



One-Year PLATFORM Trial Results Reinforce Benefits of the Heartflow FFR_{CT} Analysis for Assessing Coronary Artery Disease

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A Heartflow FFR_{CT}-Guided Strategy Helps Physicians Avoid Unnecessary Invasive Coronary Diagnostics

CHICAGO, Ill. – April 4, 2016 – Novel technology developed by [Heartflow, Inc.](#) significantly reduces the need for invasive procedures to diagnose patients suspected of having coronary artery disease. The Heartflow® FFR_{CT} Analysis also leads to a sustained reduction in the cost of care, according to one-year data presented today at the American College of Cardiology's 65th Annual Scientific Session (ACC.16).

The results were unveiled in a presentation on the multicenter, controlled, prospective PLATFORM (Prospective Longitudinal Trial of FFR_{CT}: Outcome and Resource Impacts) trial, which compared standard diagnostic strategies to a Heartflow-guided strategy in 584 patients with stable chest pain. The Heartflow Analysis is the only non-invasive technology to provide physicians insight into both the extent of a patient's arterial blockage and the functional impact the blockage has on blood flow.

Key findings of the presentation included that use of a Heartflow-guided strategy resulted in the cancellation of a planned invasive coronary angiogram (ICA) in 60 percent of patients. After one year, none of the 117 patients who had ICA cancelled had suffered an adverse clinical event. Further, the data showed that use of a Heartflow-guided strategy resulted in savings to the health care system of 33 percent after one year, as compared to patients who received standard care.*

"The one-year data affirms use of the Heartflow Analysis can in many patients safely eliminate the need for invasive catheterizations, and markedly reduce cost of care in patients with suspected coronary artery disease," said lead investigator Pamela Douglas, M.D., the Ursula Geller Professor at the Duke Clinical Research Institute, Duke University School of Medicine. "This represents a significant advance in the diagnosis and treatment of patients with stable chest pain, who previously may have been sent for unnecessary invasive testing to determine appropriate treatment pathways."

Studies have shown the need to improve the accuracy of non-invasive tests used to evaluate coronary artery disease. A recent study, which included data from more than 1,100 U.S. hospitals, found that 55 percent of the more than 385,000 patients with suspected coronary artery disease who underwent an ICA had no obstructive coronary disease.¹ In the PLATFORM trial, a Heartflow-guided strategy reduced the rate of ICAs without obstructive disease by more than 80 percent. The Heartflow FFR_{CT} Analysis is a web-based platform that aids clinicians in diagnosing coronary artery disease, and provides personalized, actionable information to physicians to manage each patient. FFR_{CT} technology solves millions of complex equations simulating blood flow in the coronary arteries to provide mathematically computed fractional flow reserve values from images derived from non-invasive coronary CT Angiography (cCTA). FFR_{CT} values indicate blood pressure differences around a coronary narrowing to determine whether it is likely to reduce blood flow to the heart.

"The PLATFORM trial has demonstrated that the Heartflow Analysis-guided strategy is an effective approach to determine how to optimally manage patients with suspected coronary artery disease – and that the benefits persist over the long term," said John H. Stevens, M.D., chairman and CEO of Heartflow. "We have seen a significant increase in the adoption of the Heartflow Analysis in practices around the world, and we believe the clinical and economic advantages demonstrated by this trial will further reinforce that Heartflow Analysis is an essential technology in the diagnosis and management of cardiovascular disease."

The Heartflow FFR_{CT} Analysis has been evaluated in four large, prospective clinical trials enrolling a total of more than 1,100 patients at major medical centers worldwide. It received CE mark in 2011 and U.S. Food and Drug Administration clearance in November 2014, and has been utilized in thousands of patients around the world.

About PLATFORM

PLATFORM is a multicenter, controlled, prospective, pragmatic, comparative effectiveness trial utilizing a consecutive cohort design. It included 584 patients with stable chest pain at 11 centers across Europe. The observational study evaluated the effectiveness of usual care testing, which was decided by the site, to testing utilizing cCTA and, when necessary, FFR_{CT}. Patients were divided into one of two groups – those with a planned invasive test and those with a planned non-invasive test. Patients in each group were then enrolled into one of two sequential cohorts – those who followed the usual diagnostic path and those who received the FFR_{CT}-guided strategy.^{2,3}

Enrollment was completed in November 2014. One year results released today showed that, in patients who were in the planned

invasive test group, the mean one-year per-patient cost for FFR_{CT}-guided strategy was \$8,127 vs. \$12,145 with a usual care strategy (p<0.0001), not accounting for the cost of the FFR_{CT} test.

About Heartflow Inc.

Heartflow Inc. is a personalized medical technology company seeking to transform the way cardiovascular disease is diagnosed and treated. The company's Heartflow FFR_{CT} Analysis is the first available non-invasive solution that enables a physician to more accurately evaluate whether a patient has significant coronary artery disease (CAD) based on both anatomy and physiology. The novel solution, which produces a model of the patient's coronary arteries, is well positioned to become an integral part of the standard of care for patients who are at risk for CAD because of its potential to improve clinical outcomes, improve the patient experience and reduce the cost of care. The Heartflow Analysis is commercially available in the United States, Europe and Japan. For more information visit Heartflow, Inc. .

*Not reported in the study results, mean costs remained 26 percent lower among the FFR_{CT} patients than among usual care patients (\$9,036 vs. \$12,145, p<0.0001) when factoring in the \$1,500 cost of the FFR_{CT} Analysis.

1. Patel, et al., Am Heart J 2014 Jun; 167(6): 846-52.
2. Douglas et al. Clinical outcomes of FFR_{CT}-guided diagnostic strategies versus usual care in patients with suspected coronary artery disease: the PLATFORM study. Eur Heart J 2015
3. Hlatky MA, De Bruyne B, Pontone G, et al., Quality-of-Life and Economic Outcomes of Assessing Fractional Flow Reserve With Computed Tomography Angiography: PLATFORM. [J Am Coll Cardiol. 2015 Dec 1;66\(21\):2315-23.](#)