Update on Coronary CTA, Heartflow CT-FFR and Plaque Analysis

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CTA – Easy and Efficient

- 0.5-0.625 mm slices
- Single Breath-hold Imaging
- 50-60 cc Non-ionic (IODINATED) contrast
- 20 minute procedure
- 5-15 minute interpretation
- High Throughput

Radiation Dose with CT

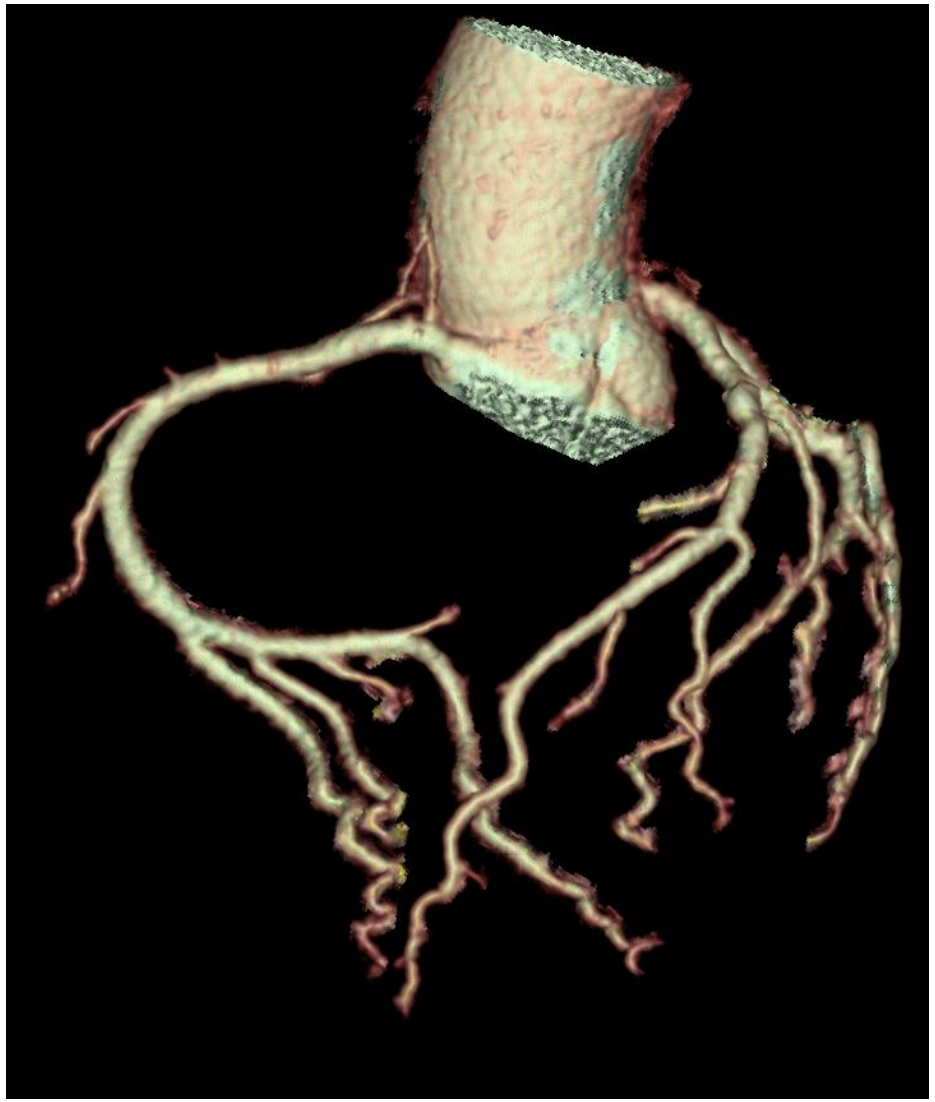
- Calcium scan: 0.5-0.6 mSv
- Mammography: 0.7 mSv
- 64 Slice CT Angiogram: 9 mSv

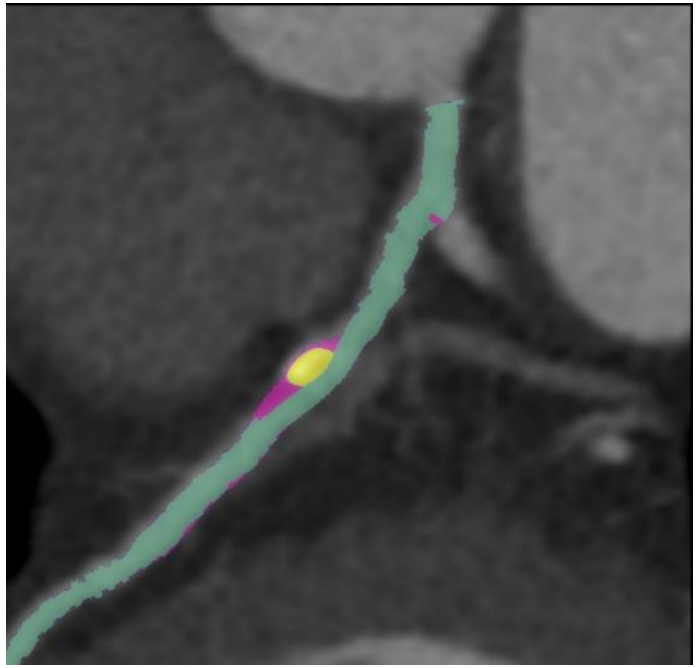
- 256 CT Angiography: **1-3 mSv**
- Background Radiation: 3 mSv/year
- Coronary Angiogram: Avg 8 mSv (2-10)
- Nuclear Imaging: 9-41 mSv

Gerber –AHA Scientific Statement Circulation 2009

Cardiac exam 0.6 mSv

HR: 69bpm, Cardiac Phase: 75%





* Obtained using a chest factor of 0.014*DLP

EVINCI Study Circ 2015

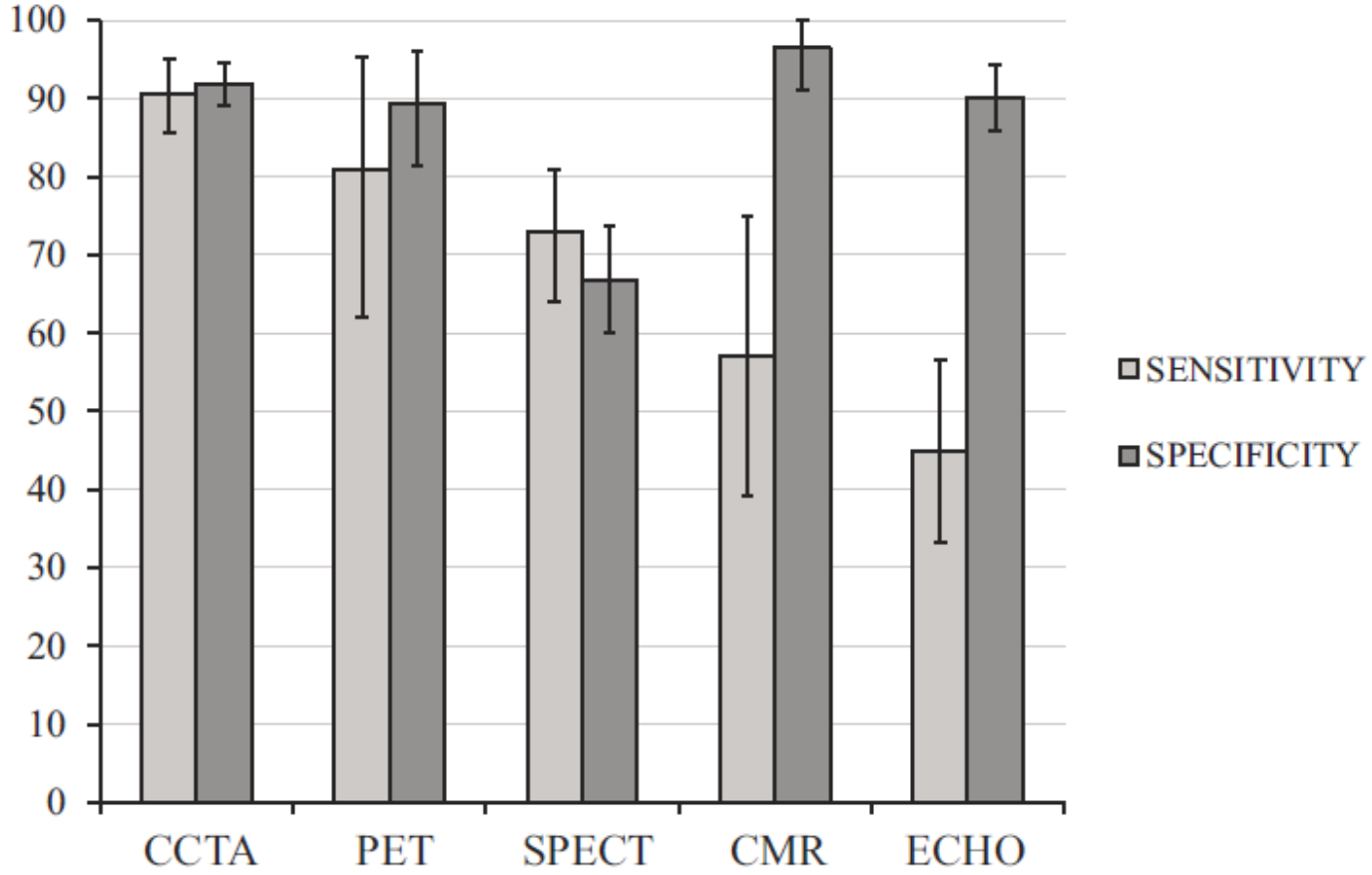


Figure 3. Sensitivity and specificity of noninvasive imaging techniques.

CCTA indicates coronary computed tomography angiography; CMR, cardiac magnetic resonance; ECHO, echocardiography; PET, positron emission tomography; and SPECT, single-photon computed emission tomography.

SCOT-HEART 5-Year Analysis: cCTA-first pathway improves outcomes

- 4,146 patients across the UK randomized between cCTA or standard care
- Early data showed impact of using cCTA for diagnosis, treatment, etc.

Key Findings

41% lower death & MI rate in cCTA group than in standard care group at 5 years

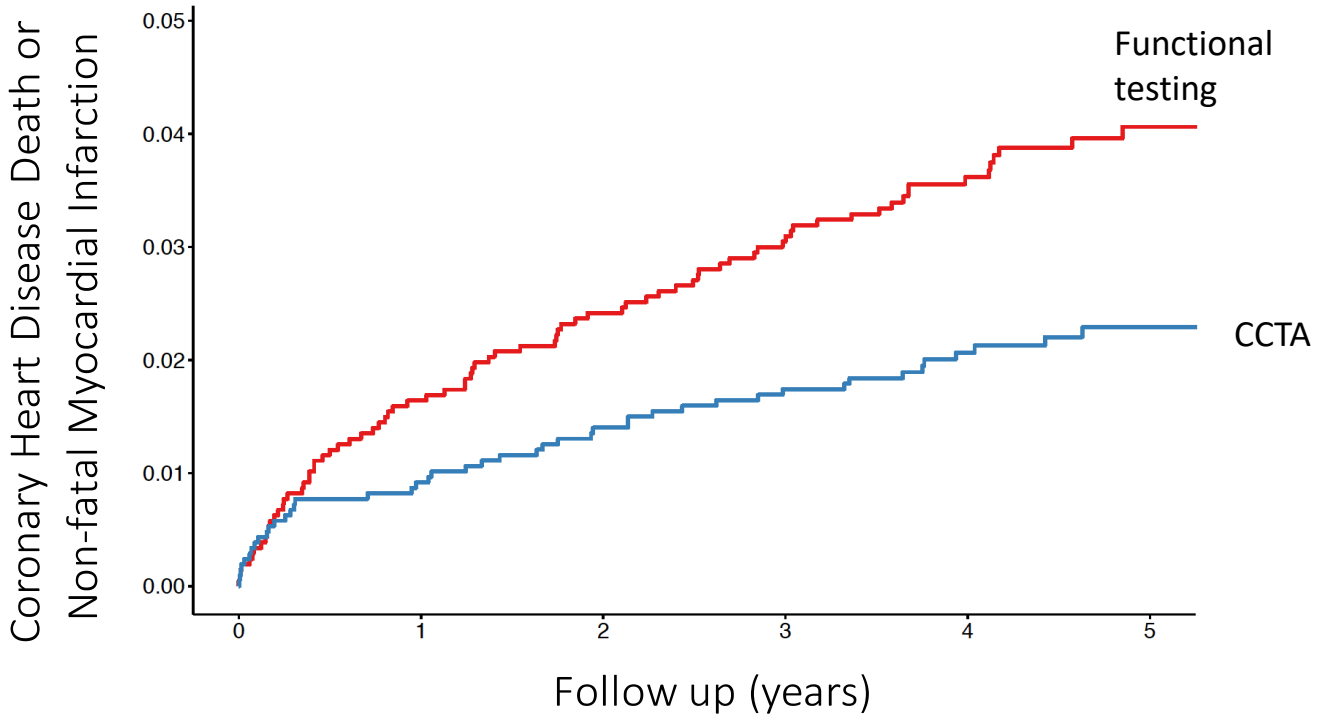
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Coronary CT Angiography and 5-Year Risk of Myocardial Infarction

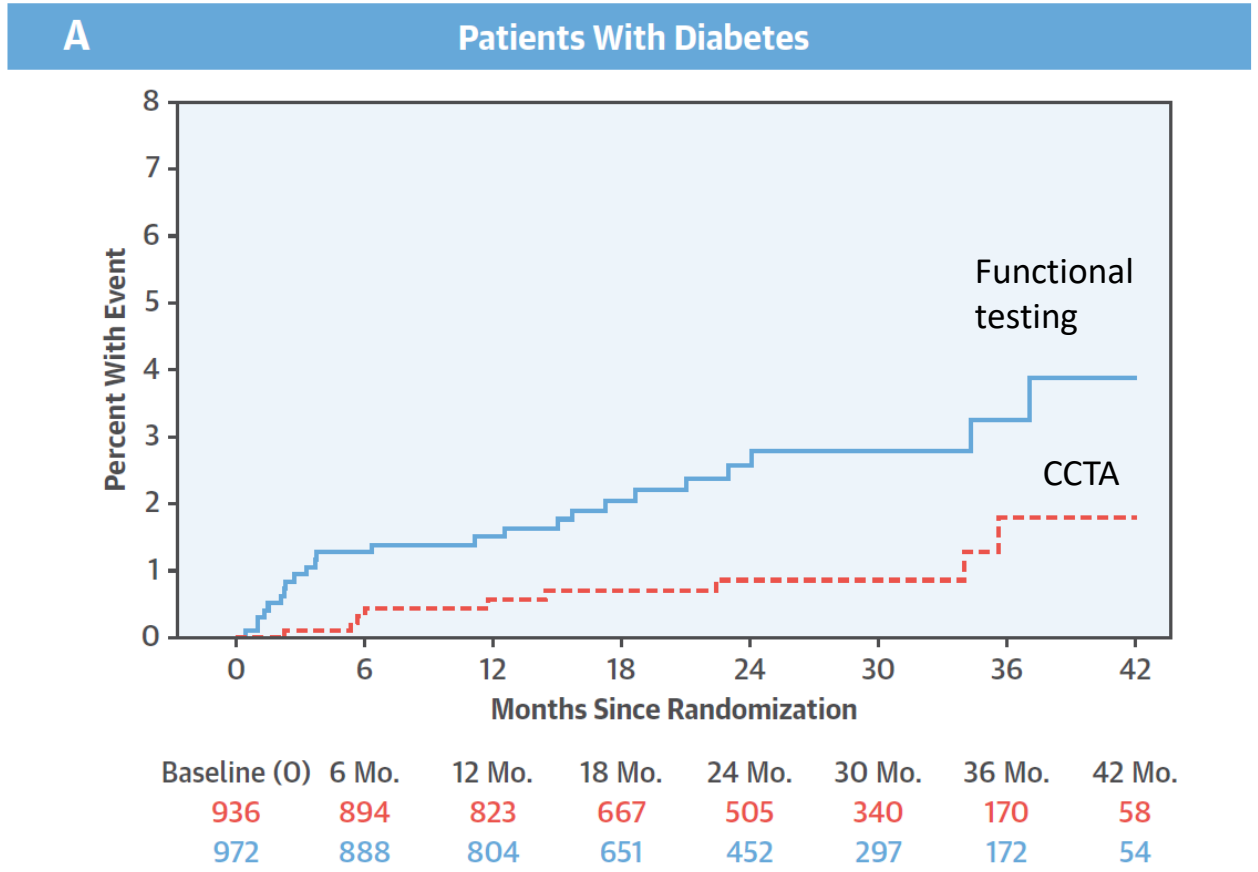
The SCOT-HEART Investigators*

Newby et al, NEJM 2018



Promise DM
JACC 2019

CENTRAL ILLUSTRATION Composite of Cardiovascular Death/Myocardial Infarction by Randomized Noninvasive Testing Modality and Diabetes History: Kaplan-Meier Curves



hazard ratio: 0.38; 95% confidence interval: 0.18 to 0.79; p = 0.01

2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain

Endorsed by the American Society of Echocardiography, American College of Chest Physicians, Society for Academic Emergency Medicine, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

Intermediate-High Risk Patients With Stable Chest Pain and No Known CAD

Recommendations for Intermediate-High Risk Patients With Stable Chest Pain and No Known CAD Referenced studies that support the recommendations are summarized in Online Data Supplements 29 and 30.		
Index Diagnostic Testing: Selecting the Appropriate Test		
COR	**LOE**	**Recommendations**
Anatomic Testing		
1	**A**	**1. For intermediate-high risk patients with stable chest pain and no known CAD, CCTA is effective for diagnosis of CAD, for risk stratification, and for guiding treatment decisions.**

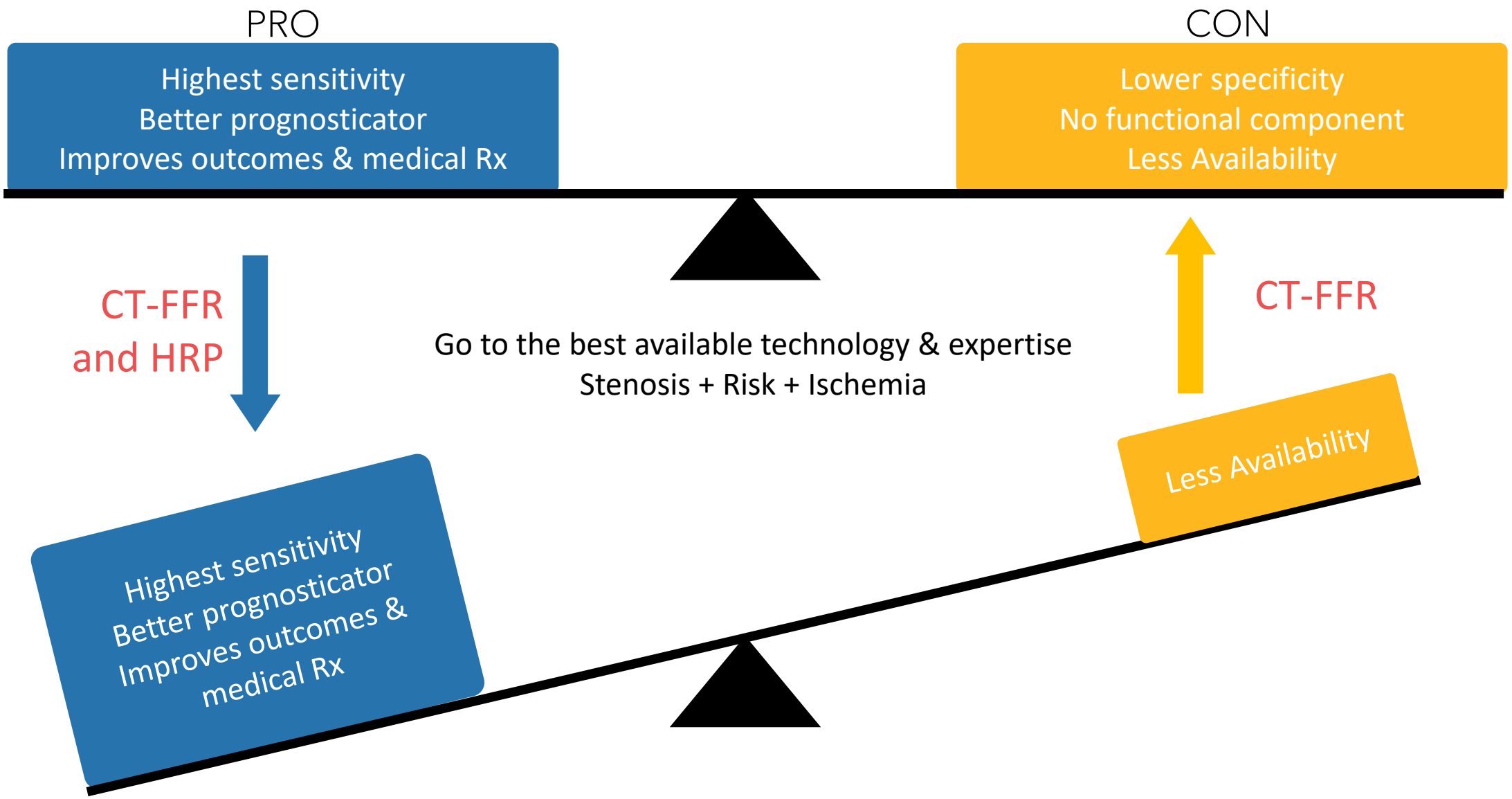
Intermediate-Risk Patients With Acute Chest Pain and No Known CAD (con't.)

Stress Testing		
1	B-NR	4. For intermediate-risk patients with acute chest pain and no known CAD who are eligible for cardiac testing, either exercise ECG, stress echocardiography, stress PET/SPECT MPI, or stress CMR is useful for the diagnosis of myocardial ischemia.

Why is CTA-Superior?

- Superior test performance
  - ↓ false negative test results/untreated CAD
    - ↓ coronary events
- Better detection of non-obstructive CAD
    - Improved preventive treatment and adherence
- Longer ‘warranty’ period with fewer repeat tests
    - ↓ hospitalizations during follow up

NICE Guideline: The Scales of CTA Evidence



Identifying appropriate patients for the CCTA + FFR_{CT} Pathway

ACC/AHA CHEST PAIN GUIDELINES

CCTA is the ONLY Class 1 non-invasive test with Level A evidence.

FFR_{CT} is designated as Class 2a with Level B evidence and provides actionable information across a broad range of patient populations.

CCTA+FFR_{CT} can be ordered across a broad patient population including those with known or suspected CAD with stable or acute chest pain

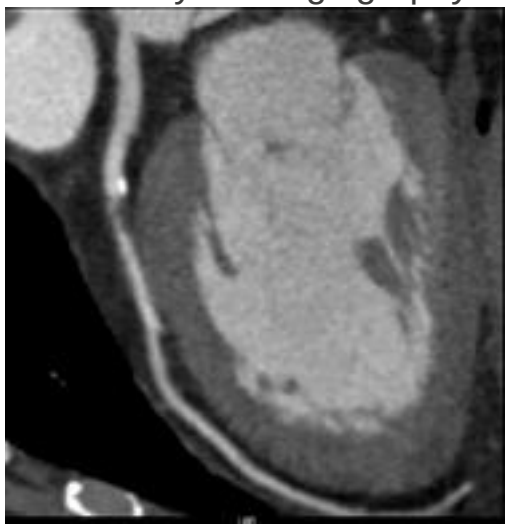
"For intermediate-risk patients with acute chest pain and no known CAD, with a coronary artery **stenosis of 40% to 90%** in a proximal or middle coronary artery on CCTA, FFR_{CT} can be useful for the diagnosis of vessel-specific ischemia and to guide decision-making regarding the use of coronary revascularization"

Gulati, et al. 2021 AHA/ACC Guideline for the Evaluation and Diagnosis of Chest Pain. J Am Coll Cardiol.

Imaging in Coronary Artery Disease — Hope of Combining Anatomy and Function

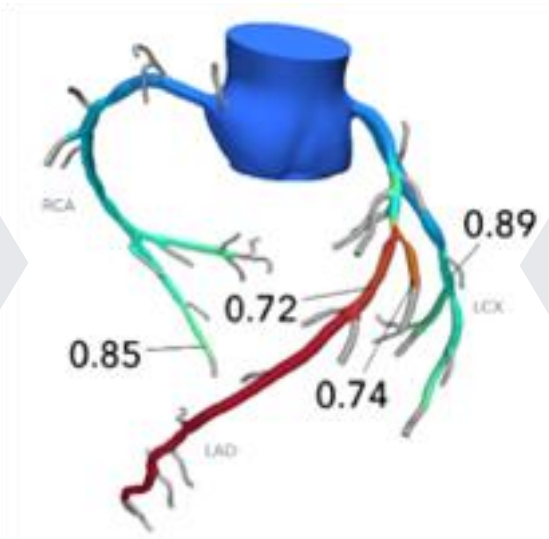
Anatomical Testing

Coronary CT Angiography



Anatomical and Functional

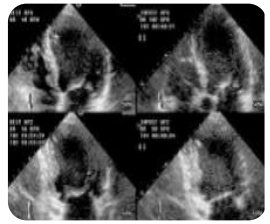
FFR_{CT}



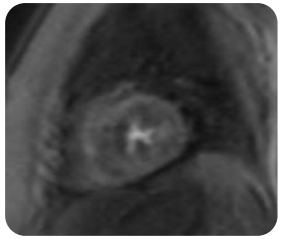
Functional Testing

Treadmill ECG

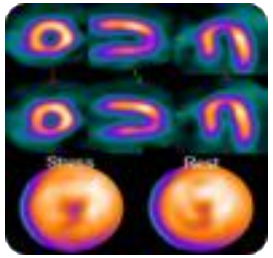
Stress Echo



Stress MRI



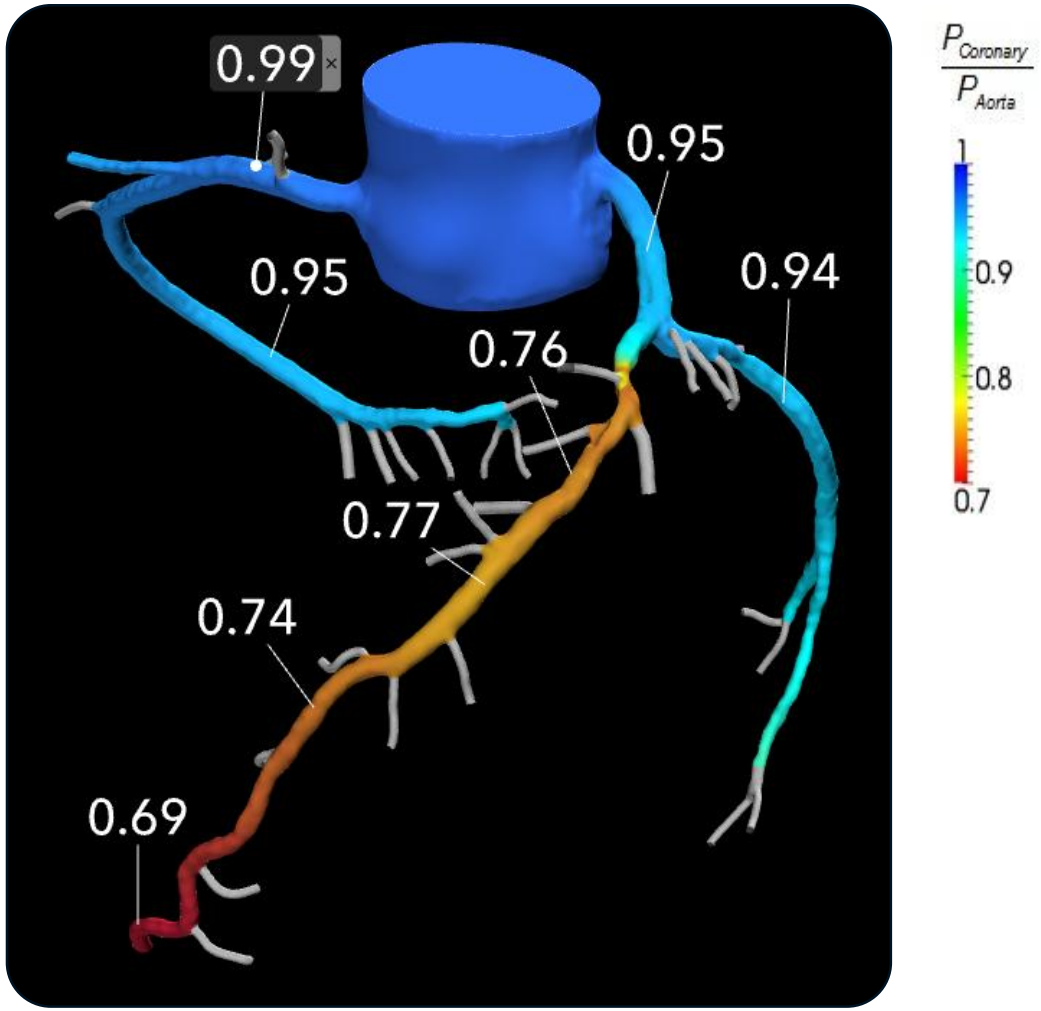
SPECT



Physiology from CT is a reality

1. From typical CCTA
2. No radiation
3. No Δ image protocols
4. No medications

3D FFR_{CT} map computed



New Guidelines Elevate CTA & FFR_{CT} as Frontline Tests

2021 ACC/AHA Guidelines[1]

Patients with stable chest pain

Coronary CTA

To diagnose CAD and guide treatment decisions

Class 1 Recommendation
Level A Evidence

FFR_{CT}

To help guide treatment decisions

Class 2a Recommendation
Level B Evidence

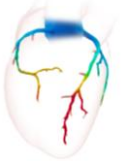
2024 ESC Guidelines[2]

Patients with chronic coronary syndrome

Coronary CTA

To diagnose CAD in patients with suspected coronary artery disease

Class 1 Recommendation
Level A Evidence



FFR_{CT}

In high-risk cases, stenosis >70% in proximal LAD

Class 2a Recommendation
Level B Evidence

2a
B-NR

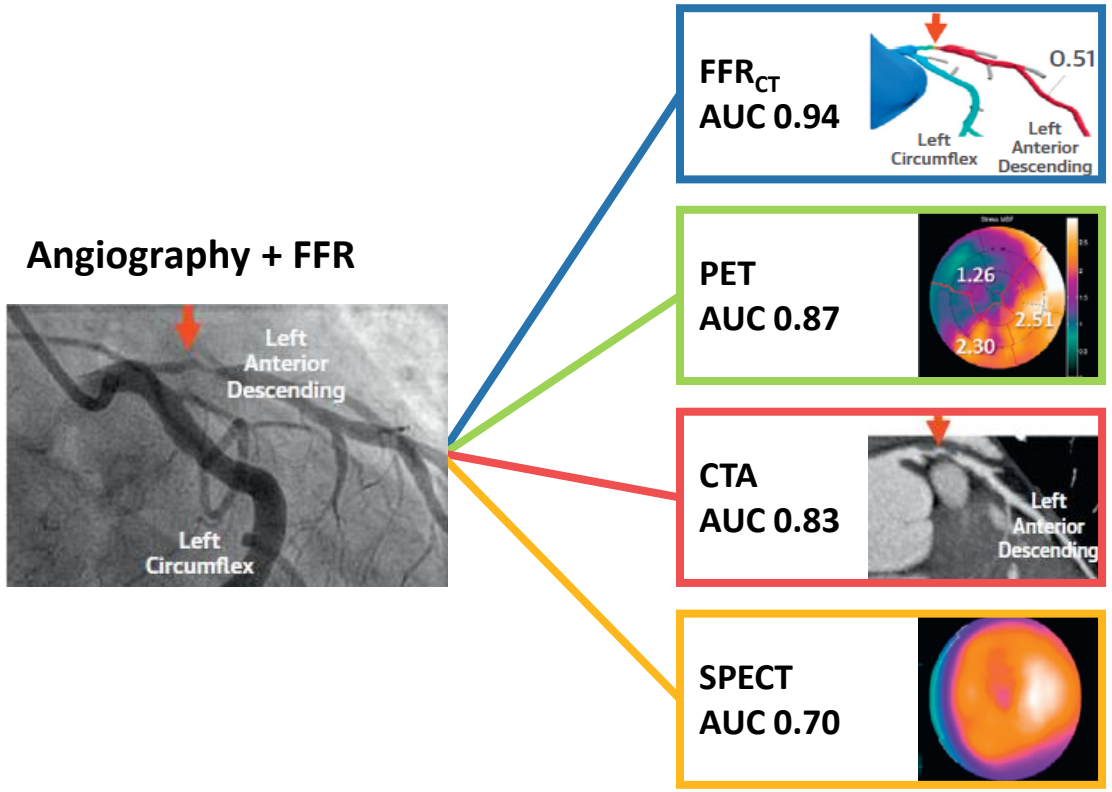
ACC/AHA Guidelines Anatomic Testing[1]

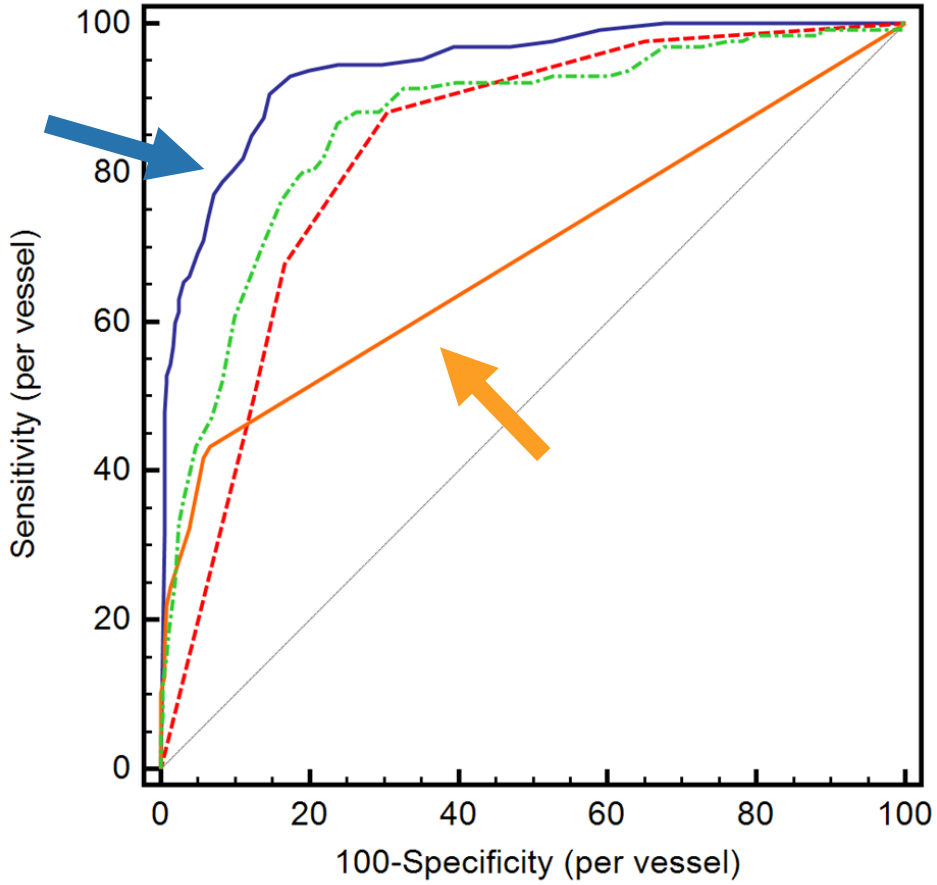
For patients with known coronary **stenosis from 40% to 90% on CCTA**, FFR can be useful for diagnosis of vessel-specific ischemia and to guide decision-making regarding the use of ICA

1. Gulati M, et al. Circulation. 2021;144(22):e368-e454. doi:10.1161/CIR.0000000000001029
2. Vrints C, et al. Eur Heart J. 2024;45(36):3415-3537. doi:10.1093/eurheartj/ehae177

CCTA with physiology assessment had the highest diagnostic performance

Discriminative ability for the detection of per per-vessel FFR-defined ischemia

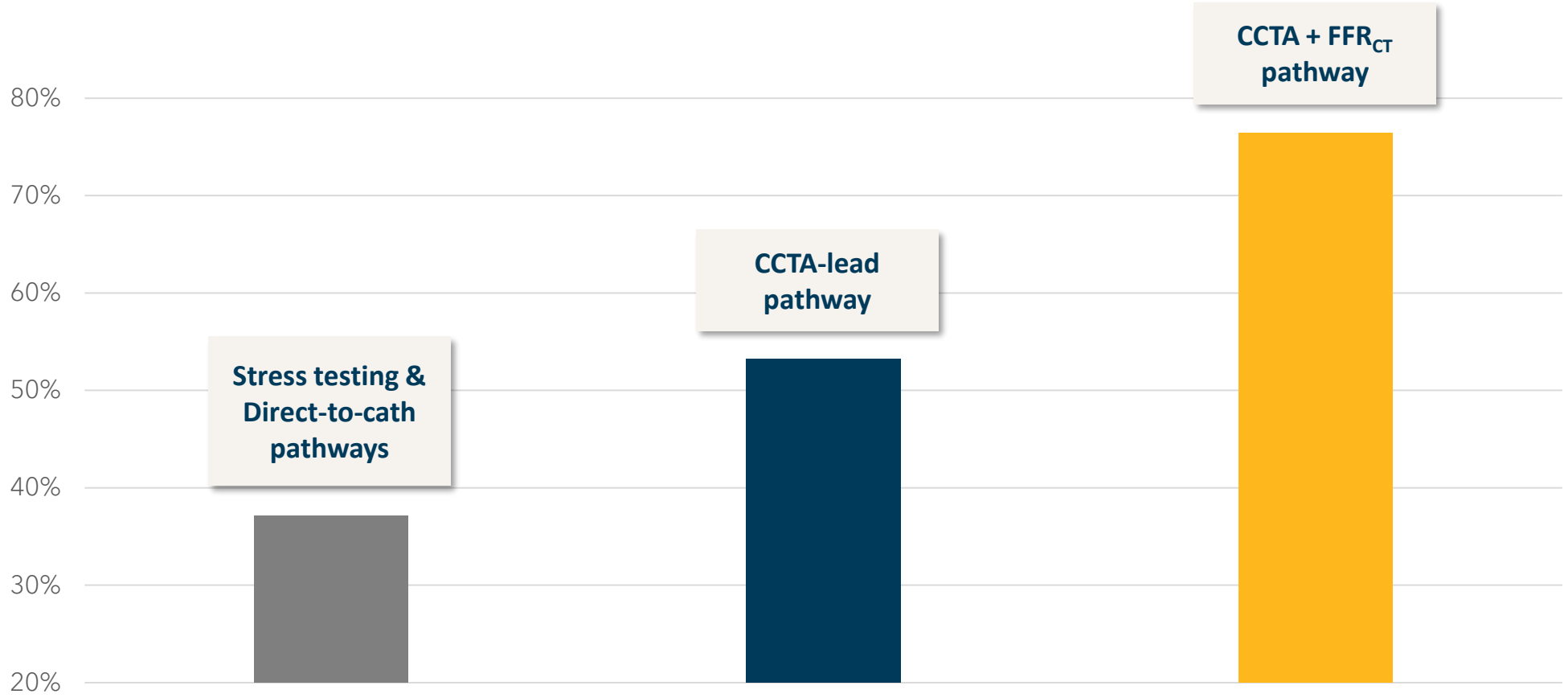




Driessen R et al. J Am Coll Cardiol. 2019; 73(2):161-173. https://www.jacc.org/doi/10.1016/j.jacc.2018.10.056

CCTA + FFR_{CT} Enables Increased Cath Lab Efficiency

Revascularization: ICA Ratio in Stable Chest Pain Patients



1. Curzen N, et al. Eur Heart J. 2021;42(37):3844-3852. doi:10.1093/eurheartj/ehab444
2. Douglas PS, et al. N Engl J Med. 2015;372(14):1291-1300. doi:10.1056/NEJMoa1415516
3. Curzen NP, et al. JACC Cardiovasc Imaging. 2016;9(10):1188-1194. doi:10.1016/j.jcmg.2015.12.026
4. Patel MR, et al. JACC Cardiovasc Imaging. 2020;13(1 Pt 1):97-105. doi:10.1016/j.jcmg.2019.03.003
5. SCOT-HEART Investigators, et al. N Engl J Med. 2018;379(10):924-933. doi:10.1056/NEJMoa1805971
6. Douglas PS, et al. J Am Coll Cardiol. 2016;68(5):435-445. doi:10.1016/j.jacc.2016.05.057
7. Lu MT, et al. JACC Cardiovasc Imaging. 2017;10(11):1350-1358. doi:10.1016/j.jcmg.2016.11.024

The Precision Pathway enables clinicians to perform more of the right interventions in the right patients

Appropriate Revascularization

	Suspected CAD	ICA	PCI	CABG	No Obstructive Disease Found or No Revasc
Traditional Testing	100 Patients	18 patients	4 patients	2 patients	12 patients
Precision Pathway	100 Patients	14 patients	8 patients	2 patients	4 patients

PRECISE trial - Presented at AHA 2022
ICA: 16.9% TT, 12.8% PP
PCI: 3.5%, 7.3% PP
CABG: 1.7% TT, 2.0% PP

The CCTA + FFR_{CT} Pathway leads to more high-value, clinically indicated interventions in the right patients

Appropriate Revascularization

	Suspected CAD	ICA	PCI	CABG	No Obstructive Disease Found or No Revasc
Traditional Testing	100 Patients	18 patients	4 patients	2 patients	12 patients
Precision Pathway	100 Patients	14 patients	8 patients	2 patients	4 patients

78% more likely to identify patients in need of revascularization

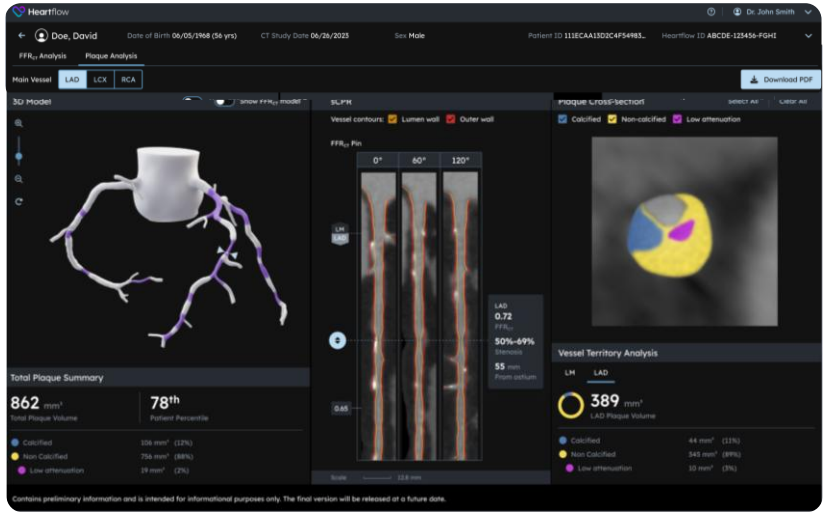
3X fewer unnecessary ICAs

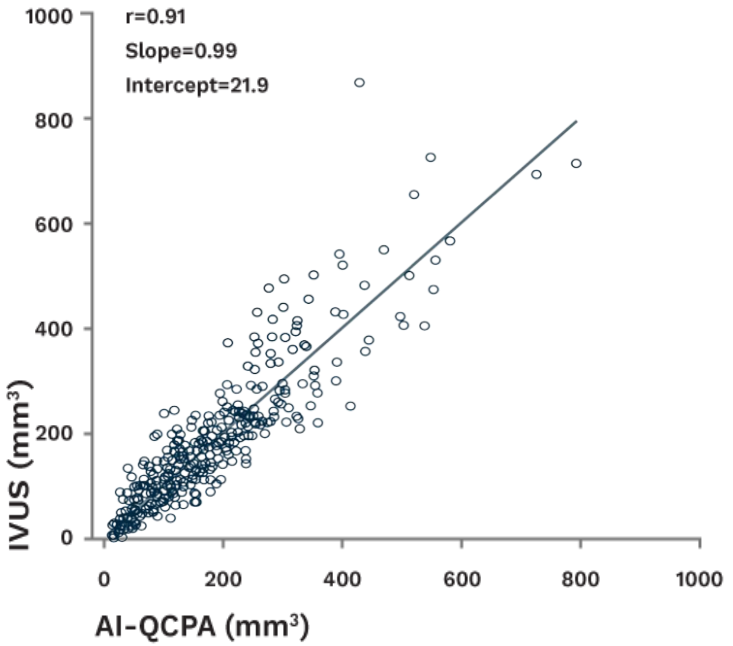
PRECISE trial - Presented at AHA 2022
ICA: 16.9% TT, 12.8% PP
PCI: 3.5%, 7.3% PP
CABG: 1.7% TT, 2.0% PP

Only a Clinically Validated Tool Can Set the Standard

REVEALPLAQUE Study

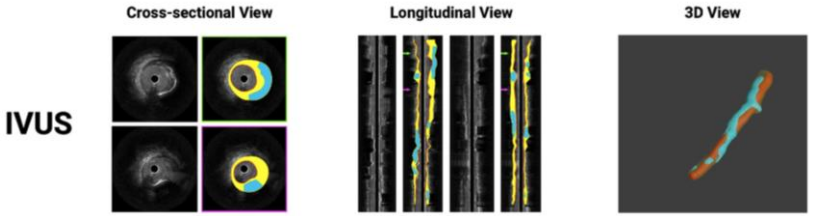
The Heartflow Plaque Analysis is the only product with prospective, blinded RCT, published showing **95% agreement with IVUS** to quantify and characterize coronary plaque.





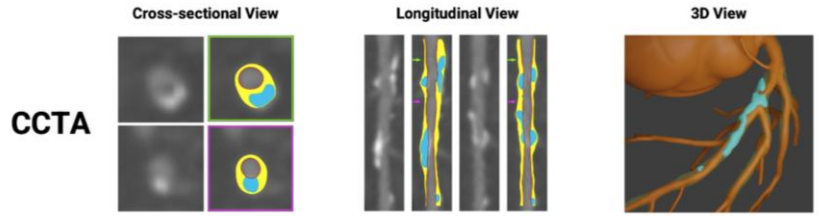
Total Plaque Volume per lesion

Heartflow Plaque from CCTA vs. Core Lab Plaque from IVUS



CCTA vs IVUS Plaque Volume Correlations

Total Plaque Volume	0.91
Calcified Plaque Volume	0.91
Non-calcified Plaque Volume	0.87



Narula, et al. EHJ CVI 2024. DOI: 10.1093/ehjci/jeae115
Ihdayhid, et al. Radiol CTI 2024. DOI: 10.1148/ryct.230312

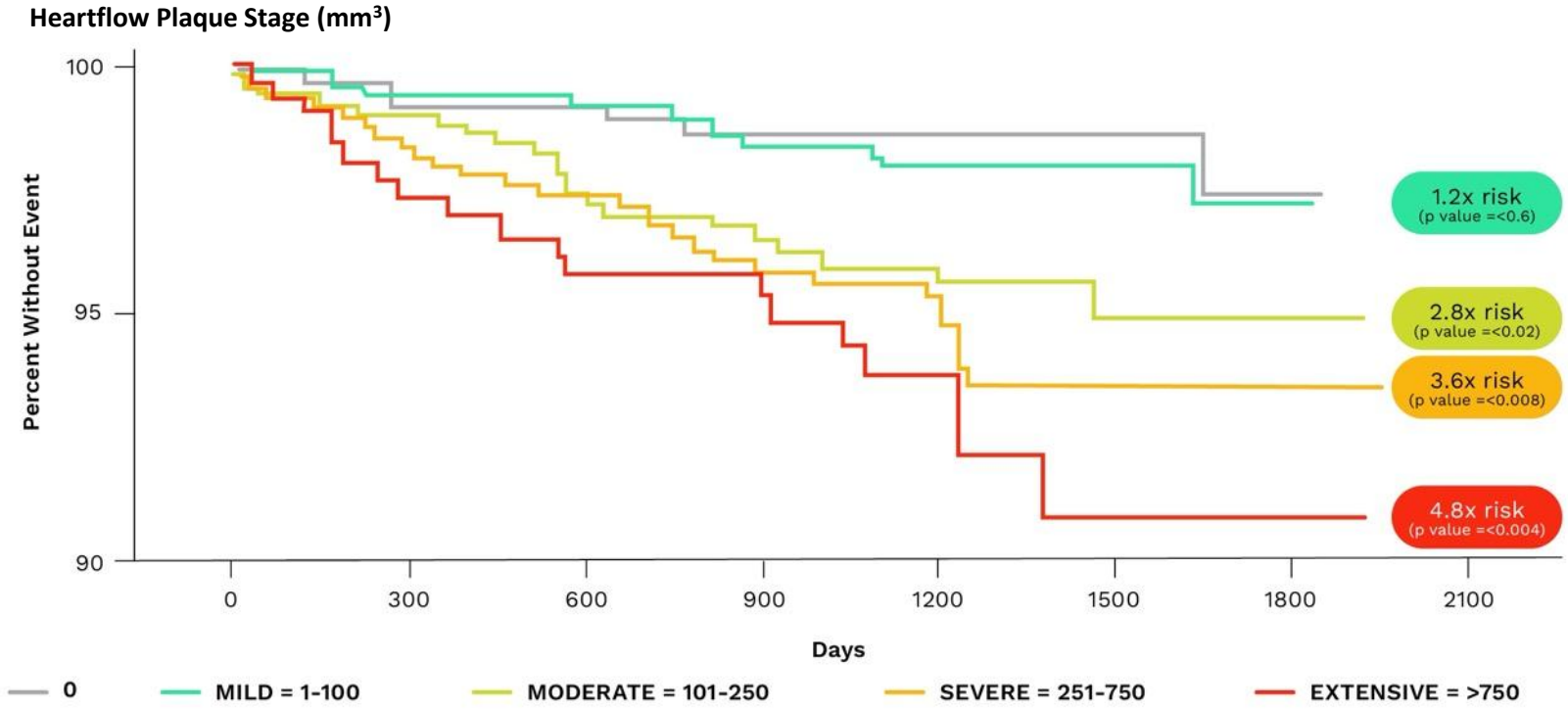
Plaque staging informs cardiovascular outcomes

Study Design

- 2,827 patients from FISH&CHIPS Liverpool cohort were stratified according to Heartflow Plaque Staging* based on total plaque volume
- Patient outcomes (CV death and MI) were reviewed out to 3.3 yrs (median)

FISH&CHIPS Liverpool: Prediction of Cardiovascular Outcomes

Results: Higher TPV-based stages were associated with statistically significant higher CV event rates even after adjusting for risk factors, stenosis, and FFR_{CT}**



Fairbairn, et al. HEART. 2025. doi:10.1136/heartjnl-2025-BSCI.5

*Heartflow Plaque Analysis is an FDA-cleared device. Heartflow Plaque Staging is an investigational only framework and its safety and effectiveness have not been reviewed by the FDA.

** Adjusted for age, sex, hypertension, dyslipidemia, diabetes, stenosis, and FFRCT

Parsa et al – AJPC 2026

Population

FISH&CHIPS

Patients undergoing clinically indicated CCTA for suspected or known stable CAD

- N= 6,054 with coronary plaque
- Mean age ~59 years
- 43% women

AI-Enabled Plaque Assessment → Risk Staging

Total plaque volume (TPV)-guided personalized prevention

	DECIDE Stages based on TPV (mm^3)	LDL-C Goal (mg/dL)
Stage 1	1-100	<100
Stage 2	101-250	<70
Stage 3	251-750	<55
Stage 4	>750	<40

Predicted NNT at 10 Years

	NNT
Stage 1	1,686
Stage 2	59
Stage 3	27
Stage 4	11

Overall 10-year impact:

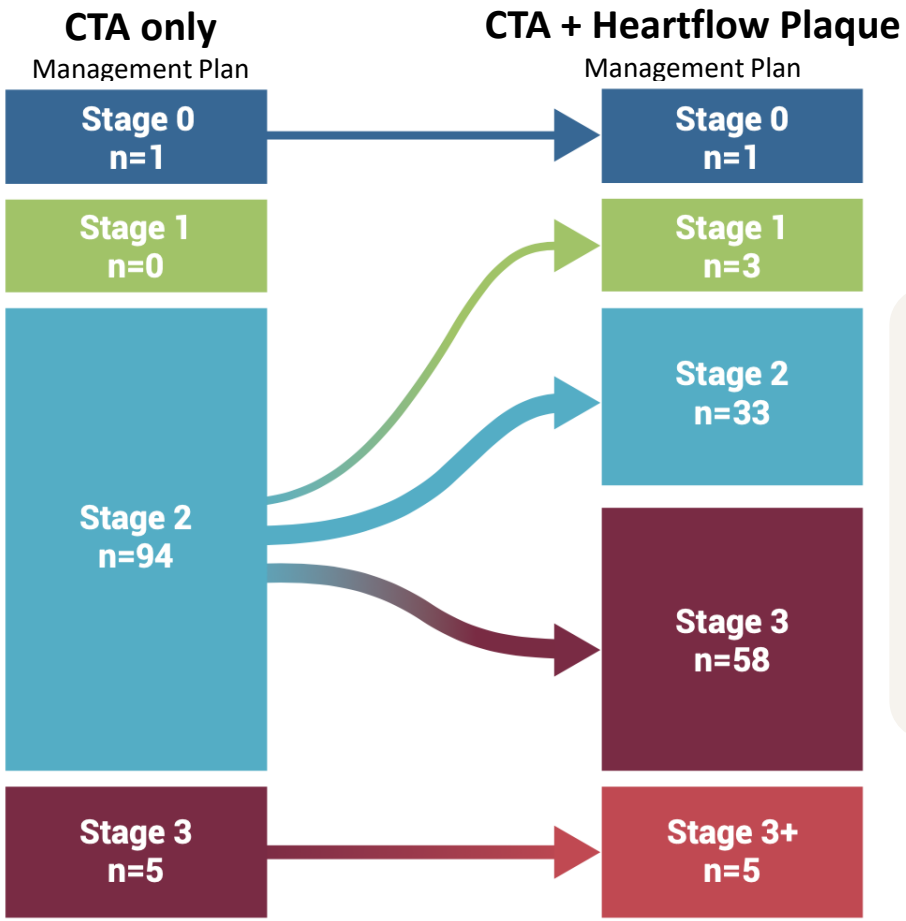
19% relative risk reduction ↓
NNT= 61

Conclusion

AI-derived total plaque volume from CCTA enables personalized lipid-lowering strategies that substantially reduce long-term cardiovascular risk.

Guide patient treatment with plaque quantification

<u>DECODE Results</u>: 2 out of 3 patients (66%) received a refined management plan following physician review of the Heartflow Plaque Analysis



Three practicing cardiologists with level 3 CTA reading certification assessed 100 patients based on patient demographics, clinical history, and CCTA report

Nearly **50% of patients** with a CACS of 0 were reclassified.

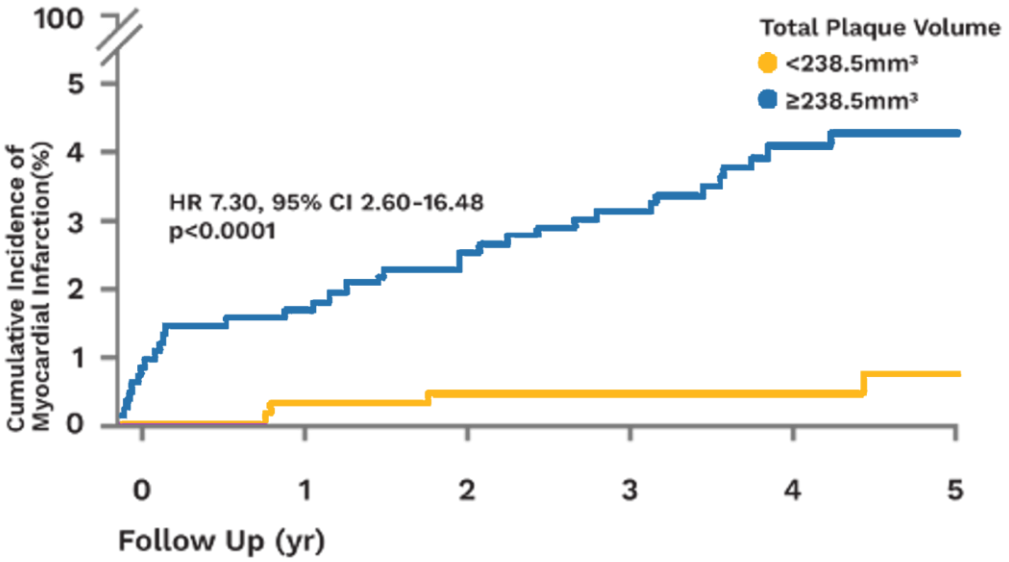
Stage	Treatment
0	GDMT
1	Low-dose Statin
2	High-intensity statin +/- PCSK-9 inhibitor
3	High-intensity statin +/- PCSK-9 inhibitor + additional medications

Rinehart, S. et al.. JCCT. 2023; 17(4): S33. DOI: https://doi.org/10.1016/j.jcct.2023.05.084

Plaque Quantification & Characterization Improves Risk Stratification

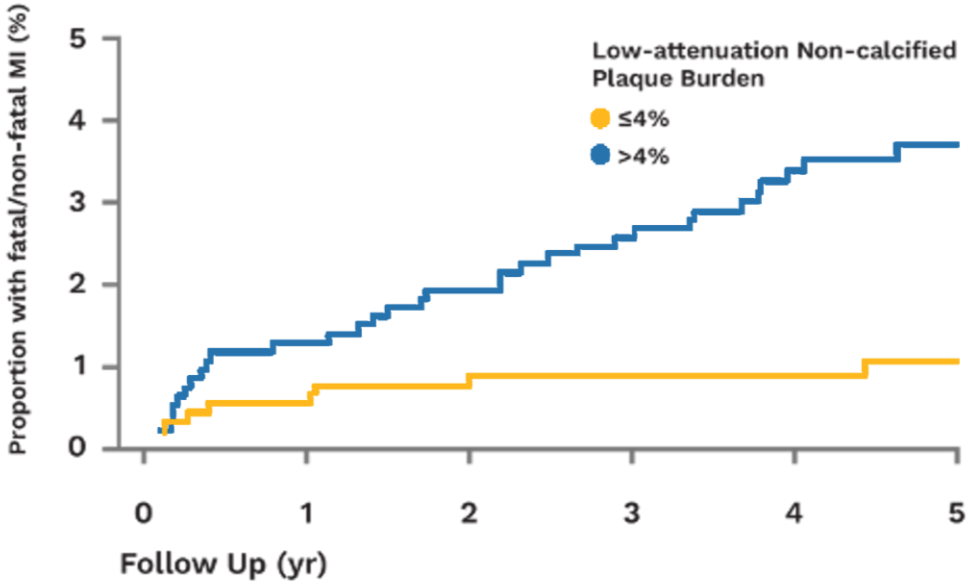
Prognostic: Total plaque volume (TPV) is a strong predictor of MI

- Independent of CV risk score, CAC, or stenosis[1]



No. at Risk					
<238.5mm³	700	698	694	554	314
≥238.5mm³	895	884	873	690	383

Characterization: Low-attenuation plaque (LAP) presence is the strongest predictor of MI (4.65x HR)[2]



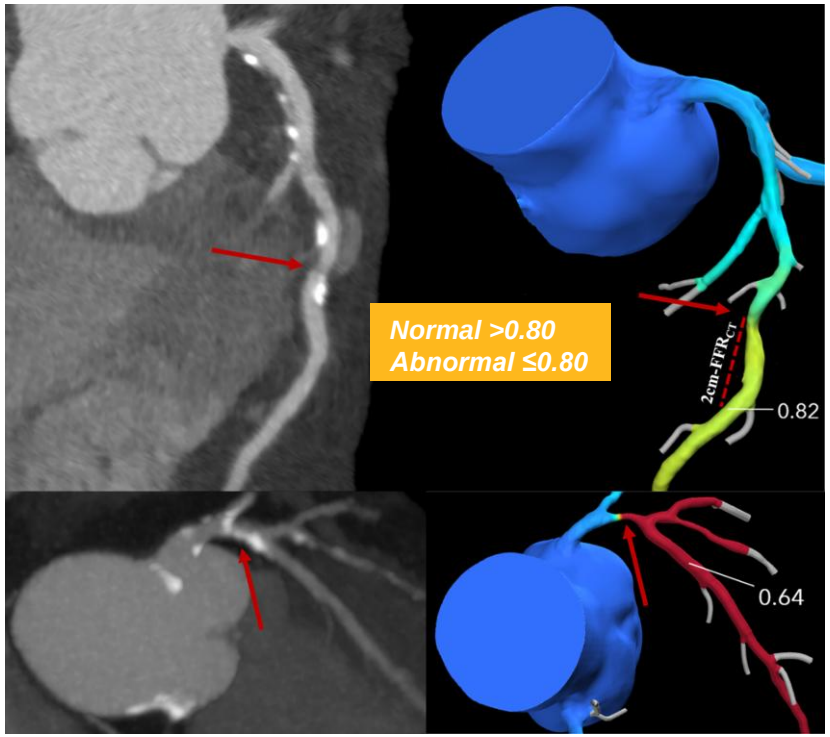
Low-attenuation Non-calcified Plaque Burden					
≤4%	862 (100)	859 (99)	849 (98)	659 (76)	360 (42)
>4%	895 (99)	885 (98)	874 (96)	694 (77)	383 (42)

1. Lin, et al. Lancet 2022. DOI: 10.1016/S2589-7500(22)00022-X
2. Williams, et al. Circulation 2020. DOI: 10.1161/CIRCULATIONAHA.119.044720

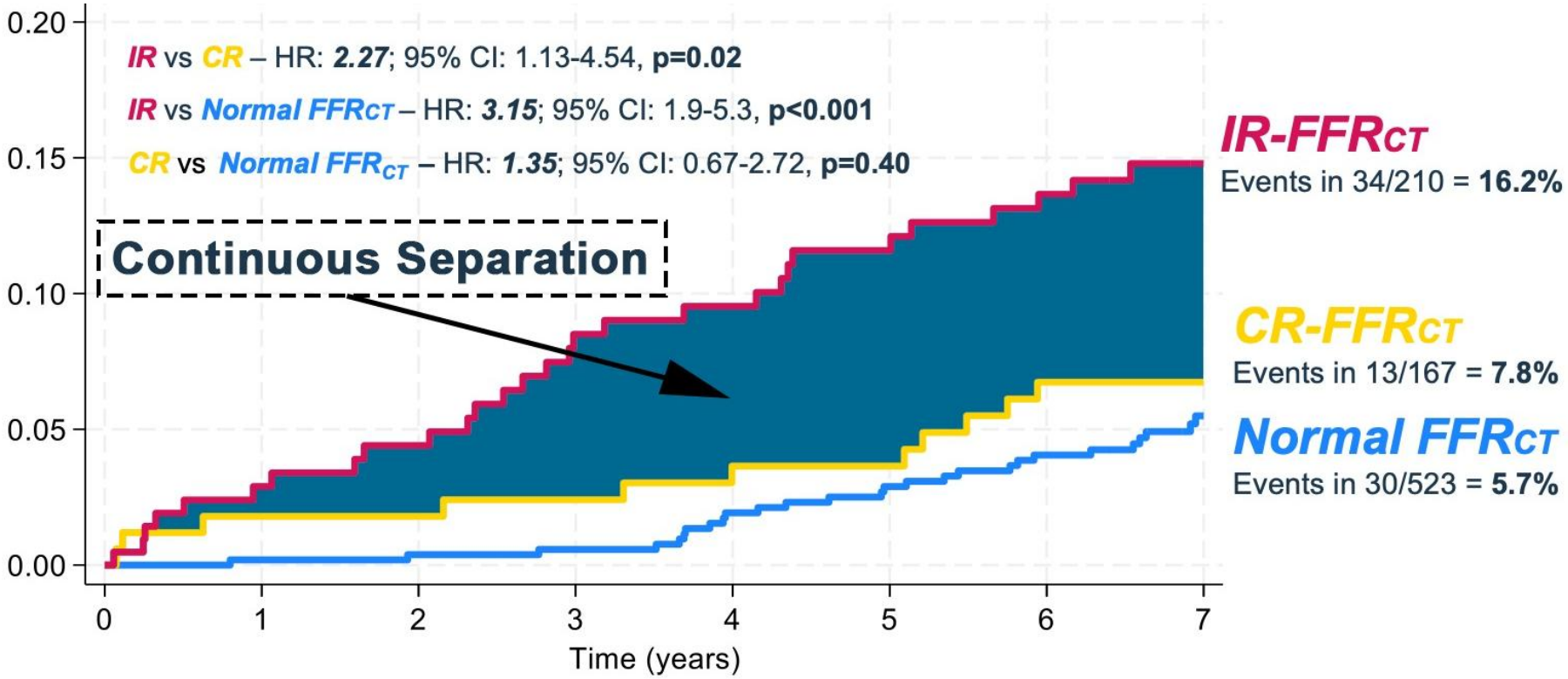
Completeness of Revascularization by FFR_{CT} and Long-term Prognosis in Stable Angina

A 7-year Follow-up of the ADVANCE-DK Registry

- **900 patients undergoing CTA and FFR_{CT}**
  All symptomatic with at least one coronary stenosis ≥30%
- **Cardiovascular death or spontaneous MI**
  All endpoints adjudicated by independent event committee
  No periprocedural MI's included
- **Completeness of revascularization by FFR_{CT}**
  IR-FFR_{CT} : ≥1 vessels with abnormal FFR_{CT} not revascularized
  CR-FFR_{CT} : All vessels with abnormal FFR_{CT} revascularized
  Normal FFR_{CT} : All vessels with normal FFR_{CT}



CVD or spontaneous MI

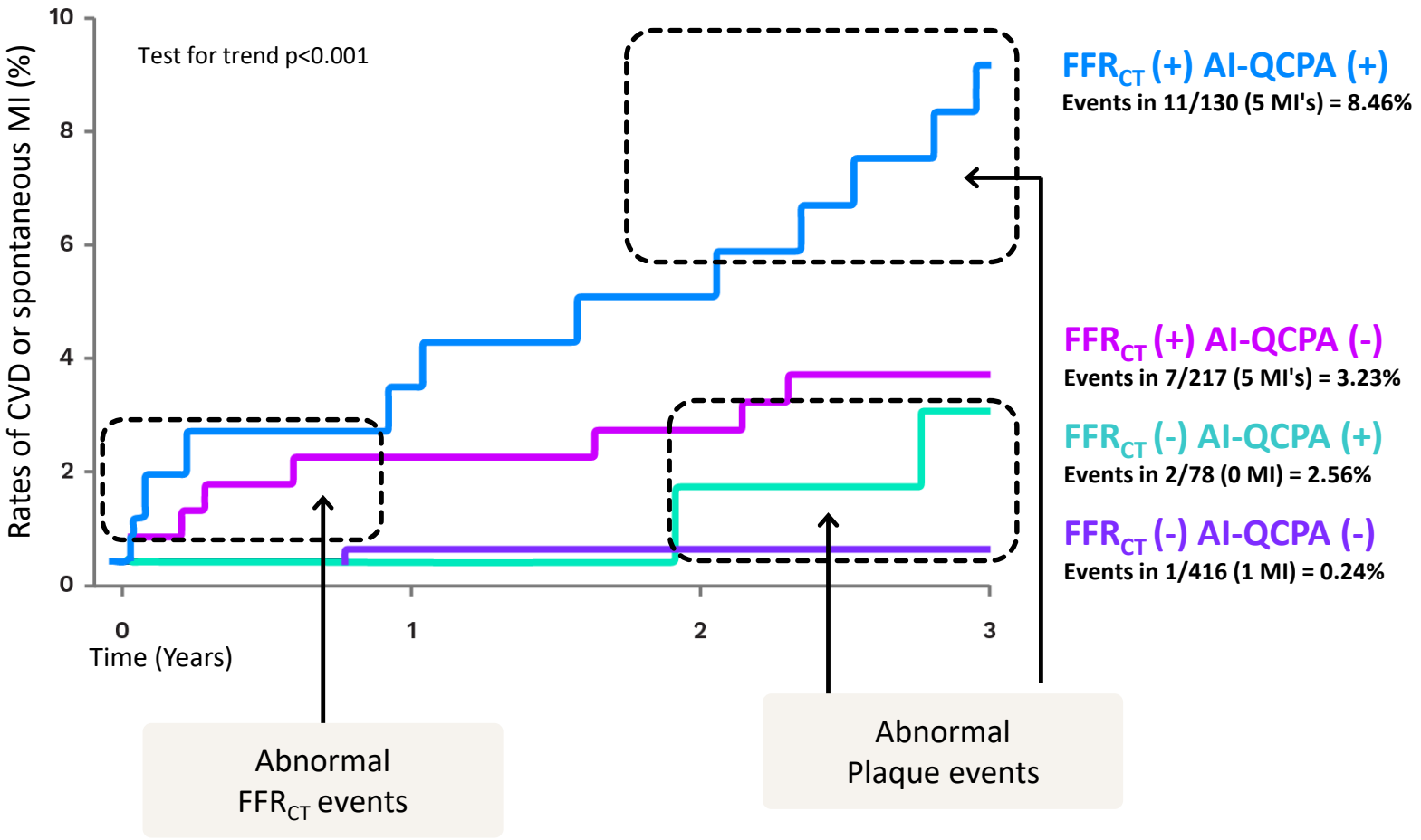


Number at risk								
Normal FFR_{CT}	523	516	509	507	497	490	473	280
CR FFR_{CT}	167	162	157	155	152	149	142	85
IR FFR_{CT}	210	193	188	175	172	164	153	78

Coronary Plaque + Physiology

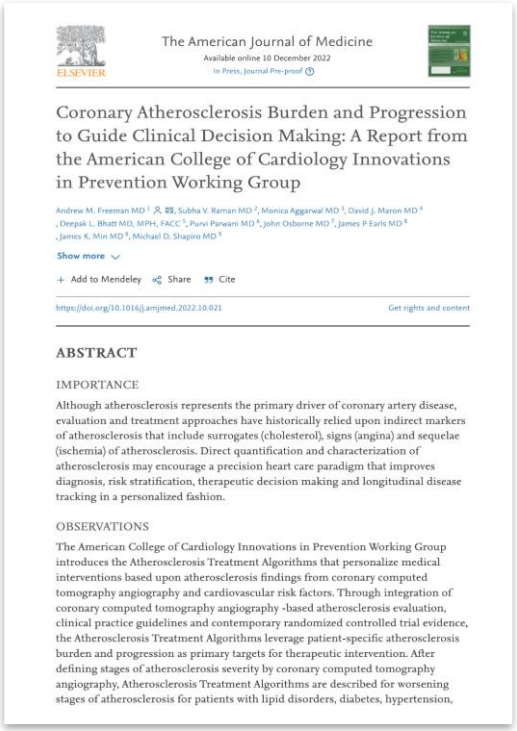
ADVANCE-DK Study

- Assessment of coronary plaque and physiology help to answer interrelated clinical questions regarding short- and long-term patient risk.
- The combined information from FFR_{CT} and Plaque Analysis further stratified the 3Y risk of CV events.



Madsen KT, et al. JACC. 2023 ; 82 (17_Supplement) B173. https://doi.org/10.1016/j.jacc.2023.09.439
Madsen KT, et al. Presented at TCT 2023. https://www.tctmd.com/slide/tct-430-prognostic-value-combined-coronary-ct-angiography-derived-fractional-flow-reserve-and

TREAT: Therapy Based on Plaque Stage + RF



The American Journal of Medicine

Available online 10 December 2022

In Press, Journal Pre-proof

Coronary Atherosclerosis Burden and Progression to Guide Clinical Decision Making: A Report from the American College of Cardiology Innovations in Prevention Working Group

Andrew M. Freeman MD [1], Subha V. Raman MD [2], Monica Aggarwal MD [3], David J. Maron MD [4], Deepak L. Bhatt MD, MPH, FACC [5], Purvi Parwani MD [6], John Osborne MD [7], James P Earls MD [8], James K. Min MD [8], Michael D. Shapiro MD [9]

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ABSTRACT

IMPORTANCE

Although atherosclerosis represents the primary driver of coronary artery disease, evaluation and treatment approaches have historically relied upon indirect markers of atherosclerosis that include surrogates (cholesterol), signs (angina) and sequelae (ischemia) of atherosclerosis. Direct quantification and characterization of atherosclerosis may encourage a precision heart care paradigm that improves diagnosis, risk stratification, therapeutic decision making and longitudinal disease tracking in a personalized fashion.

OBSERVATIONS

The American College of Cardiology Innovations in Prevention Working Group introduces the Atherosclerosis Treatment Algorithms that personalize medical interventions based upon atherosclerosis findings from coronary computed tomography angiography and cardiovascular risk factors. Through integration of coronary computed tomography angiography -based atherosclerosis evaluation, clinical practice guidelines and contemporary randomized controlled trial evidence, the Atherosclerosis Treatment Algorithms leverage patient-specific atherosclerosis burden and progression as primary targets for therapeutic intervention. After defining stages of atherosclerosis severity by coronary computed tomography angiography, Atherosclerosis Treatment Algorithms are described for worsening stages of atherosclerosis for patients with lipid disorders, diabetes, hypertension,

Stage	Stenoses	Action	Rescan (until stable):
Stage 0: No Plaque	**0**	• **GDMT / Consider de-escalation**	**4 years**
Stage 1: Mild	**<50%**	• **Statin, Ezetimibe**	**3 years**
Stage 2: Moderate	**<50%**	**Stage 1 Plus** • **Aspirin, Rivaroxaban** • **GLP1 if diabetic**	**2 years**
Stage 3: Severe	**<50%**	**Stage 2 plus** • **Consider PCSK9, Icosapent ethyl, Inclisirin, Bempedoic acid, Colchicine** • **GLP1 and SGLT2 if diabetic**	**1 year**

Freeman, A et al Am J Med 2022

Introducing Heartflow Plaque Analysis

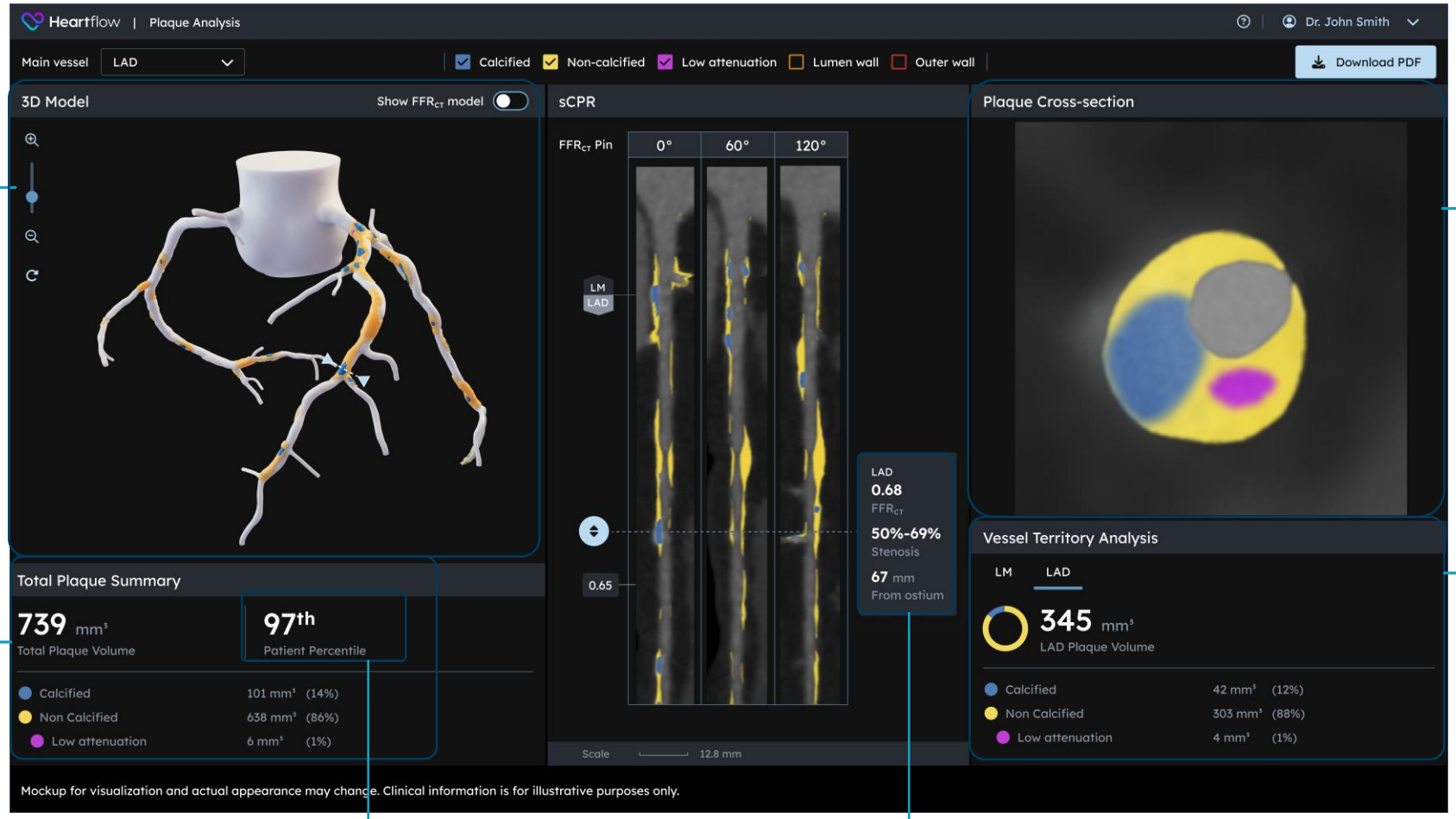
AI-enabled plaque quantification and characterization

- **Comprehensive**
  Personalized 3D color-coded model of plaque type, burden, and distribution with plaque quantity to rapidly assess disease
- **Accurate**
  The only non-invasive plaque assessment with 95% agreement vs. the gold standard, IVUS[1]
- **Actionable**
  Demonstrated over 50% real-world change in management in the largest prospective registry of its kind[2]

Mockup for visualization and actual appearance may change. Clinical information is for illustrative purposes only.

1. Ihdayhid A, et al. Radiol Cardiothorac Imaging. 2024. doi: 10.1148/ryct.230312 and internal bridging study with ICC correlation between first generation and second generation Plaque Analysis algorithm
2. DECIDE Registry. Rinehart, et al., presented at SCCT 2025.

Comprehensive: Heartflow Plaque Analysis



1. Interactive 3D plaque model with plaque by type to quickly understand the distribution of disease

2. Accurate plaque volume across calcified, non-calcified and low attenuation plaque[1]

3. Age- and sex-stratified nomogram percentile based on the largest population of plaque quantification data[2]

4. FFR_{CT}, Stenosis, and sCPR with plaque type by color to identify high-risk disease faster[3]

5. Detailed comprehensive plaque quantification by territory

6. Co-registered cross-sectional reference and sCPR with plaque by type

1. Measured in mm3 in vessels that are >1.8mm in diameter; Narula et al. Eur Heart J 2024. https://doi.org/10.1093/ehjci/jeae115
2. Tzimas, et al., Presentation SCCT July 2025.
3. FFR_{CT} values available when performed

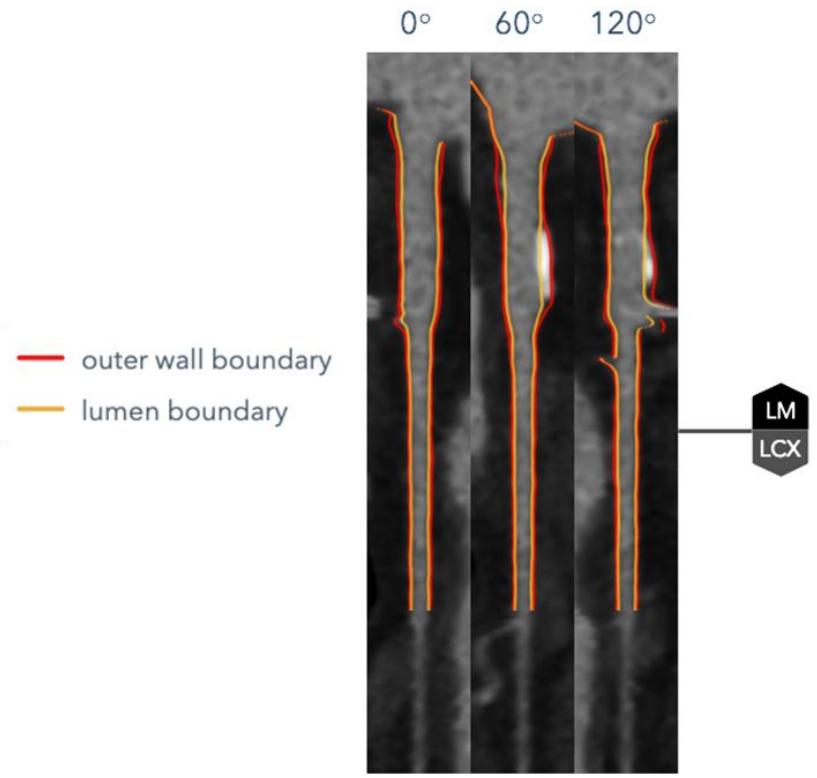
Mockup for visualization and actual appearance may change. Clinical information is for illustrative purposes only.

Heartflow Plaque Analysis

LM

Calcified Plaque	38 (31%)
Non Calcified Plaque	85 (69%)
Low Attenuation Plaque	1 (<1%)
Total Plaque (mm^3)	123

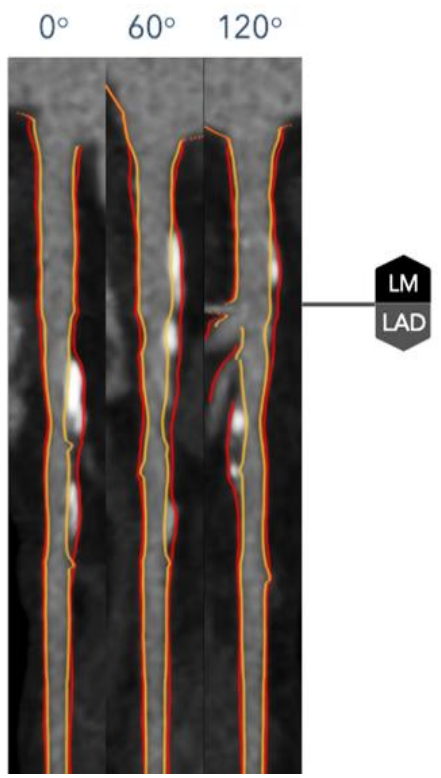
Quantitative plaque is provided on vessels > 1.8 mm.



LAD

Calcified Plaque	83 (34%)
Non Calcified Plaque	162 (66%)
Low Attenuation Plaque	3 (1%)
Total Plaque (mm^3)	245

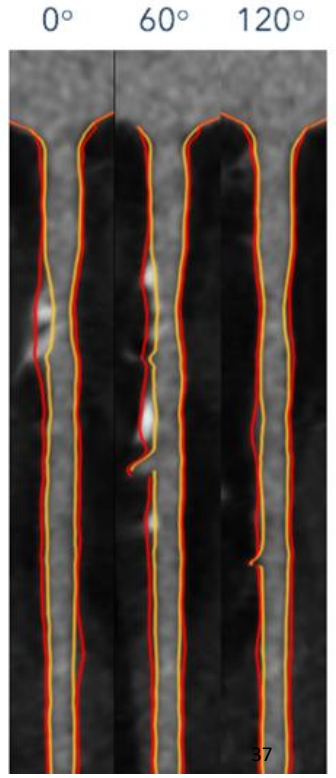
Quantitative plaque is provided on vessels > 1.8 mm.



RCA

Calcified Plaque	51 (26%)
Non Calcified Plaque	149 (75%)
Low Attenuation Plaque	2 (1%)
Total Plaque (mm^3)	200

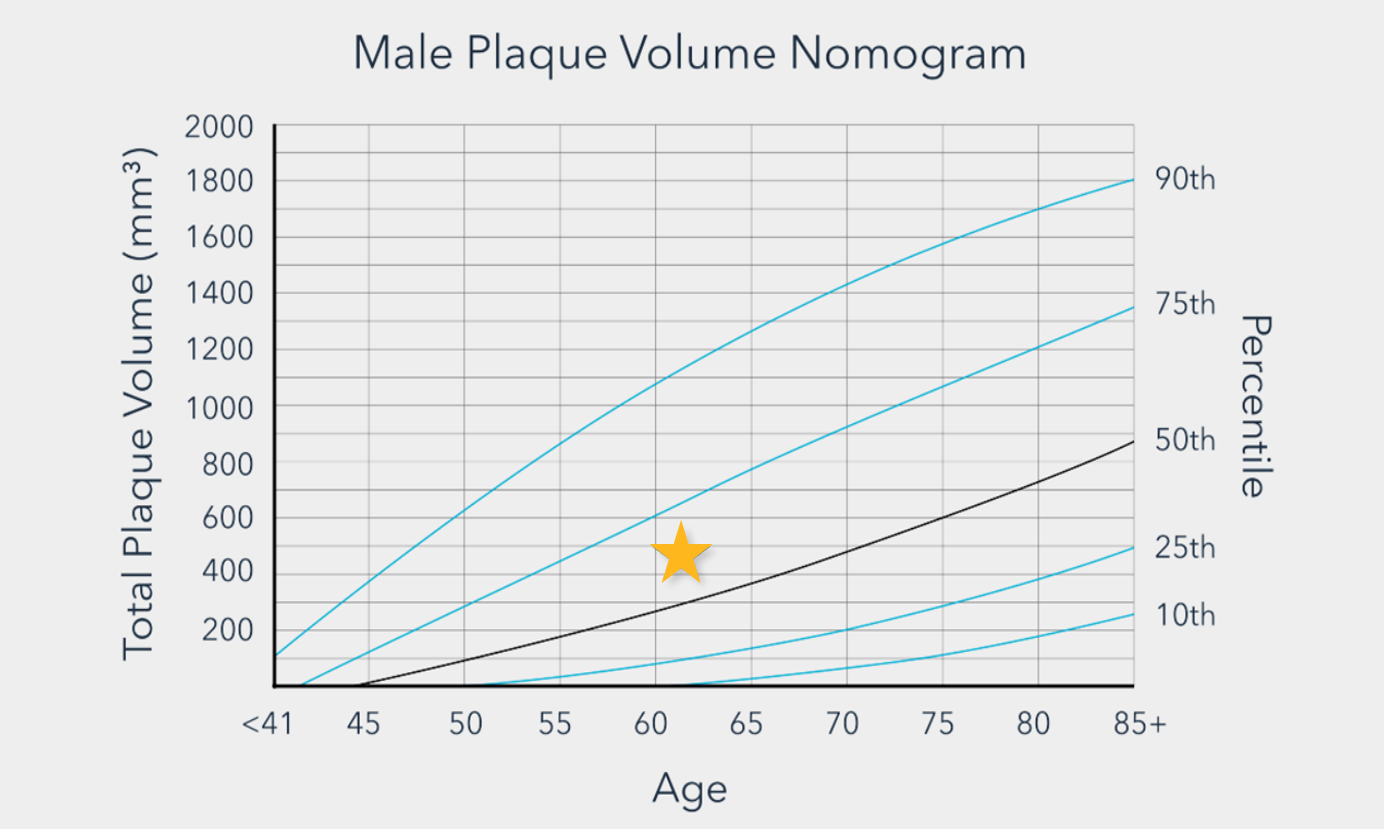
Quantitative plaque is provided on vessels > 1.8 mm.



Heartflow Plaque Analysis for Disease Characterization

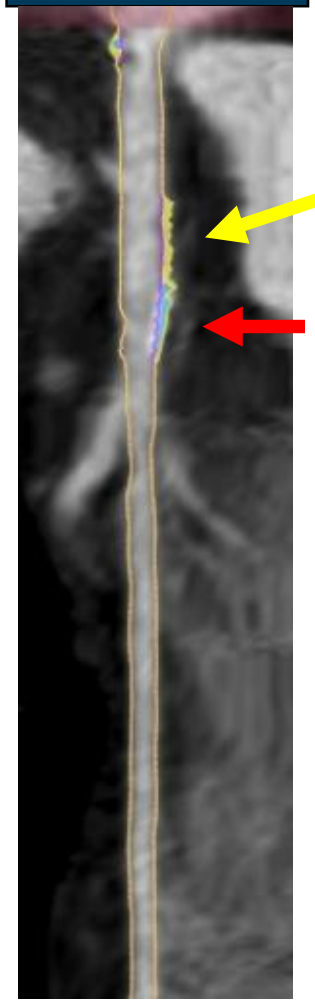
Plaque Types	LM	LAD	LCX	RCA	Total
Calcified Plaque	38	83	0	51	172 (30%)
Non Calcified Plaque	85	162	0	149	396 (70%)
Low Attenuation Plaque	1	3	0	2	6 (1%)
Total Plaque (mm^3)	123	245	0	200	568

Quantitative plaque is provided on vessels > 1.8 mm.



Serial CCTA Images to personalize Lipid Lowering

2019



Fibrofatty Plaque

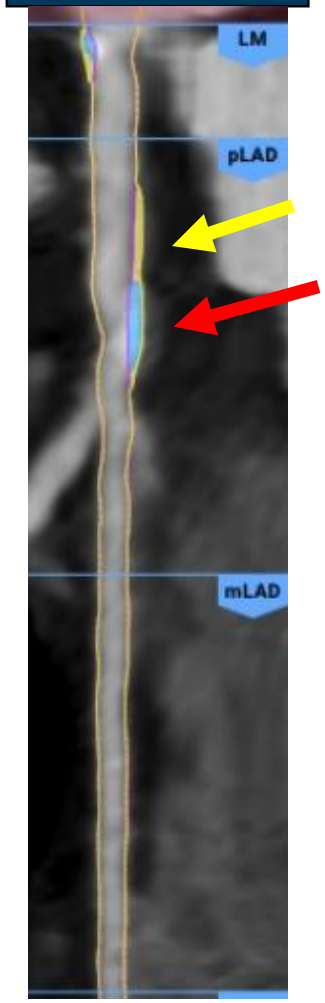
Low Attenuation Plaque

High Intensity statin started

2020

Plaque Progressed PCSK9i Added

2023



Heartflow One: The Platform to Manage CAD for Life

1 Bittner et al. JACC Cardiovasc Imaging 2020. (PROMISE) doi: 10.1016/j.jcmg.2019.09.012; Data on file.

Representative images for illustrative purposes only.

Take Home Messages

- Clinicians need better tools to **identify which patients have disease** and need more aggressive treatment
- **Coronary CTA is a front-line pathway** that opens new options for disease identification
- CTA-driven AI-enabled techniques to **quantify, characterize, and inform disease severity are validated, rapid, and reimbursed.**
- These **accurate, patient-specific disease insights impact treatment decisions** which may improve long-term disease management

Comprehensive Platform to Diagnose and Manage CAD

Roadmap Analysis

Read CCTA more efficiently and consistently

STENOSIS AND CAD DETECTION

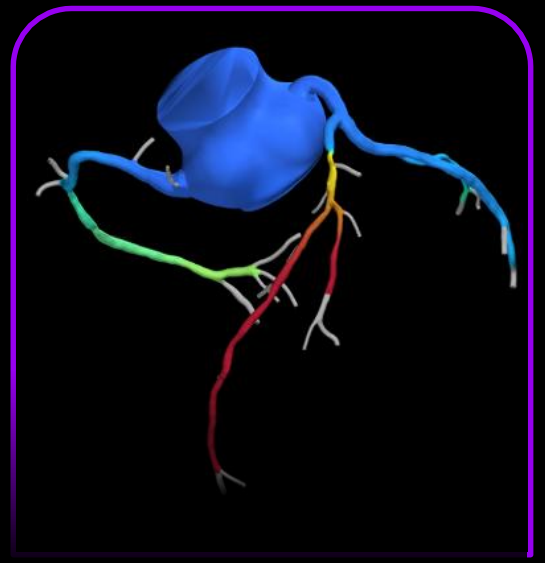
Plaque Analysis

Quantify and characterize plaque

MEDICAL MANAGEMENT

FFR_{CT} Analysis

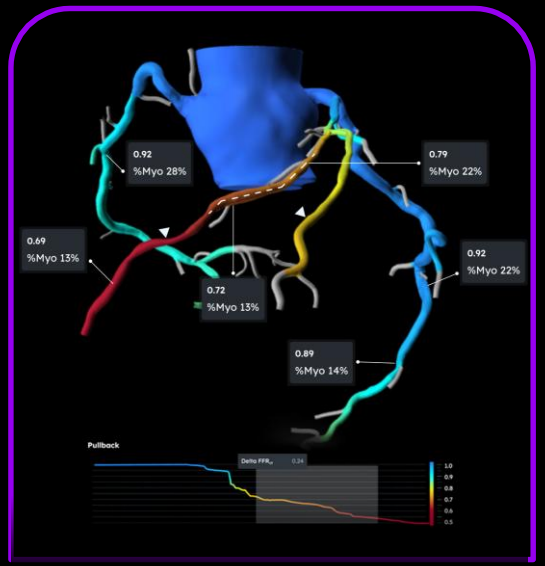
Assess impact to blood flow



INTERVENTIONAL DECISION

PCI Navigator

Plan PCI



INTERVENTIONAL PLANNING

Heartflow Analysis consists of four main functions; FFR_{CT}, Planner, Roadmap, and Plaque. All four functions are cleared for clinical use in 43 countries/regions, including the United States, United Kingdom and Europe. Only FFR_{CT} and Planner functions are cleared for clinical use in Canada and Japan. Please see Heartflow Indications for Use and Instructions for Use for more information.

PCI Navigator Will Deliver a Streamlined View of Essential Information for Cath Lab Decision-making

- **Procedural Complexity:** Lesion-specific FFR_{CT} values, stenosis, plaque location and composition, as well as percent myocardium fed by a vessel, to help understand lesion significance in context.
- **Stent Landing Zones:** Cross-sectional and longitudinal reconstructions providing lumen diameter and length measures alongside plaque morphology and stenosis severity to help precisely plan and guide procedures.
- **Planning for Optimal Outcomes:** Physiology changes along the lesion (ΔFFR_{CT}) to ensure the stenting procedure addresses the maximal flow gradient for optimal outcomes.

New SCAI/SCCT Consensus Paper

SCAI
Society for Cardiovascular Angiography & Interventions

SCCT
SOCIETY OF CARDIOVASCULAR COMPUTED TOMOGRAPHY

"...increasing evidence and real-world experience suggest that CTA can be used for the ***preprocedural planning of PCI*** *and can inform* ***patient triage, shared decision making, case complexity, and resource use****."*

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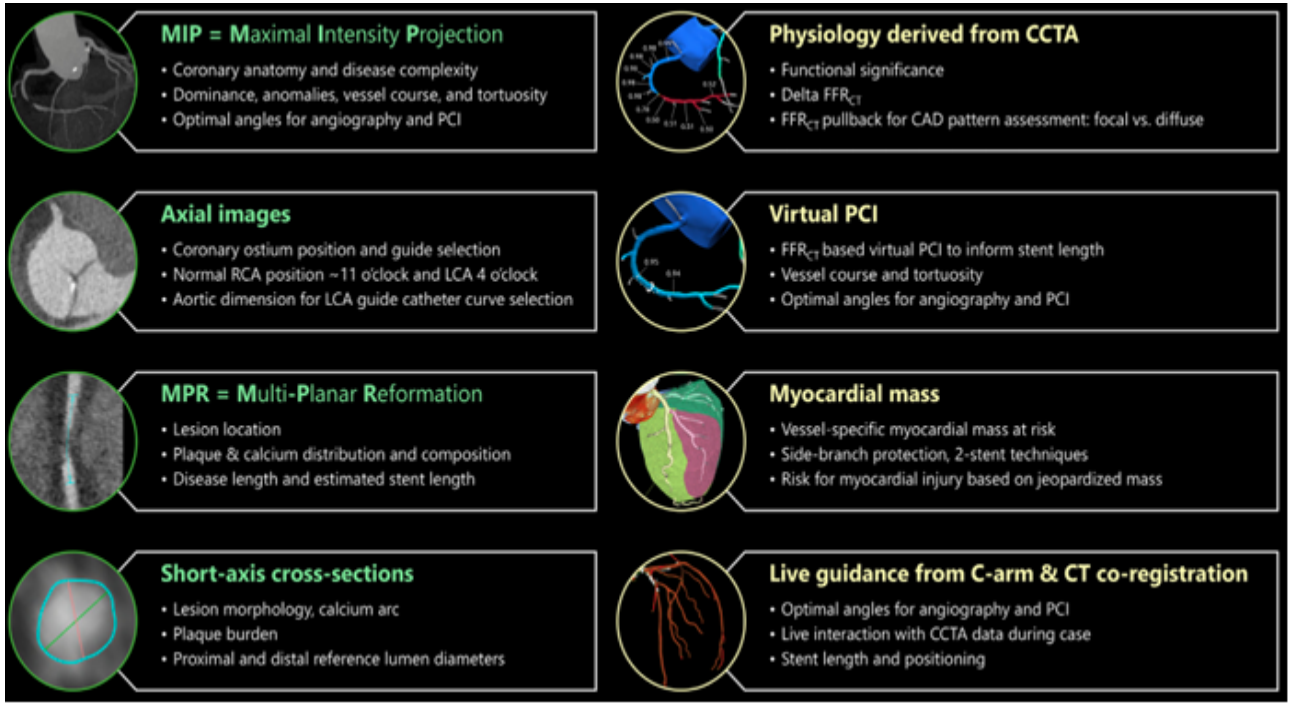
Central Illustration: Components of coronary computed tomography angiography-guided percutaneous coronary intervention




JSCAI

Standards and Guidelines

Coronary Computed Tomography Angiography to Guide Percutaneous Coronary Intervention: Expert Opinion from a SCAI/SCCT Roundtable

ABSTRACT

Introduction

Consensus paper here

Introducing PCI Navigator

THOUGHTS ON PREVENTION

- ***…at the beginning a disease is easy to cure but difficult to diagnose; but as time passes, not having been recognized or treated at the outset, it becomes easy to diagnose but difficult to cure.***

- ***Niccolò Machiavelli (1469-1527)***

“All truth passes through three stages.
First, it is ridiculed.
Second, it is violently opposed.
Third, it is accepted as being self-evident.”

- Arthur Schopenhauer

Thank you for listening!

Questions?