



Positive Long-term Outcomes with Heartflow FFR_{CT} and Plaque Analysis Demonstrated in ADVANCE-DK Registry at TCT 2024

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— Data confirm the use of FFR_{CT} and Plaque Analysis helps assess long-term risks, informing more personalized and effective treatment plans for patients with coronary artery disease

– FFR_{CT} further validated in new study demonstrating diagnostic accuracy and greater ability than CCTA alone to rule out hemodynamically significant stenoses in patients with high-risk NSTEMI-ACS

WASHINGTON, D.C. — Oct. 27, 2024 — [Heartflow, Inc.](#), the global leader in non-invasive artificial intelligence (AI) heart care solutions, today announced seven-year data confirming the use of Heartflow's AI-enabled fractional flow reserve computed tomography (FFR_{CT}) and Plaque Analysis in the assessment of long-term risk of coronary artery disease (CAD) in clinically stable, symptomatic patients. The data show the Heartflow platform provides clinicians with the insights needed to anticipate and mitigate adverse events, including myocardial infarctions, in symptomatic patients with stable chest pain. The data were presented at the 36th annual Transcatheter Cardiovascular Therapeutics® (TCT) conference in Washington, D.C.

ADVANCE-DK is data from a subset of the larger [ADVANCE Registry](#), which prospectively evaluated the use of a coronary computed tomography angiography (CCTA) and FFR_{CT} diagnostic pathway in real-world settings to determine the impact on decision-making, downstream invasive coronary angiography (ICA), revascularization, and major adverse cardiovascular events (MACE). ADVANCE-DK assessed three patient sets: those with normal FFR_{CT}, those with subsequent complete revascularization (CR), and those with subsequent incomplete revascularization (IR).

Seven-year follow-up data from ADVANCE-DK demonstrates the completeness of revascularization predicts clinical outcomes and can be assessed non-invasively using coronary CCTA and FFR_{CT}.

- Patients with IR, as assessed by FFR_{CT}, had a higher long-term risk of adverse events than patients whose FFR_{CT} assessment showed CR or patients who had normal FFR_{CT} (16.2% IR versus 7.8% CR and 5.7% normal FFR_{CT}, respectively)
- The combination of plaque quantification and characterization and lesion-specific physiology from FFR_{CT} is a superior predictor of adverse cardiovascular events, through seven-year follow-up (AUC 0.73 vs 0.63 inclusive of baseline risk variables + CCTA)

"We theorized that by leveraging non-invasive FFR_{CT} we could identify critical issues that had previously gone unnoticed, such as significant coronary lesions that would likely have been mistakenly categorized as visually insignificant," said Kristian Tækker Madsen, M.D., cardiologist at University Hospital of Southern Denmark. "The prospective data with long-term follow-up in ADVANCE-DK alongside Plaque Analysis data gave us far more than that. FFR_{CT} remains valuable for patients across all categories, and the combination of FFR_{CT} and quantitative plaque data, especially after four years of follow up, can offer providers invaluable insight into a patient's long-term risks informing more personalized and effective treatment plans."

In a separate study, "Usefulness of FFR_{CT} to Exclude Hemodynamically Significant Lesions in High-Risk NSTEMI-ACS," lesion-specific FFR_{CT} was further validated in patients with non-ST-segment elevation acute coronary syndrome (NSTEMI-ACS). The authors found that the use of CCTA with or without FFR_{CT} "would have avoided 54% to 64% of unnecessary invasive assessments" in the high-risk population studied. At the lesion level, FFR_{CT} far outperformed CCTA alone in identifying significant lesions likely to benefit from revascularization (AUC 0.84 versus 0.65, $p < 0.01$), suggesting an enhanced capability to avoid unnecessary invasive coronary angiography (ICA). The data were published concurrently in the *EuroIntervention* journal in a peer-reviewed article titled "Usefulness of FFR-CT in Patients with High-risk NSTEMI-ACS." ¹

"The ADVANCE-DK data show that our technologies go beyond identifying the immediate risks of CAD to include long-term residual risks across the spectrum of the disease. Data from patients with high-risk NSTEMI-ACS further suggest lesion-specific FFR_{CT} provides an enhanced capability to avoid unnecessary invasive tests. With Heartflow, clinicians receive actionable insights and data that are currently missing from traditional non-invasive and invasive diagnostic tools," said Campbell Rogers, M.D., F.A.C.C., Chief Medical Officer of Heartflow. "We're grateful to all the participants and investigators who supported the collection of these valuable data as we build upon our clinical evidence demonstrating the value of Heartflow ONE including FFR_{CT} Analysis and AI-enabled Plaque Analysis in managing CAD."

Cardiovascular diseases are the most common cause of death globally for both men and women, yet four out of five heart attacks and strokes are preventable with lifestyle and nutrition changes if patients at high risk are identified early.¹ Understanding plaque burden – where plaque is in the coronary arteries, the amount of plaque, and the type of plaque – is one of the best ways for physicians to identify patients at high risk of death from a heart attack.²

Heartflow is dedicated to defeating heart disease through partnering with physicians to generate robust, high-quality clinical evidence. Heartflow has been adopted by more than 1,300 institutions globally and continues to strengthen its commercial presence to make this cutting-edge solution more widely available to an increasingly diverse patient population worldwide.

About Heartflow, Inc.

Heartflow is transforming precision coronary care with the only AI-powered, non-invasive integrated heart care solution across the CCTA pathway. As the pioneer of FFR_{CT}, which is now supported by the ACC/AHA Chest Pain Guideline, Heartflow continues to advance the diagnosis and management of CAD. Heartflow's suite of non-invasive technologies includes its [FFR_{CT} Analysis](#), [Roadmap™ Analysis](#) and [Plaque Analysis](#). More than 500 peer-reviewed publications have validated our approach and more importantly, our technologies have helped clinicians diagnose and manage over 250,000 patients. For more information, visit www.Heartflow.com.

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References

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