Trial Demonstrates Heartflow FFRCT Analysis Significantly Lowers Cost of Care, Improves Quality of Life for Coronary Artery Disease

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Up to 32% reduction in cost when using FFRCT-guided treatment strategy compared to invasive coronary angiography

SAN FRANCISCO – Oct. 13, 2015 – New data shows that technology developed by Heartflow, Inc. could lower the cost of evaluating patients with suspected coronary artery disease by as much as 32 percent. The late-breaking data, presented at the annual Transcatheter Cardiovascular Therapeutics (TCT) meeting and simultaneously published in the Journal of the American College of Cardiology, also demonstrates the potential for use of the Heartflow® FFR_{CT} Analysis to improve patient quality of life.

The findings were part of the multicenter, controlled, prospective PLATFORM (Prospective Longitudinal Trial of FFR_{CT}: Outcome and Resource Impacts) trial, which included more than 580 patients. The study compared standard diagnostic strategies to the company's Heartflow Analysis, the only non-invasive technology to offer physicians insight into both the extent of a patient's arterial blockage and the impact the blockage has on blood flow.

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 stable chest pain who underwent an invasive coronary angiogram had no obstructive coronary disease.[1]

"Non-invasive coronary angiography with cardiac CT is very sensitive in detecting anatomic abnormalities, but does not evaluate whether the lesion seen by CT is actually impeding coronary blood flow," said lead investigator Mark A. Hlatky, M.D., Stanford University School of Medicine. "Our study suggests that the information about the effects of lesions on blood flow that is provided by FFR_{CT} could reduce the use of invasive coronary angiography, and thereby reduce costs, in patients who otherwise would have been scheduled for invasive procedures."

In the PLATFORM trial, 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. Cumulative medical costs for all patients were measured over 90 days using the 2015 Medicare reimbursement rates and online pharmacy costs as the standard in order to provide an accurate cost comparison.

In patients with a planned invasive test, the 90-day, per-patient cost of medical care was 32 percent lower in the FFR_{CT}-guided strategy than in the usual care strategy ($7,343 vs. $10,734, $p<0.0001$). The savings did not account for the cost of FFR_{CT} because Medicare has not set a reimbursement rate for the technology. However, the authors concluded that use of FFR_{CT} guided evaluation could be cost saving compared with invasive testing under most likely levels of reimbursement for FFR_{CT}. For example, they calculated that if reimbursement for the Heartflow Analysis were $2,100, use of the test would still save the healthcare system 20 percent over an invasive usual care strategy. In addition to the cost savings, FFR_{CT} showed greater improvement in quality of life at 90-day follow-up, as compared to baseline, than evaluation with usual non-invasive testing.

"We developed FFR_{CT} with the goal of not only improving clinical care and patient outcomes, but also driving down costs by helping to ensure that invasive procedures were reserved only for the patients who needed them," said John H. Stevens, M.D., chairman and CEO of Heartflow. "It is gratifying to see the promise of our technology repeatedly validated through clinical trials."

The health economics and quality of life data follow initial PLATFORM study results presented at the European Society of Cardiology in September and simultaneously published in the European Heart Journal.[2] The first set of data focused on the clinical impact of FFR_{CT}.

The FFR_{CT} platform was developed by combining computational fluid dynamics, image processing and big data technology to produce detailed models of a patient's cardiovascular anatomy and blood flow. 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 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.

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 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 noninvasive 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.

Enrollment was completed in November 2014. Results released today reflect all patients being followed for a minimum of 90 days. Subsequent follow up to one year is ongoing.

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 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 www.Heartflow.com.

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1. Patel, M. et. al. Am Heart J 2014;167:846-852
2. Douglas, P. et. al. Eur Heart J. 2015 (doi:10.1093/eurheartj/ehv444)