



PLATFORM Trial Shows Heartflow FFR_{CT} Analysis Significantly Decreases Unnecessary Invasive Diagnostic Testing for Coronary Artery Disease

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83% reduction in invasive tests showing no obstructive disease; revascularization rates unchanged

LONDON – Sept. 1, 2015 – A technology developed by [Heartflow, Inc.](#) has been shown to significantly reduce the use of invasive catheterization in patients with suspected coronary artery disease, according to a study presented today in a “Hot Line” session at the European Society of Cardiology annual scientific meeting in London. Led by Duke University School of Medicine researchers, the study compared standard diagnostic strategies to the Heartflow® FFR_{CT} Analysis, the only non-invasive technology available to offer physicians insight into both the extent of a patient’s arterial blockage and the impact the blockage has on blood flow.

The multicenter, controlled, prospective PLATFORM (Prospective Longitudinal Trial of FFR_{CT}: Outcome and Resource Impacts) trial, which was simultaneously published in the European Heart Journal, included more than 580 patients and demonstrated the following:

- Among patients with a planned invasive coronary angiography (ICA), 73 percent had an ICA that showed no significant blockage or obstruction;
- By comparison, only 12 percent of patients evaluated using an FFR_{CT}-guided strategy went on to have an ICA that showed no significant obstruction, a reduction of 83 percent;
- In 61 percent of patients, the use of an FFR_{CT}-guided strategy resulted in the cancellation of a planned invasive test;
- Despite the difference in the number of patients who required ICA, the rate of revascularization procedures, such as coronary stenting or bypass surgery, were similar between patients assigned to standard testing strategies (31.6 percent) and those assigned to FFR_{CT}-guided strategies (28.5 percent); and
- No clinical adverse events were reported at the 90-day follow up in patients whose physicians chose to cancel ICAs based on FFR_{CT}-guided strategy.

“The study demonstrated that by using FFR_{CT}, physicians were able to efficiently triage patients to the most appropriate care and dramatically reduce the use of invasive testing, which comes with greater risk and higher costs,” said lead investigator Pamela Douglas, M.D., the Ursula Geller Professor at the Duke Clinical Research Institute, Duke University School of Medicine. “While FFR_{CT} is a relatively new technology, this study shows that physicians and patients being evaluated for stable chest pain should consider including this new test in the course of standard diagnostics.”

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.

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

“After three major validation studies comparing the Heartflow Analysis to invasive FFR, PLATFORM is the first prospective trial designed to demonstrate the impact of the technology in real world practice,” said John H. Stevens, M.D., chairman and CEO of Heartflow. “The striking results of PLATFORM indicate that the Heartflow Analysis could represent a fundamental shift in the management of coronary artery 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.

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.

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.

1. Patel, et al., Am Heart J 2014 Jun; 167(6): 846-52.