compared to angiography-directed PCI (FAME; FAME 2).[1,2] The FFR_{CT} RIPCORD study was modeled after the original RIPCORD study, in which invasive FFR altered the course of patient management in 26 percent of cases when compared to angiographic assessment alone.[3]

"Three major studies validating the Heartflow FFR_{CT} Analysis have established that it has an unmatched level of accuracy in determining, non-invasively, whether a lesion is restricting blood flow to the heart," said John H. Stevens, M.D., chairman and CEO of Heartflow. "The FFR_{CT} RIPCORD study demonstrates the profound impact that this technology can have in directing patient care."

About Heartflow

Heartflow Inc. is a personalized medical technology company dedicated to transforming the way cardiovascular disease is managed. Committed to improving outcomes, reducing costs and creating a better patient experience, Heartflow's goal is to provide healthcare professionals with actionable knowledge about each patient by combining best-in-class, non-invasive healthcare imaging with advanced, computational fluid dynamics technology and the insights of big data. Its non-invasive Heartflow FFR_{CT} Analysis helps physicians diagnose coronary artery disease and provides them with information they need to manage each patient. The Heartflow Analysis received de novo clearance from the United States Food and Drug Administration in November 2014. For more information, visit www.Heartflow.com.

1. Tonino et al., NEJM 2009, 360:213
2. De Bruyne et al., NEJM 2012, 367:991
3. Curzen et al., Circ Cardiovasc Interv. 2014, 248-255