

Integration of HeartFlow FFR_{CT} into Clinical Practice

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Disclosures

- **Extramural Research Support:**
 - Dalio Institute of Cardiovascular Imaging @ NYPH / WCMC (Dalio Foundation)
 - NIH R01 HL115150
 - NIH R01 HL111141
 - NIH R01 HL118019-01
 - NIH U01 HL105907
 - NPRP 09-370-3-089
- **Equity Interest:** MDDX, Autoplaq
- **Consultant / Medical Advisory Board:** Abbott Vascular, Arineta, Astra Zeneca, Cardiovascular Research Foundation, GE Healthcare, HeartFlow, Myokardia

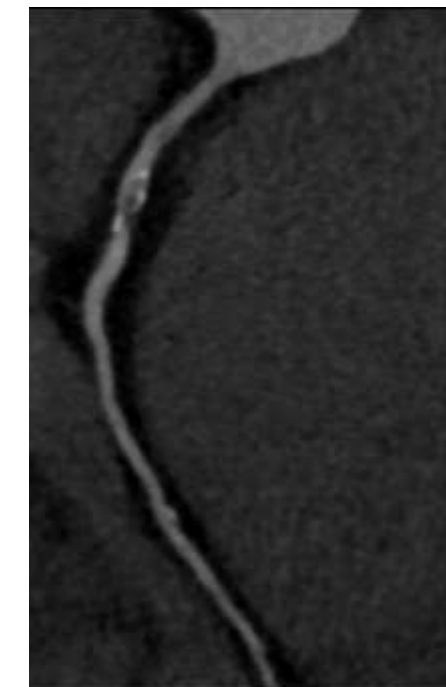
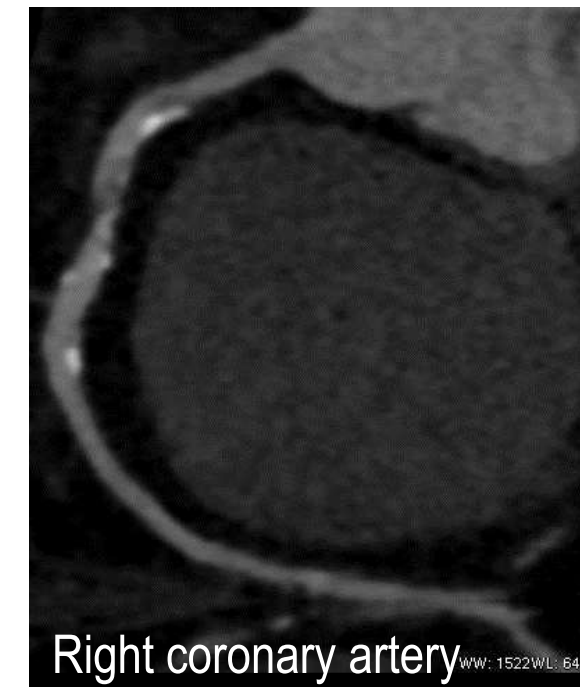
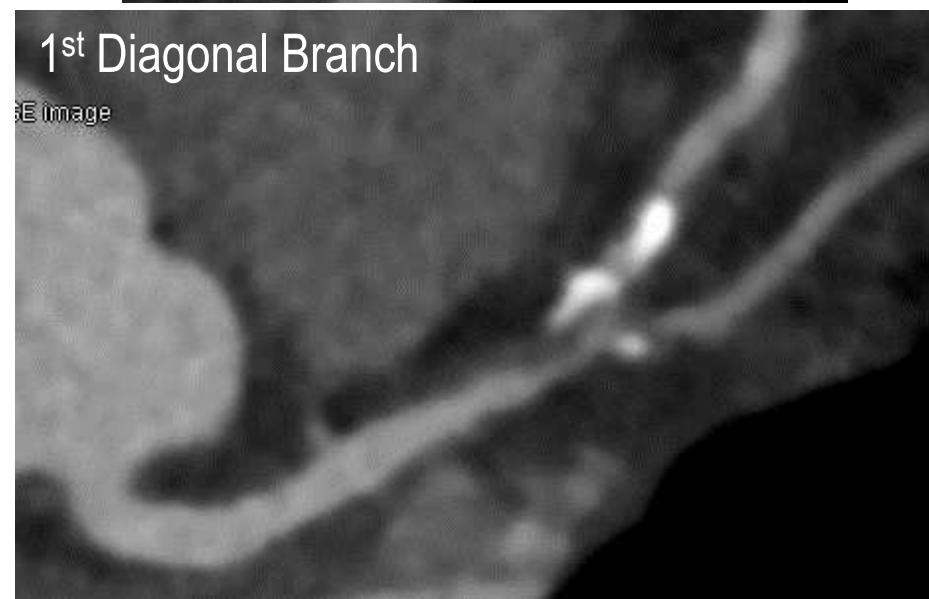
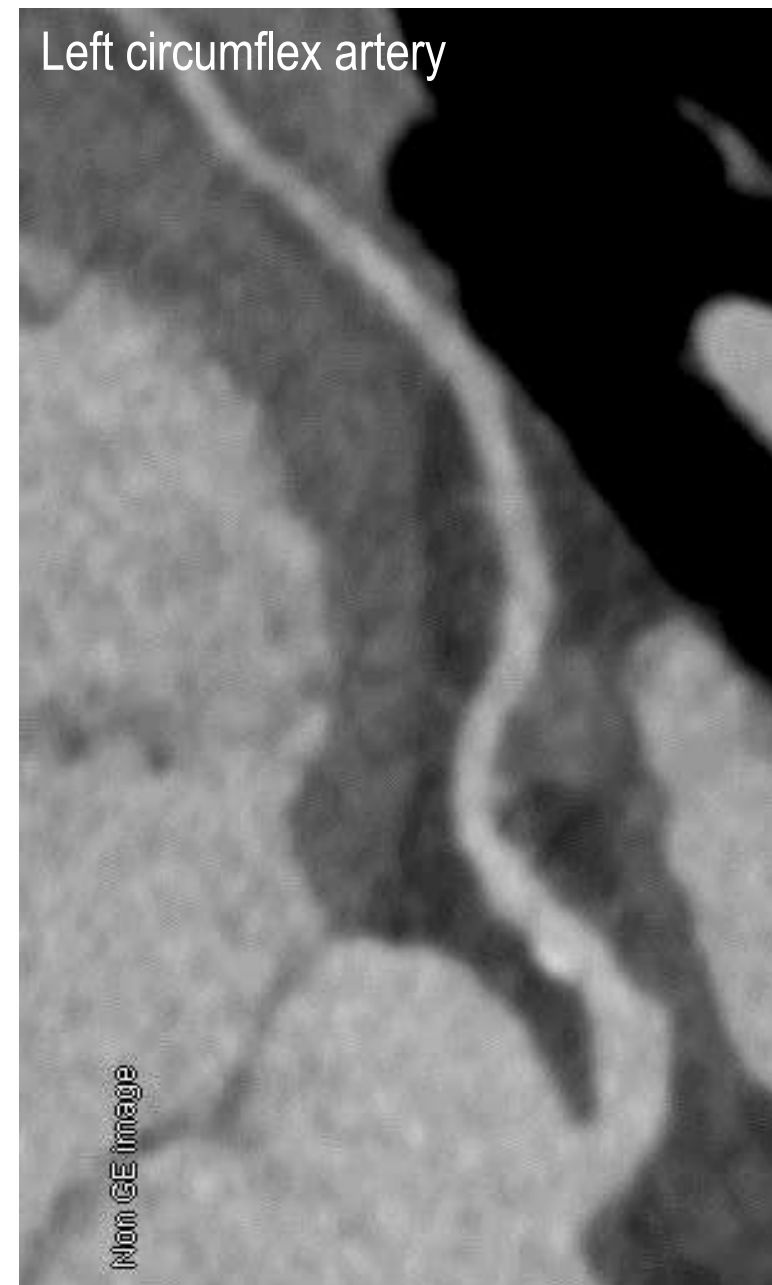
Case: 63 y/o Asian man

(Performed @ Cornell / NewYork-Presbyterian 4/17/15)

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- **Symptoms:** No specific symptoms; possible dyspnea on exertion; “slowing down”
- **Social History:** Former track sprinter; past smoker (<2 years); diet-conscious
- **Past Medical History:** renal cell carcinoma; pulmonary wedge resection
- **Medications:** ASA 81mg qd

Case: 63 y/o Asian man

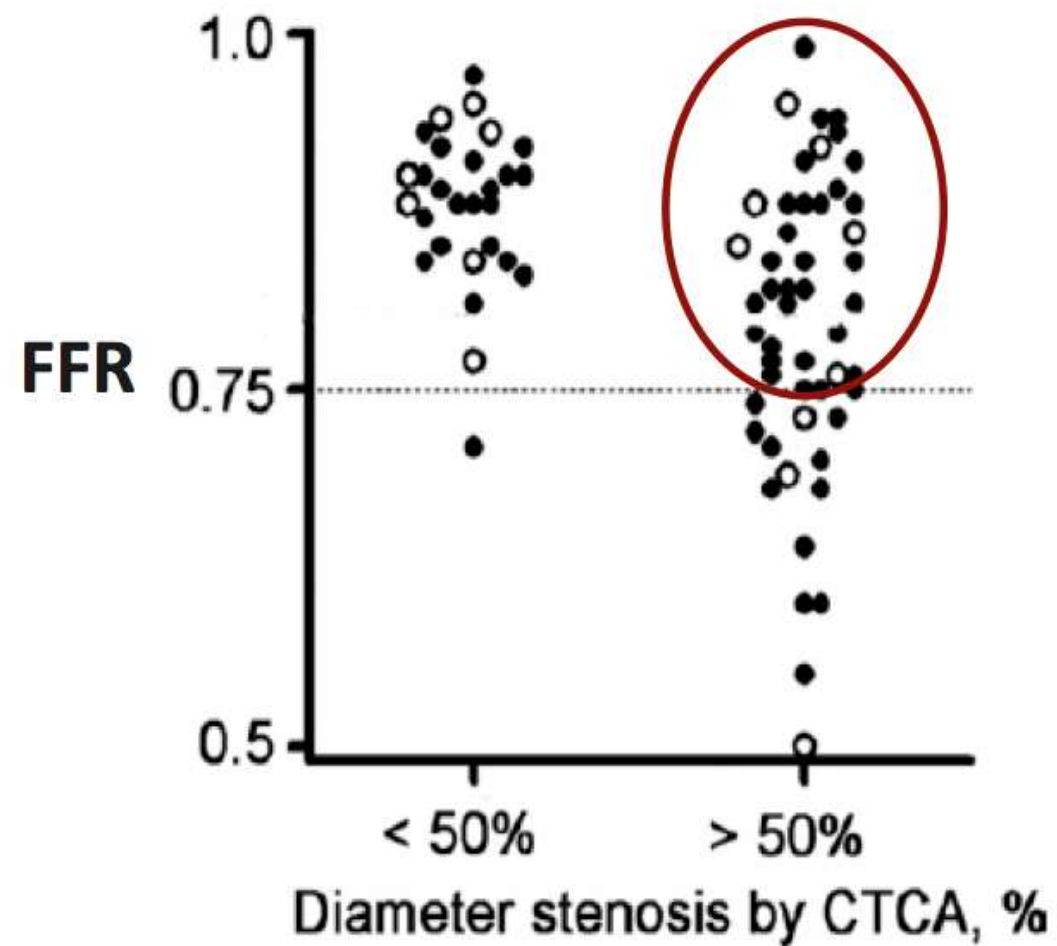


- **LM** No atherosclerosis
- **LAD** Severe stenosis, mLAD
- **D1** Severe ostial
- **RCA** Severe stenosis, mRCA

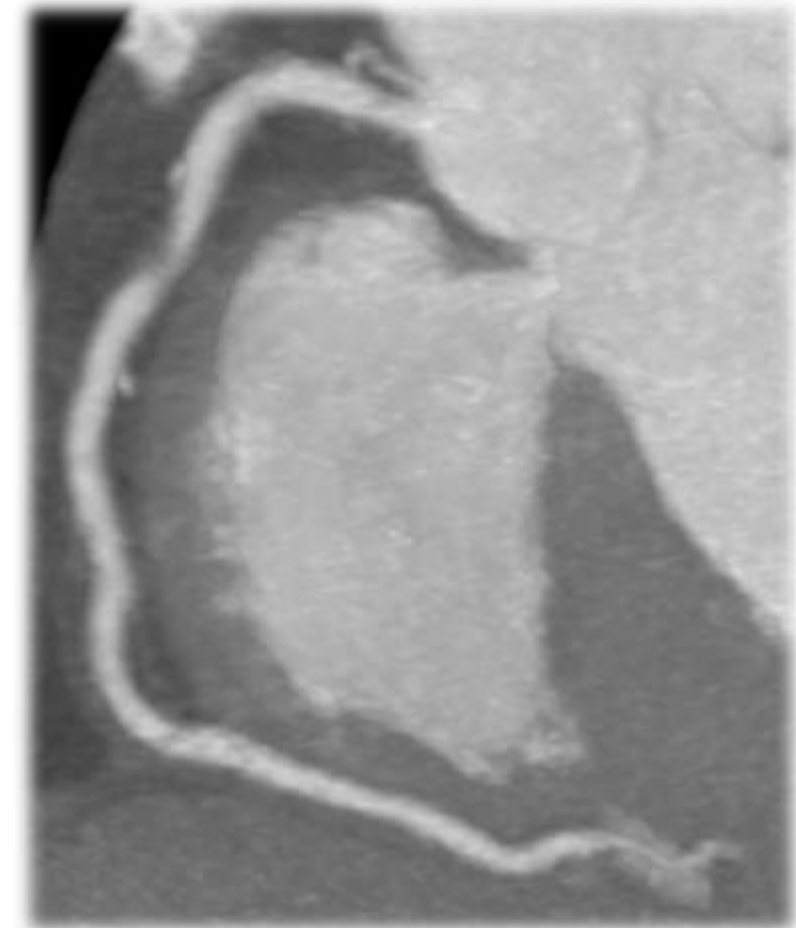
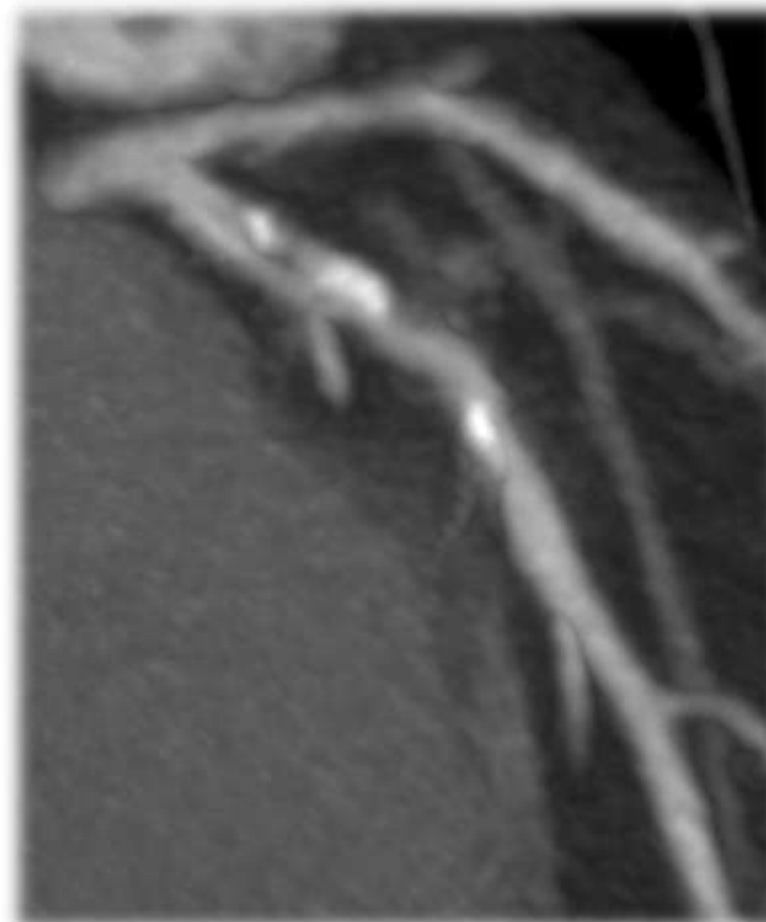
CT to Diagnosis and Exclude Lesion Ischemia

Only one of these patients has hemodynamically significant CAD.

Who has ischemia?



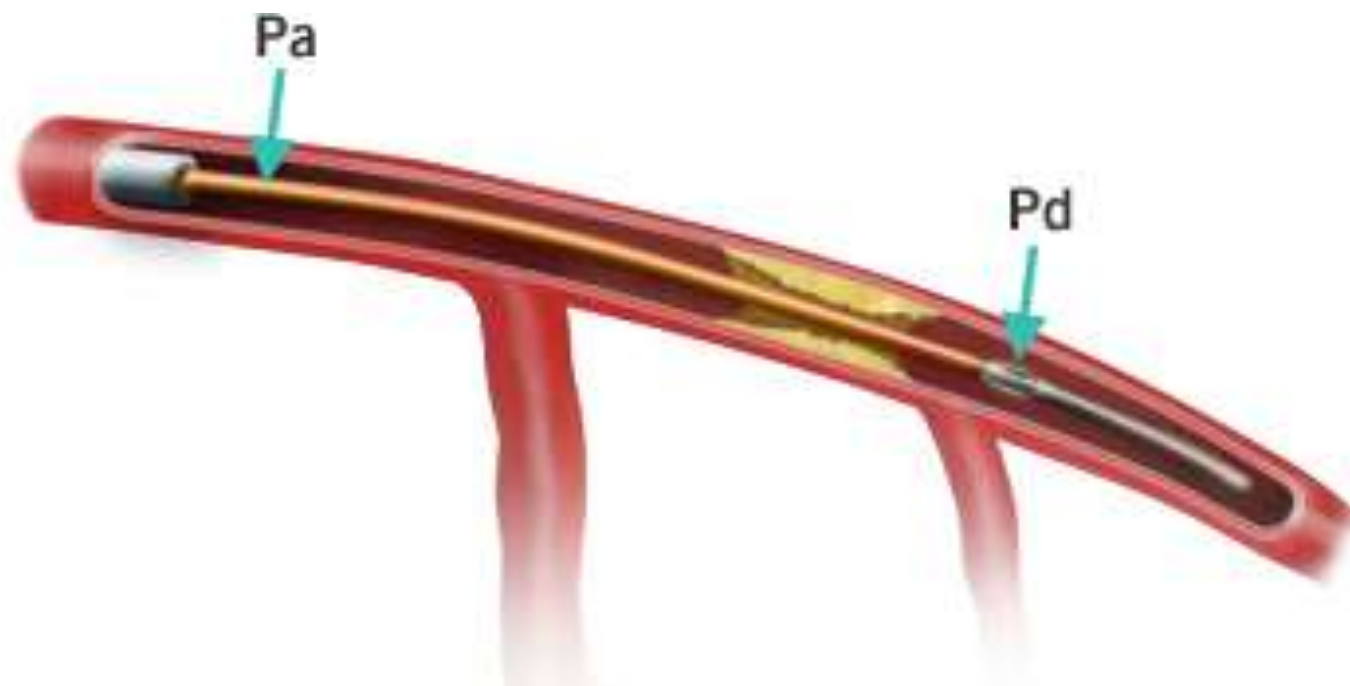
75% false positives



“Gold” standard for lesion-specific ischemia Invasive Fractional Flow Reserve (FFR)

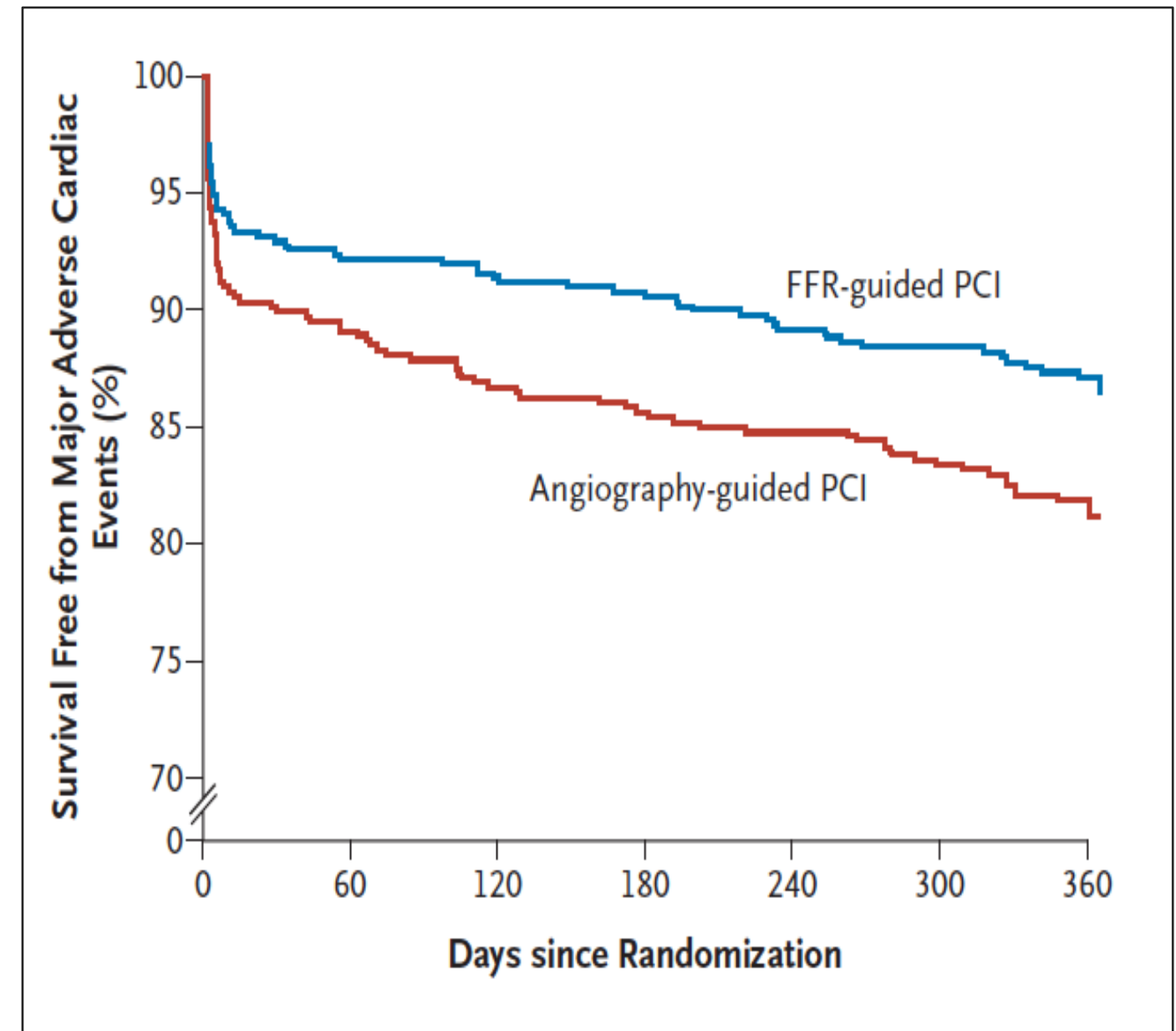
FAME RCT, N=1,005
Multivessel CAD
“Anatomy vs. Physiology”

Maximal MBF through a diseased artery
MBF in the hypothetical case the artery is normal



Lesion-specific ischemia: $FFR \leq 0.80$

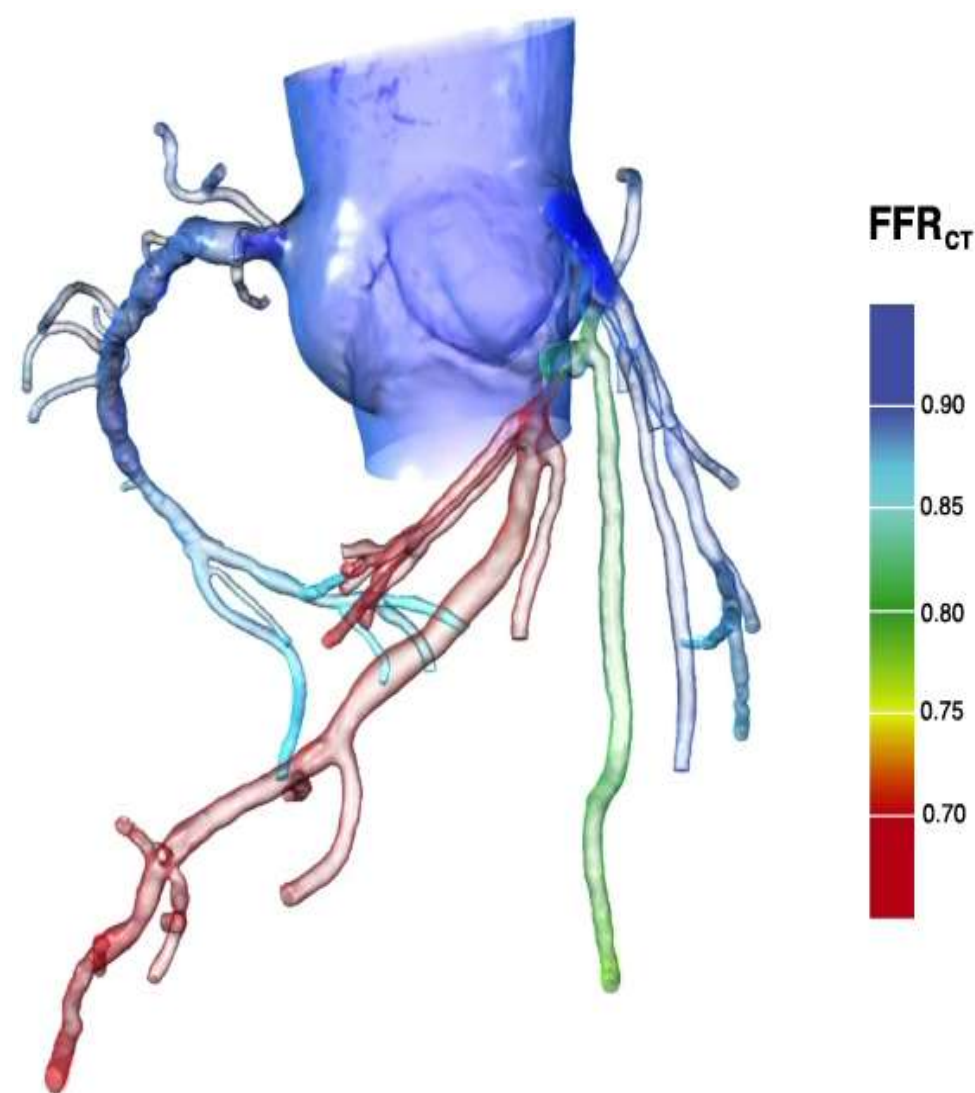
- Only method to **pinpoint ischemia-causing lesions**
- Only method to guide revascularization to **improve event-free survival**



FFR_{CT} development (22
yrs)

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Non-invasive FFR (FFR_{CT})



- From typically acquired CCTA
- No additional radiation
- No modification to imaging protocols
- No administration of medications

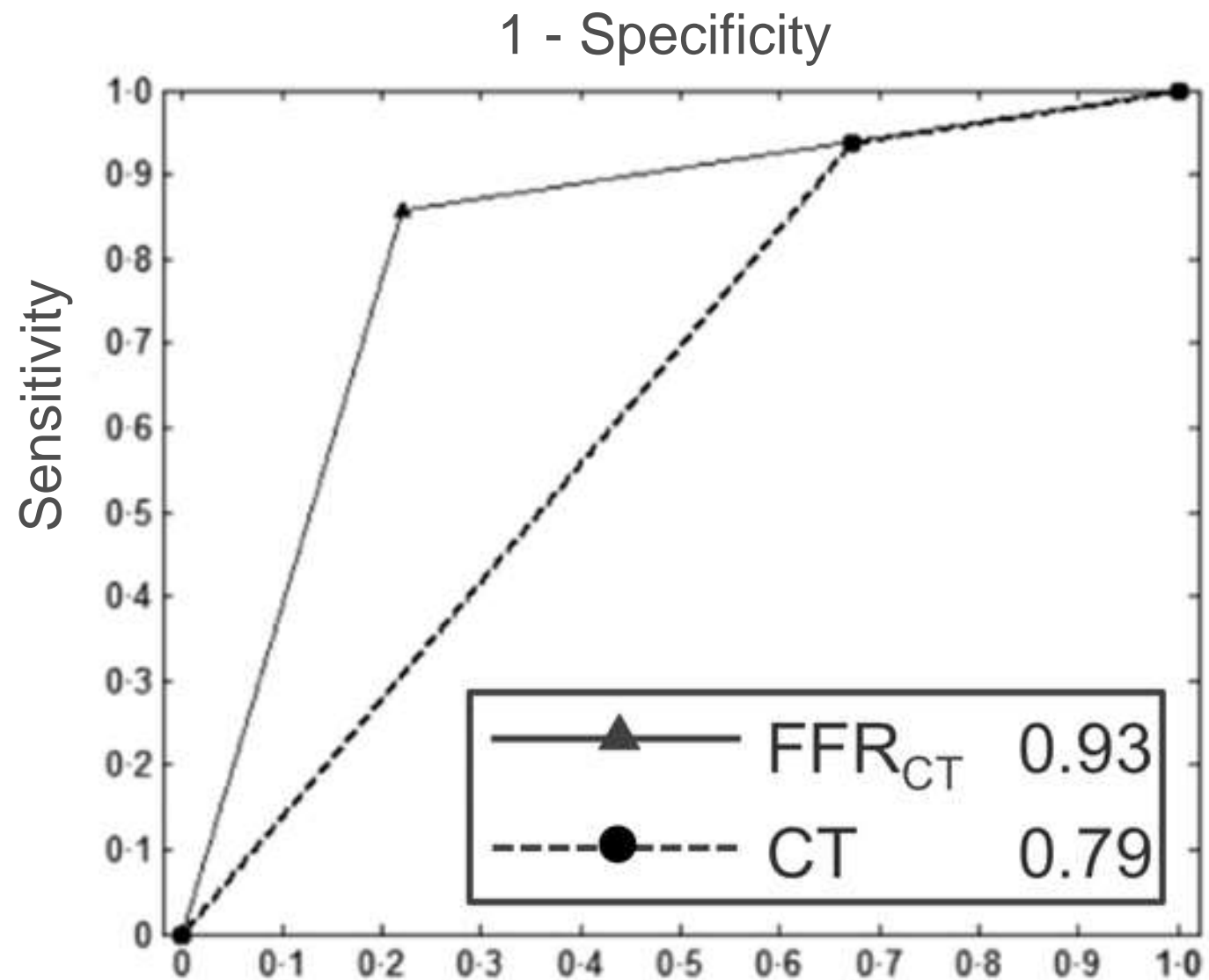
FFR_{CT}: Three (3) Prospective Multicenter Trials

	DISCOVER-FLOW	DeFACTO	NXT
Principal Investigator	Min (JACC)	Min (JAMA)	Norgaard (JACC)
Primary end point	Per pt. diag accuracy	Per pt. diag accuracy; lower limit 95% CI 0.7	Per pt. AUC
Study sites/ countries	4 / 3	17 / 5	10 / 8
Site expertise qualification	FFR	CT or FFR	CT plus FFR
CT training of site	Yes	No	Yes
FFR training of site	No	No	Yes
CT quality check	No	No	Yes
CT results reading	Core lab	Core lab	Site
FFR results report	Site	Site	Site with core lab overview
Vessel size for inclusion	≥ 2.0 mm	≥ 1.5 mm	≥ 2.0 mm
Software version*	V 1.0 manual	V 1.2 partial automation ~6 hrs	V 1.4 automation; <4 hours

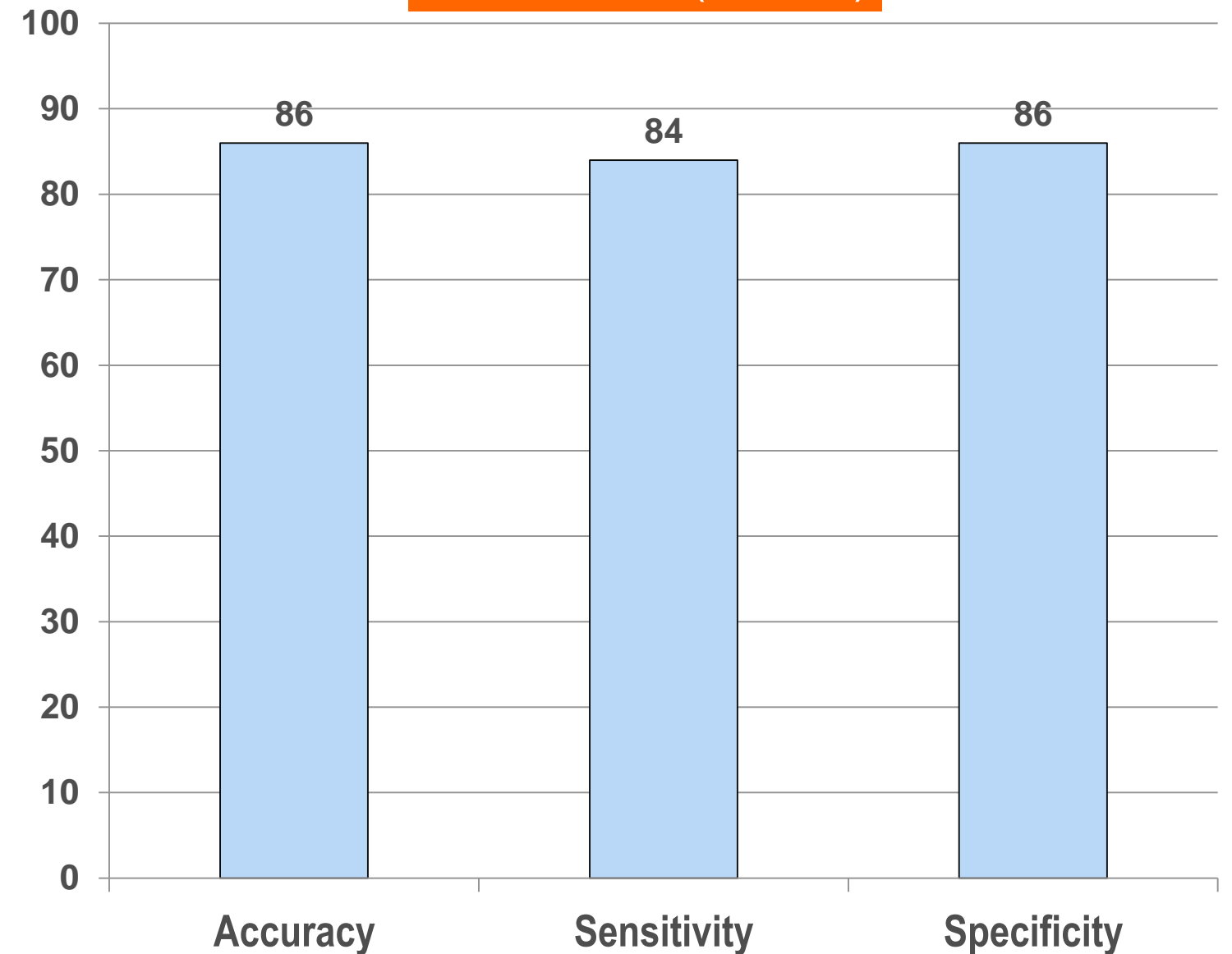
NXT: Discrimination of ischemia

Prospective multicenter
N=251 (n=484 vessels)
Comparator: Invasive FFR

Per-Patient (n=251)



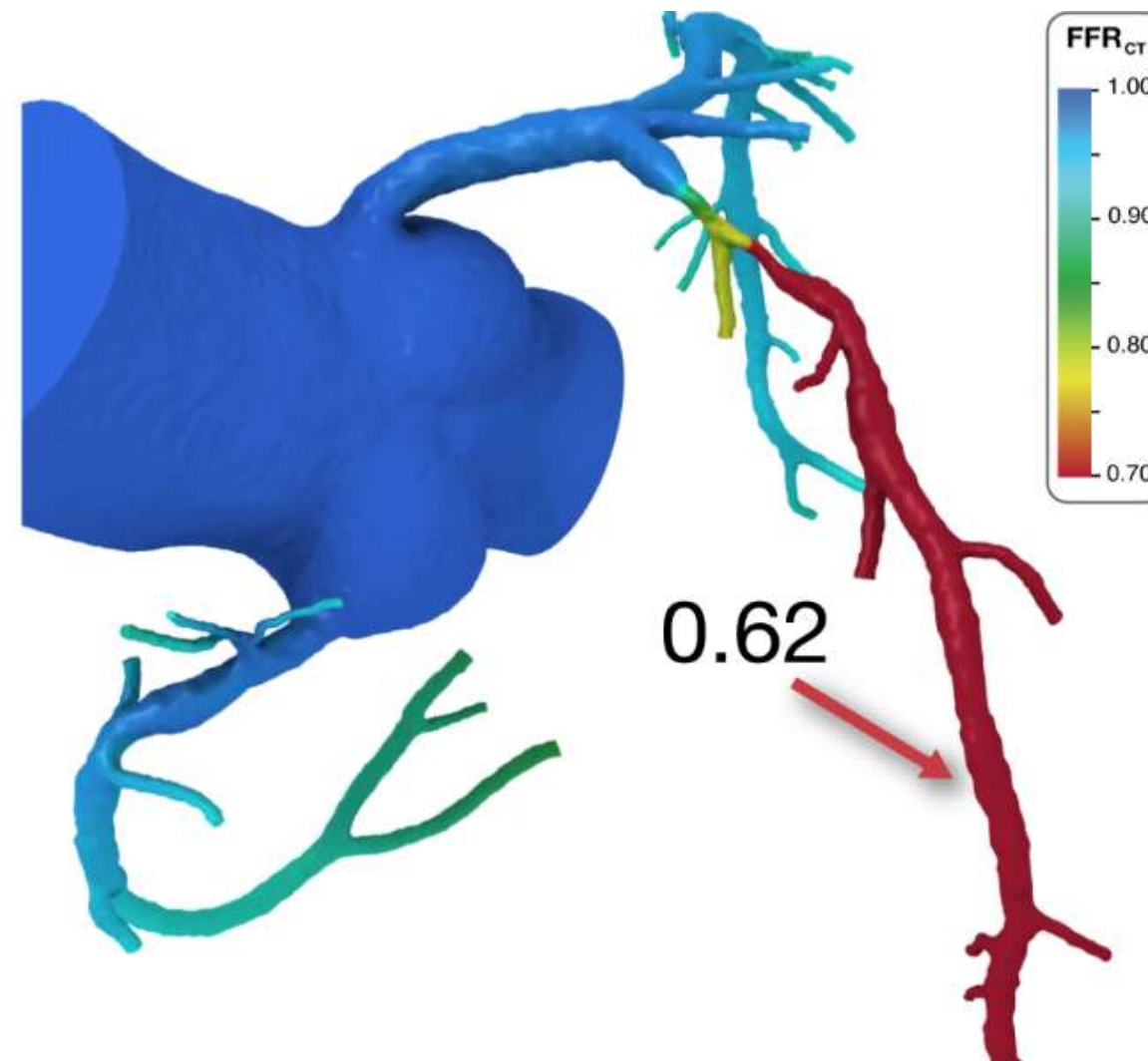
Per-Vessel (n=484)



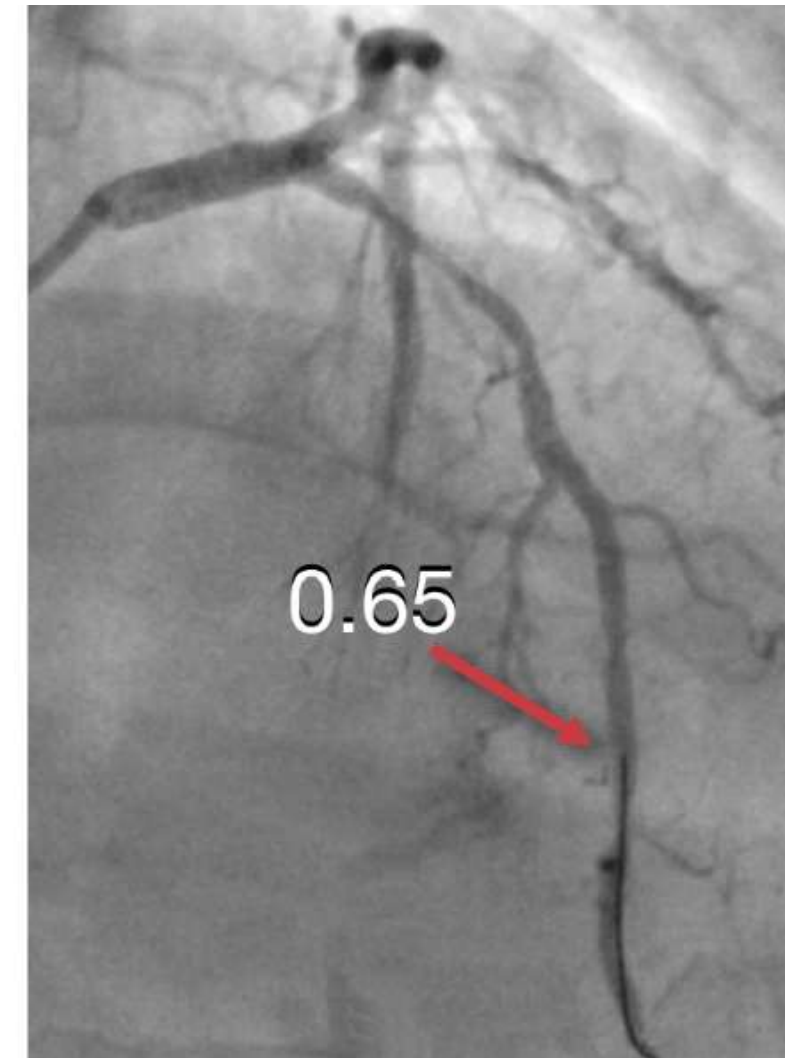
FFR_{CT}: Severe LAD Stenosis



CT: Severe Stenosis

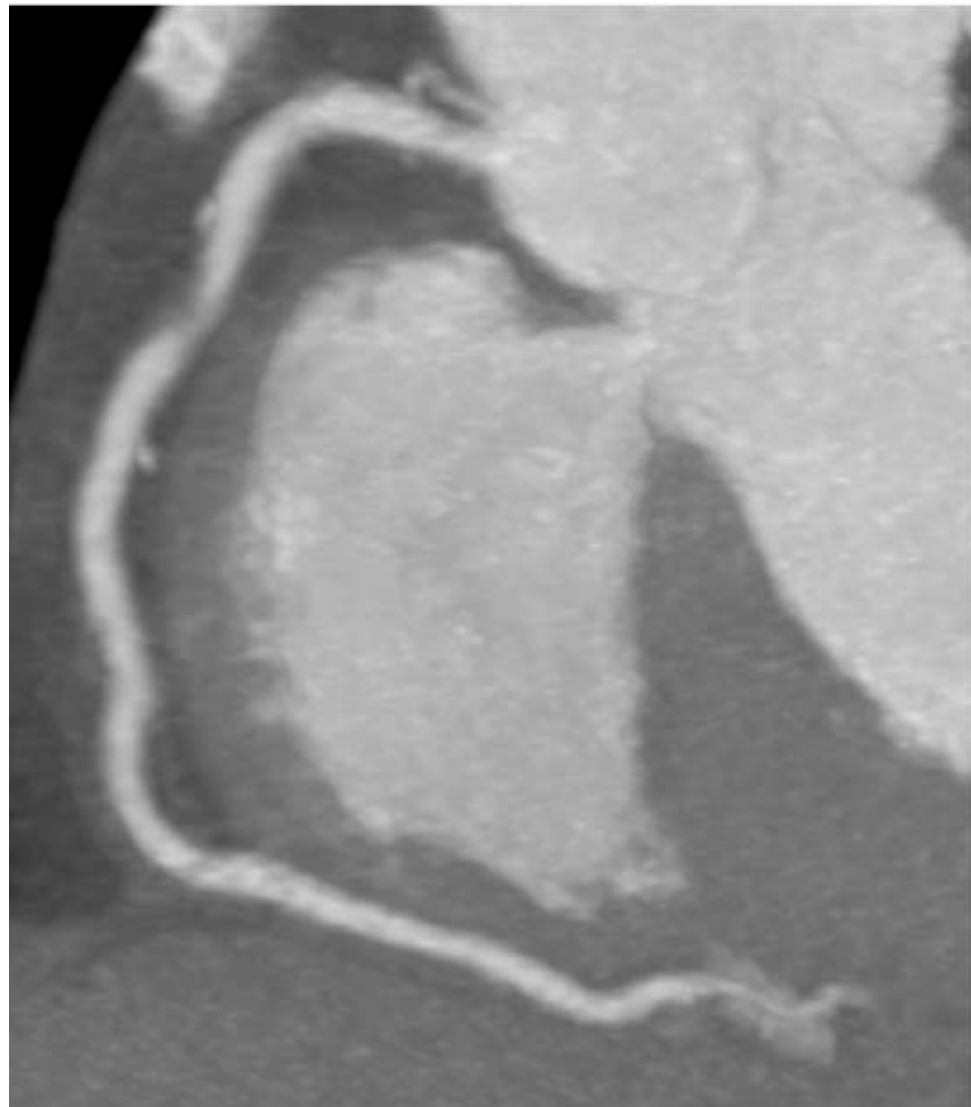


FFR_{CT}: Lesion-specific Ischemia

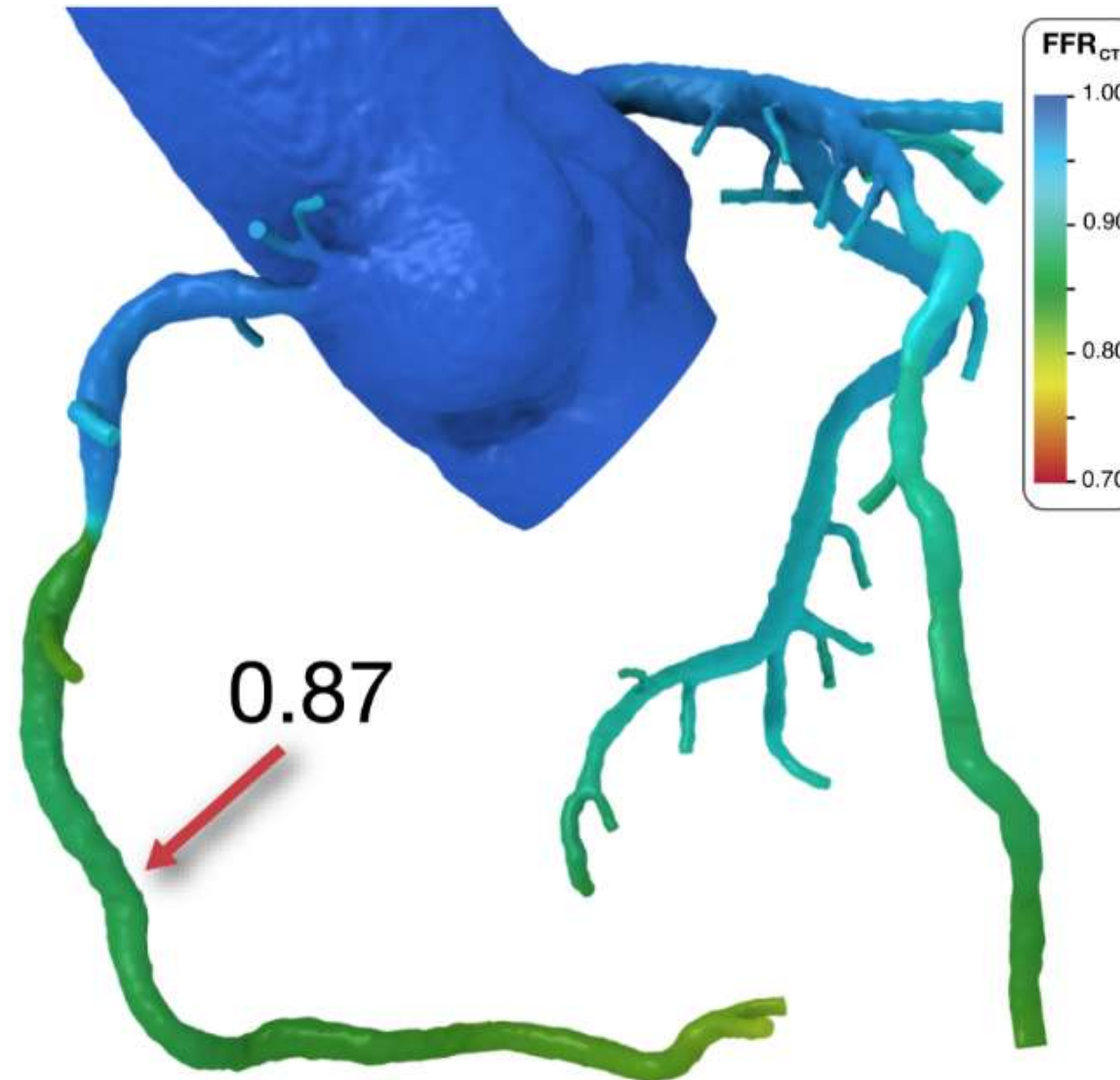


FFR: Ischemia

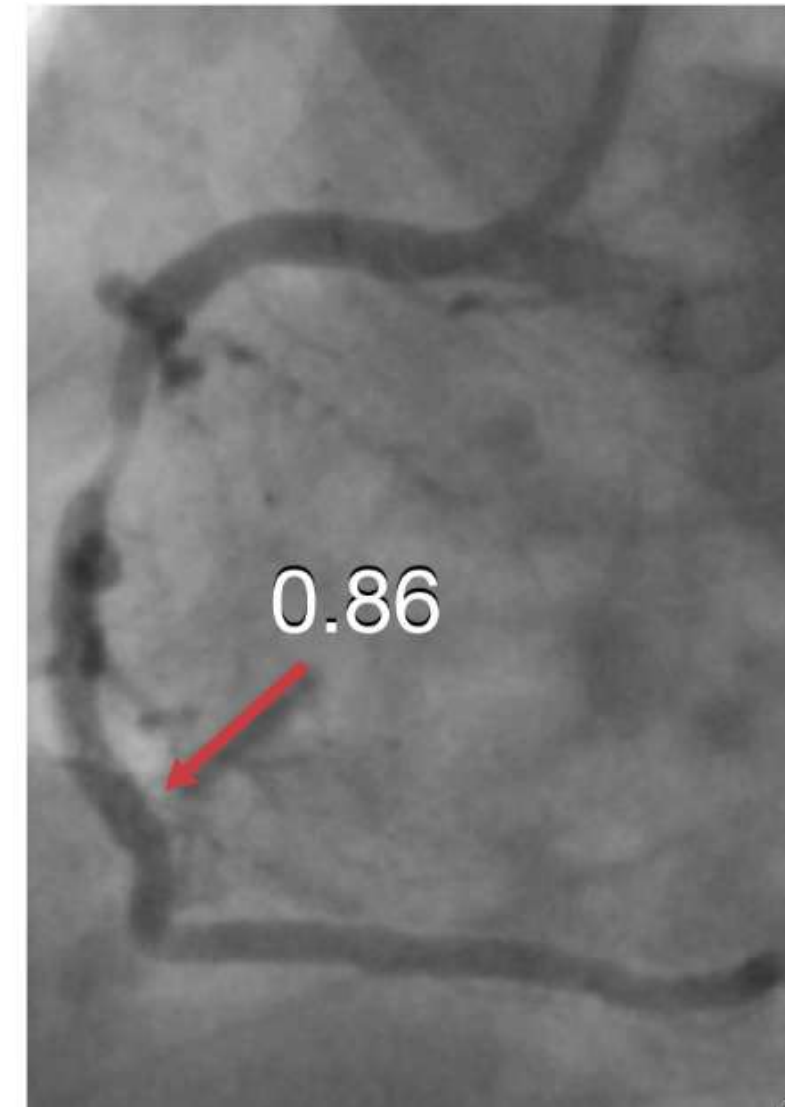
FFR_{CT}: Severe RCA Stenosis



CT: Severe Stenosis



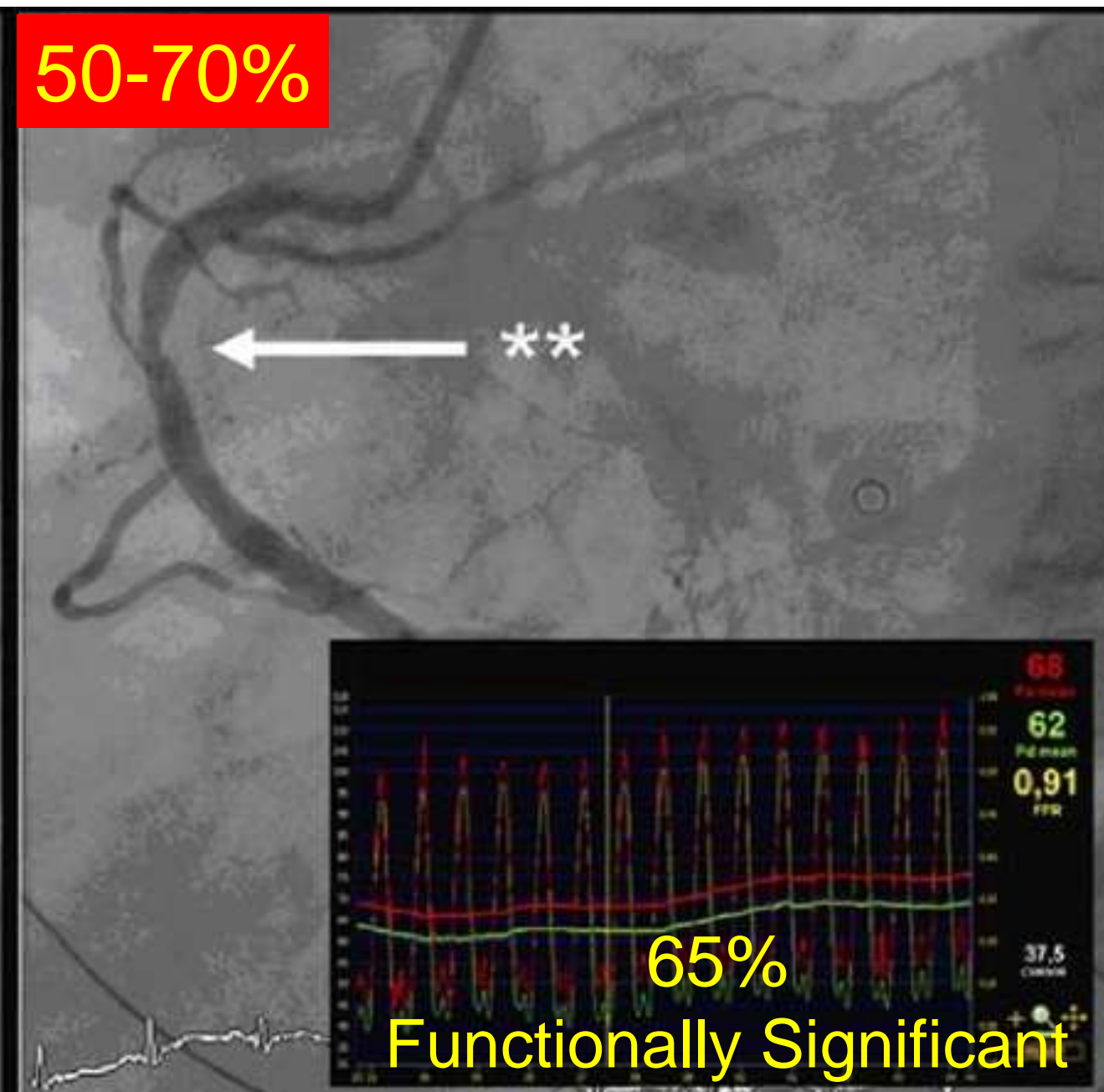
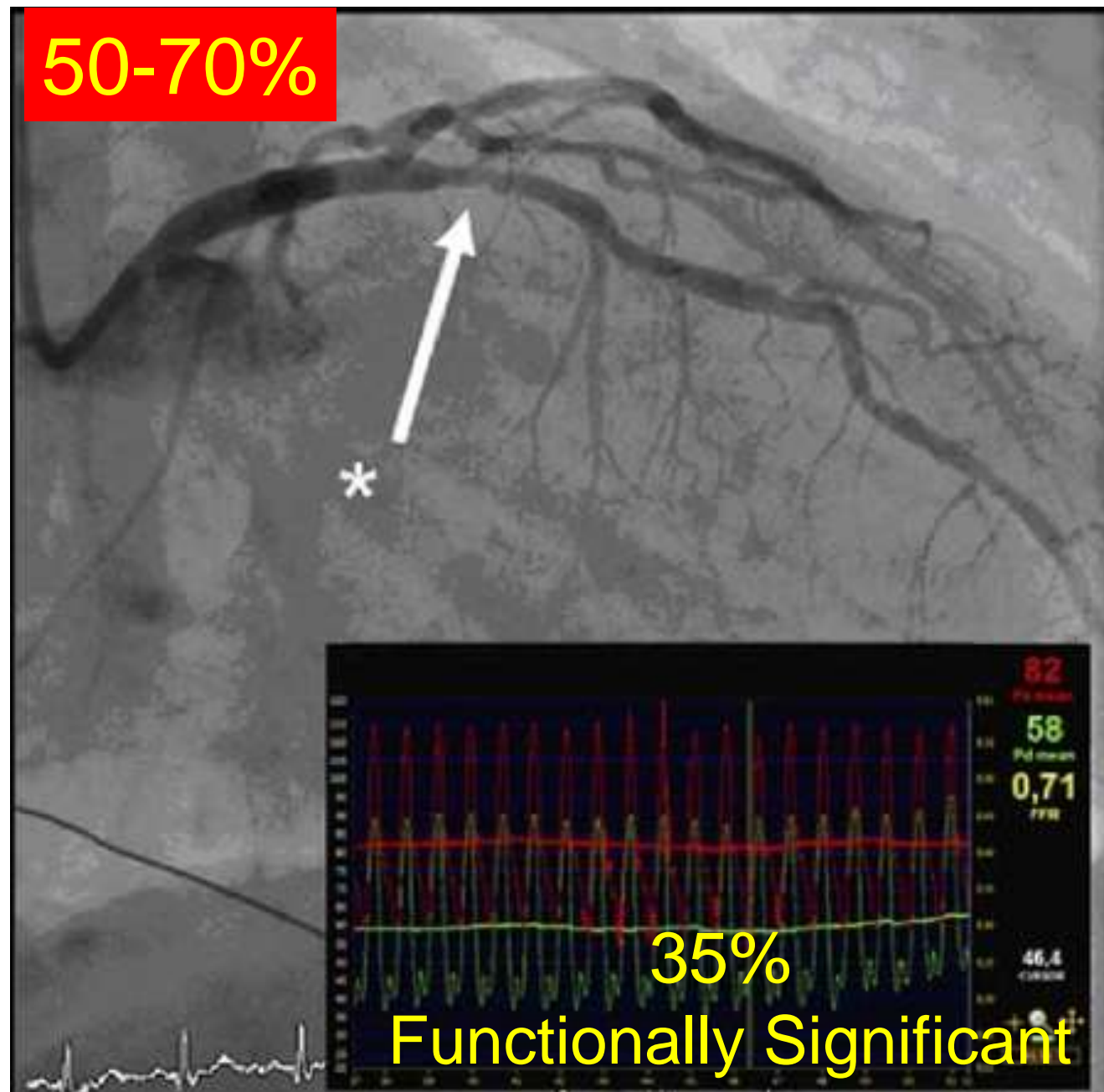
FFR_{CT}: No Ischemia



FFR: No Ischemia

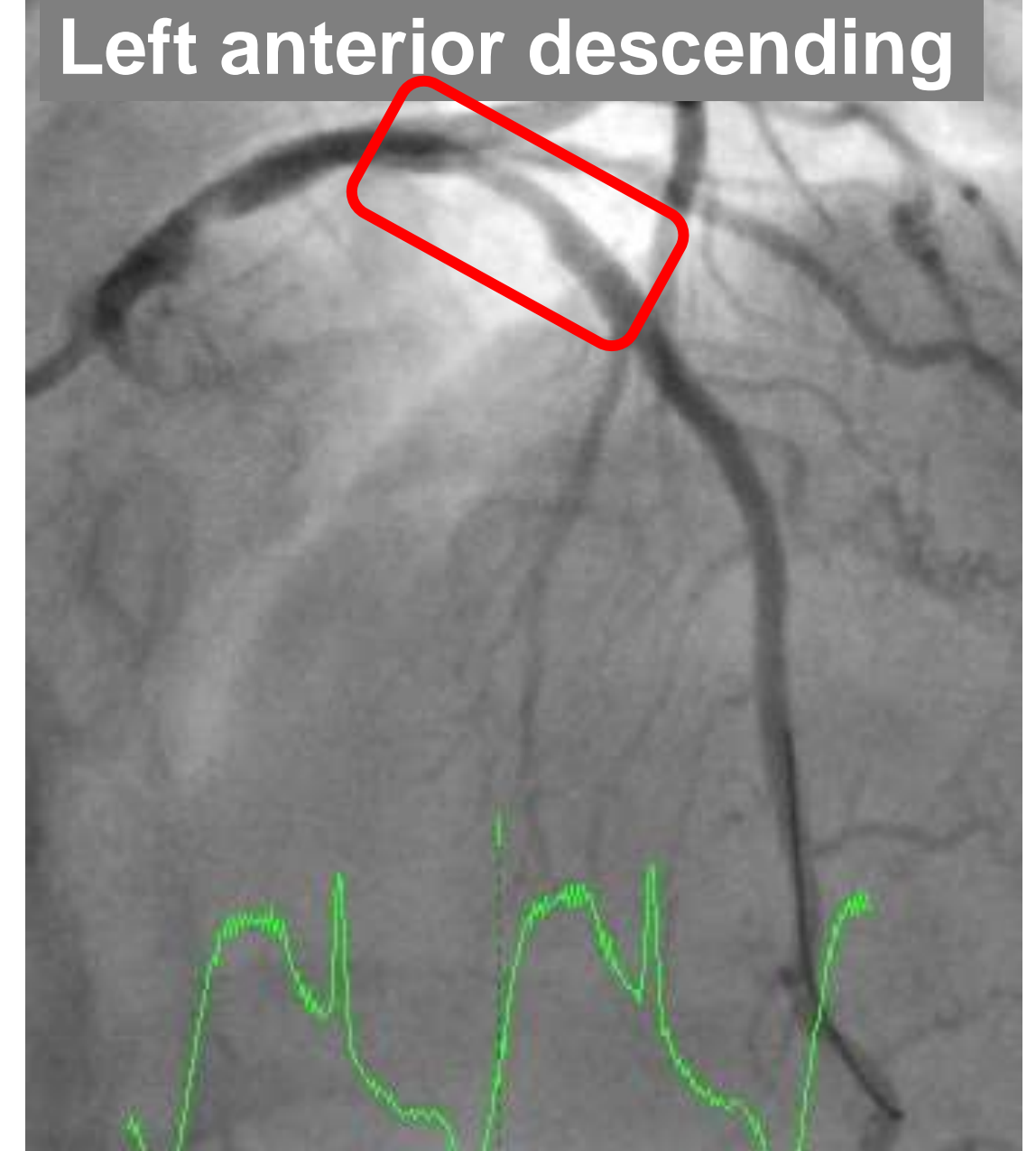
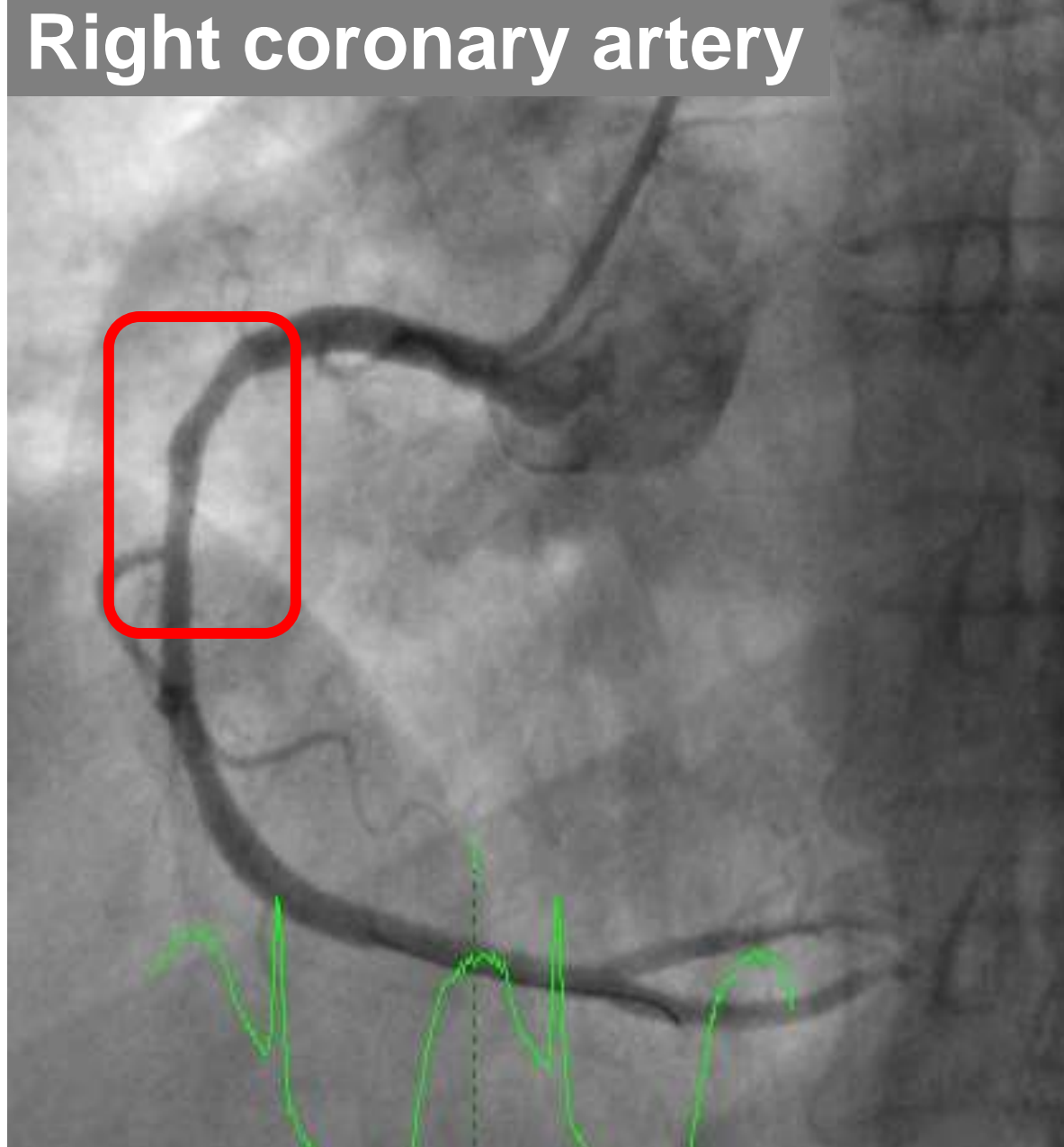
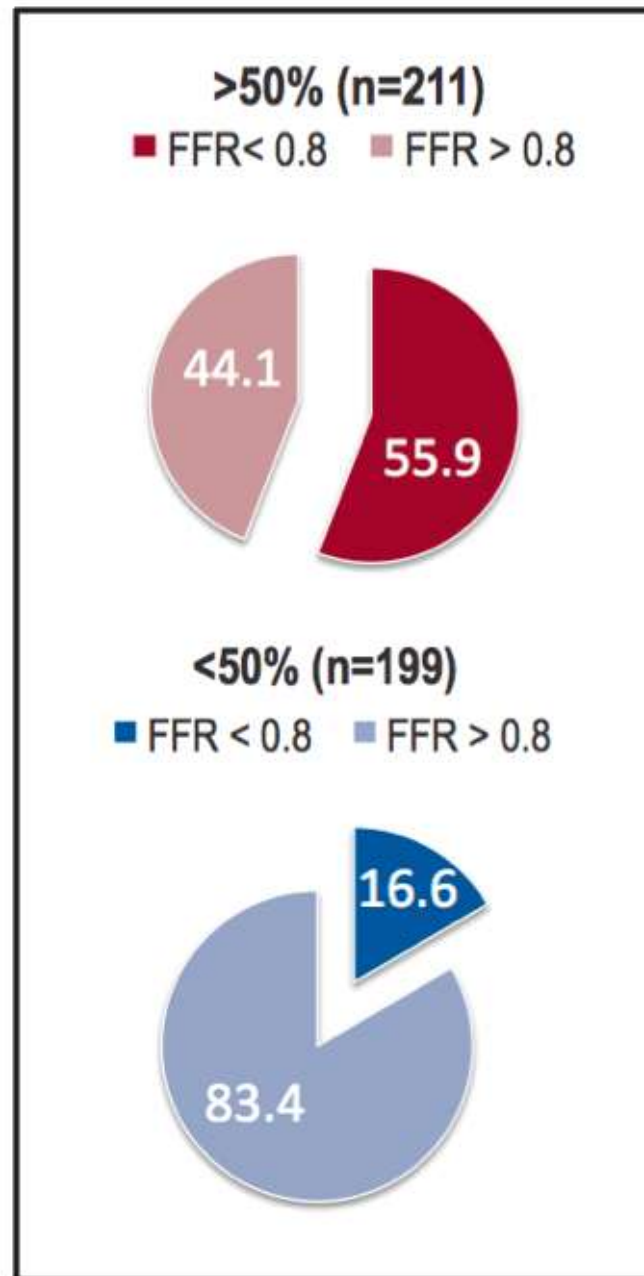
FFR: Beyond High-Grade Stenoses

FAME Trial
47% of all lesions

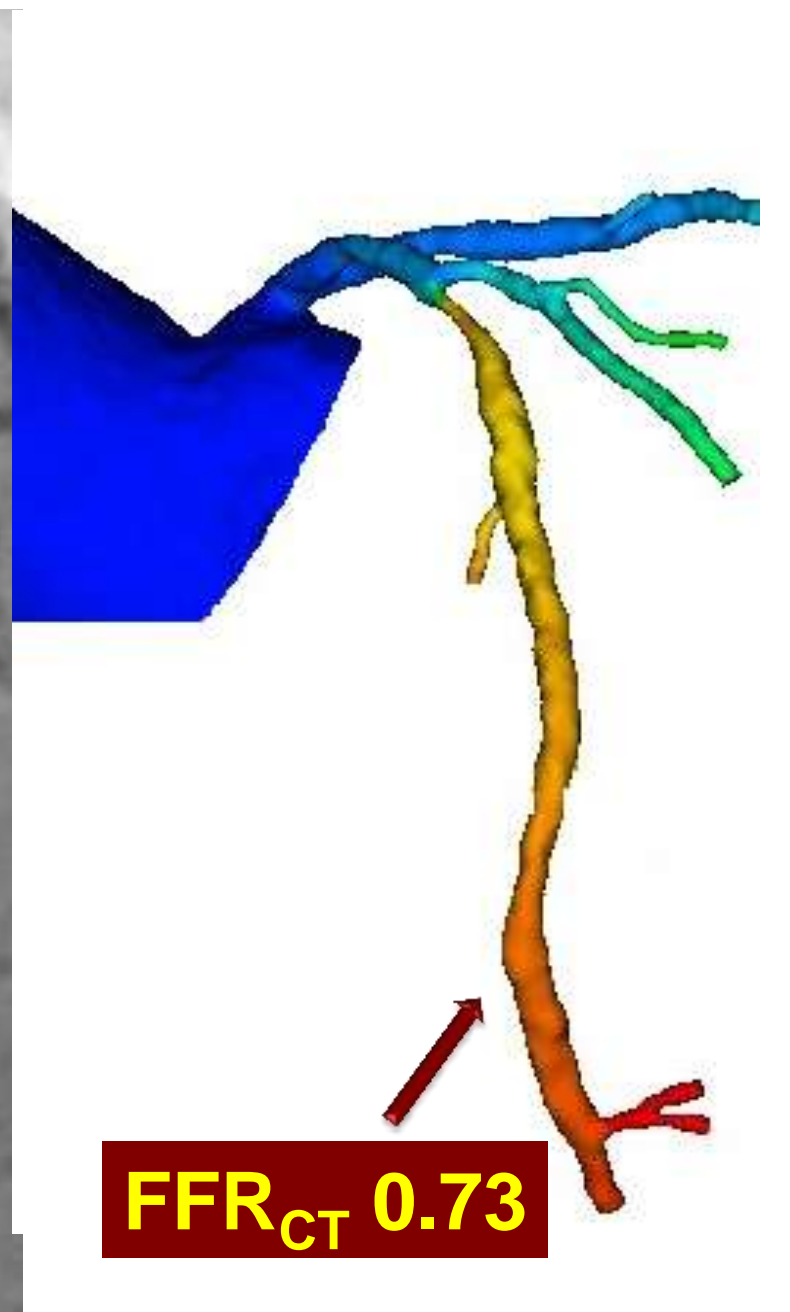
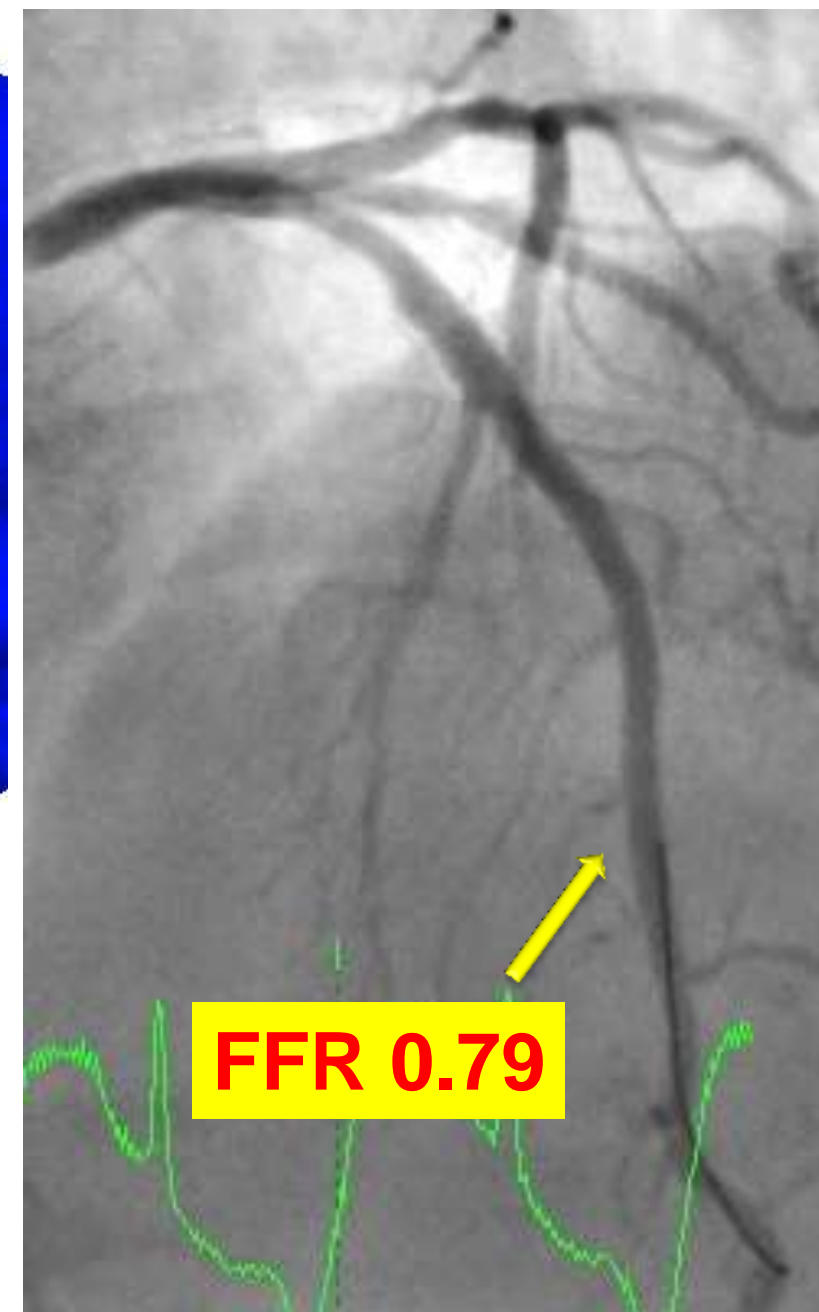
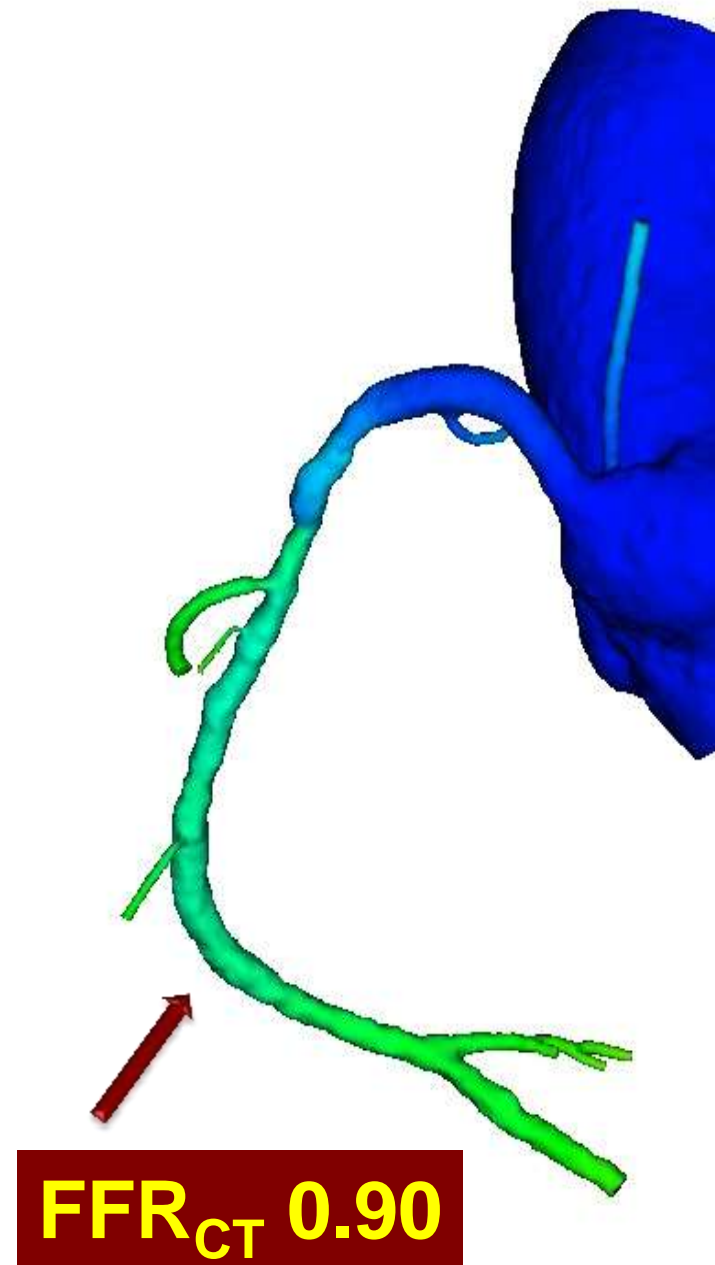


FFR_{CT}: “Non-obstructive” Stenoses

Prospective multicenter
N=252
Comparator: Invasive FFR

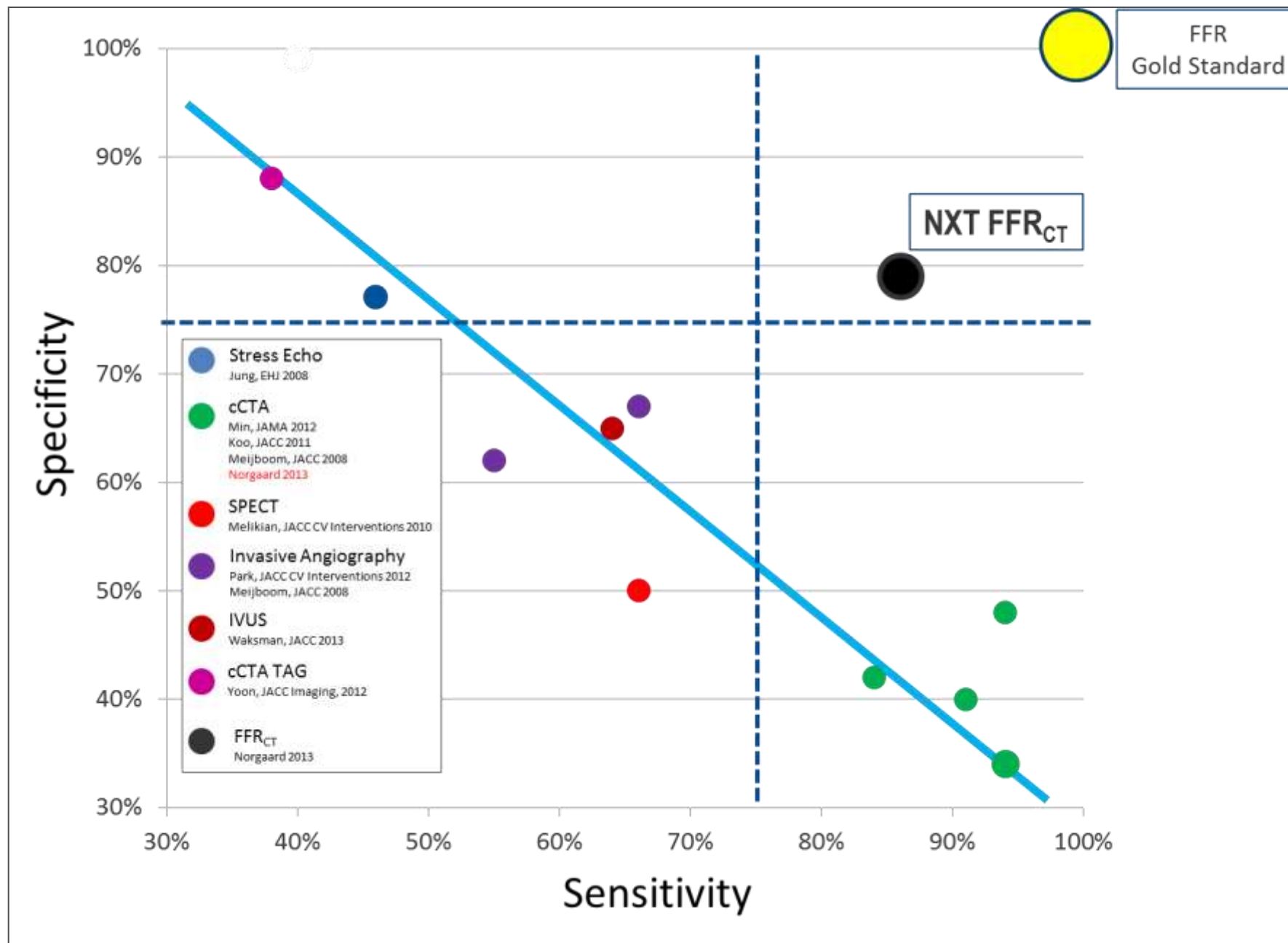


FFR_{CT}: “Non-obstructive” Stenoses



FFR_{CT}: Lesion-specific ischemia

FFR_{CT} superior to all methods to date

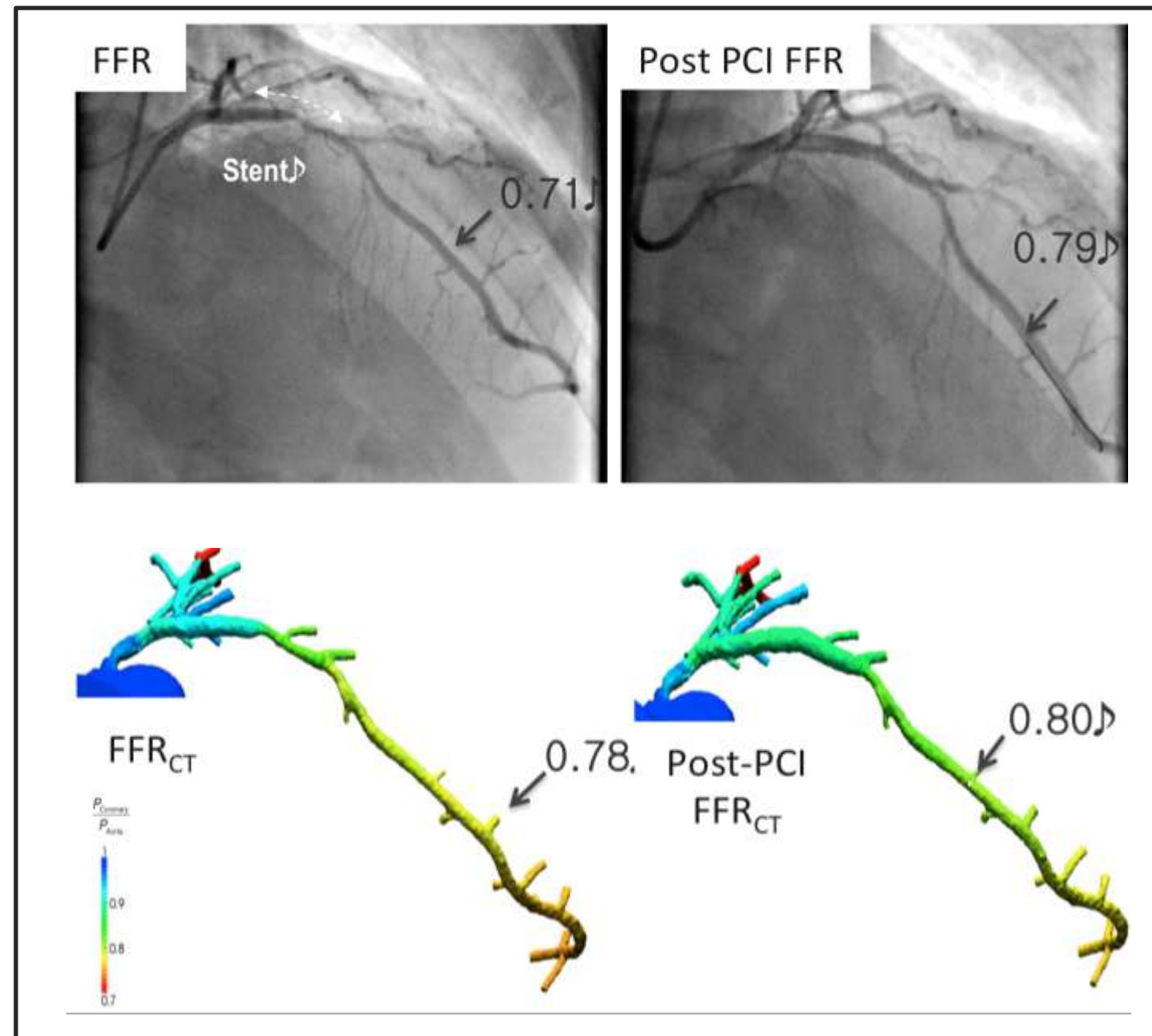
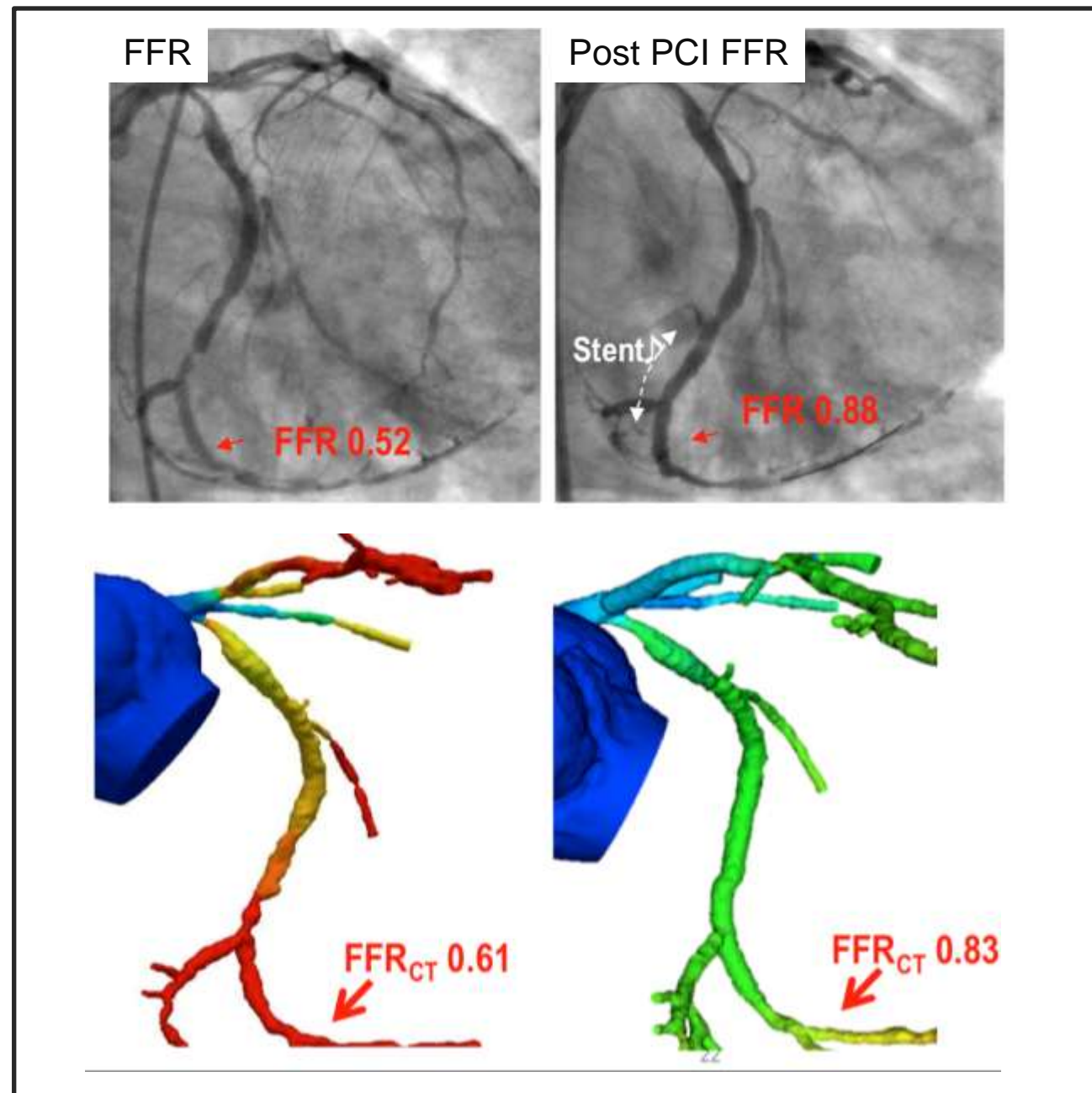


Future of FFR_{CT} : Virtual Stenting

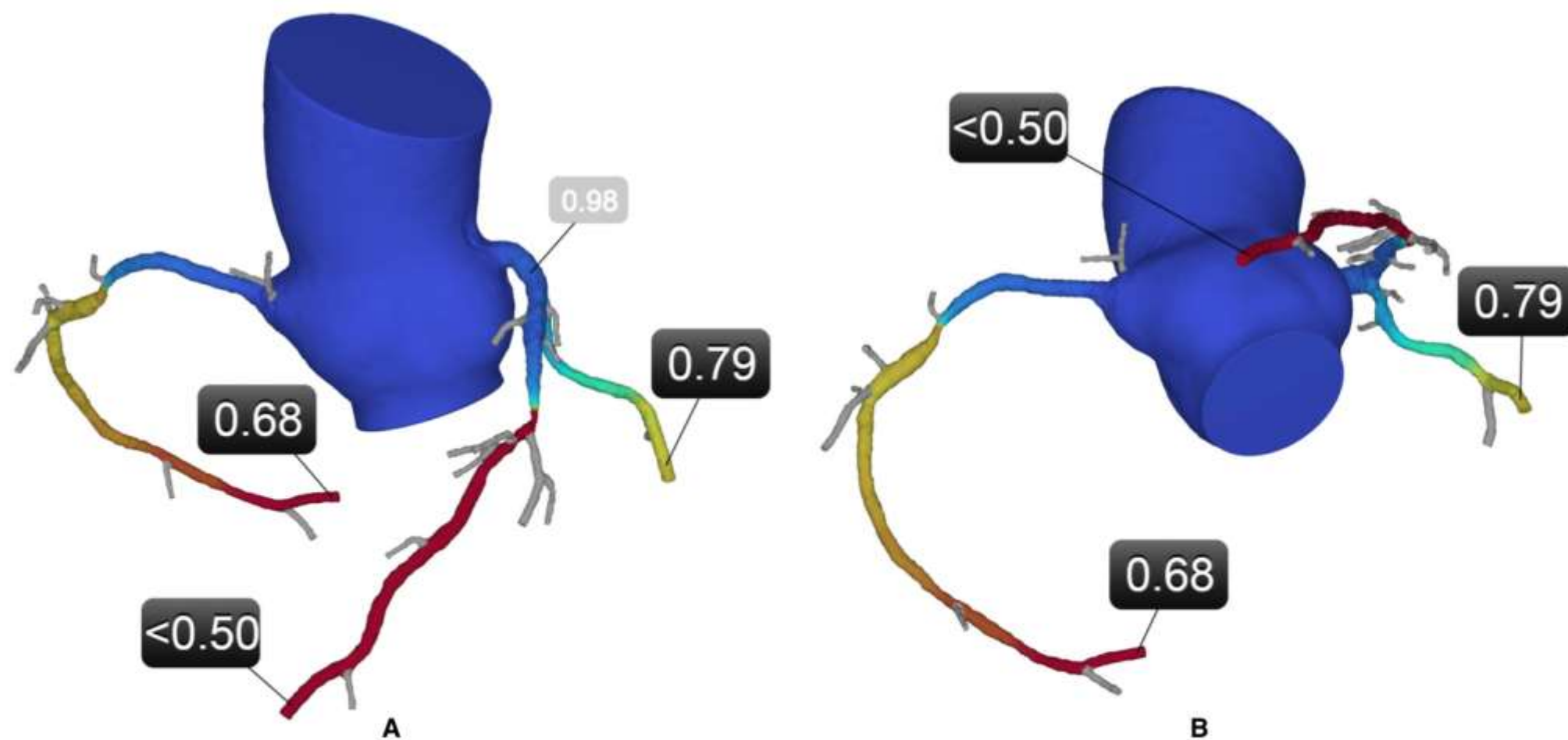


Future of FFR_{CT} : Virtual Stenting

44 patients
Accuracy 96%
Sens / Spec 100% / 96%



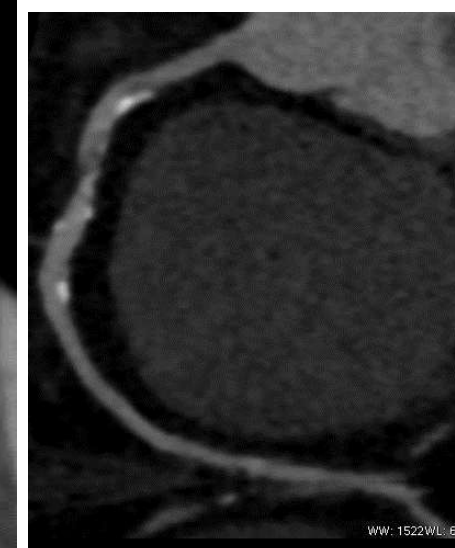
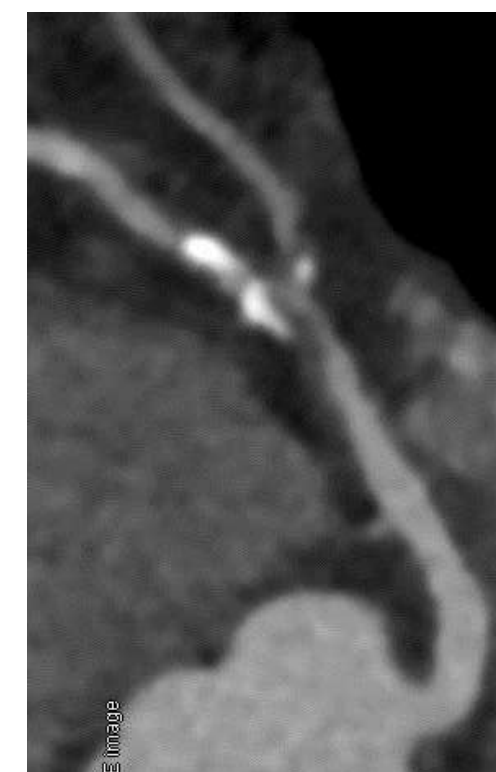
Case: 63 y/o Asian man (HeartFlow FFR_{CT} Analysis)



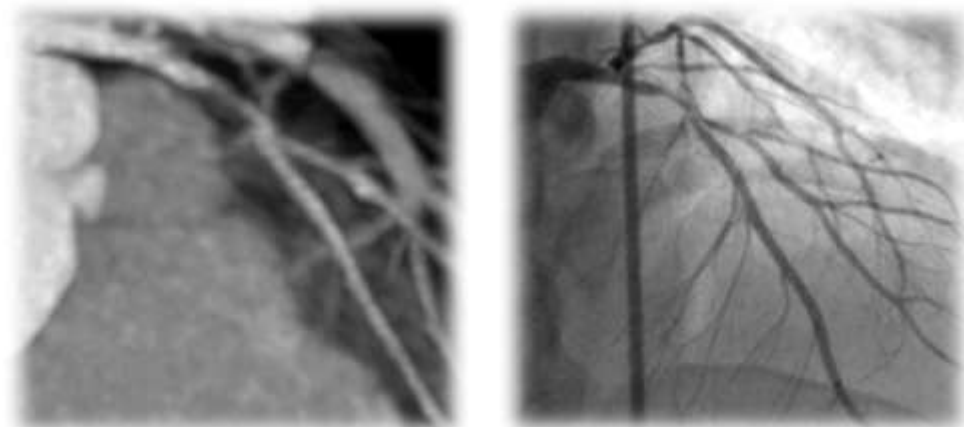
Summary: The Left Anterior Descending System, Left Circumflex System, and Right Coronary Artery System each have an FFR_{CT} ≤ 0.80.

CORONARY ARTERIES & SYSTEMS	FFR _{CT}	FFR _{CT} (0.00 to 1.00)
Left Main Artery	0.98	Blue bar (0.98)
Left Anterior Descending System	< 0.50	Red bar (< 0.50)
Left Circumflex System	0.79	Yellow bar (0.79)
Right Coronary Artery System	0.68	Red bar (0.68)

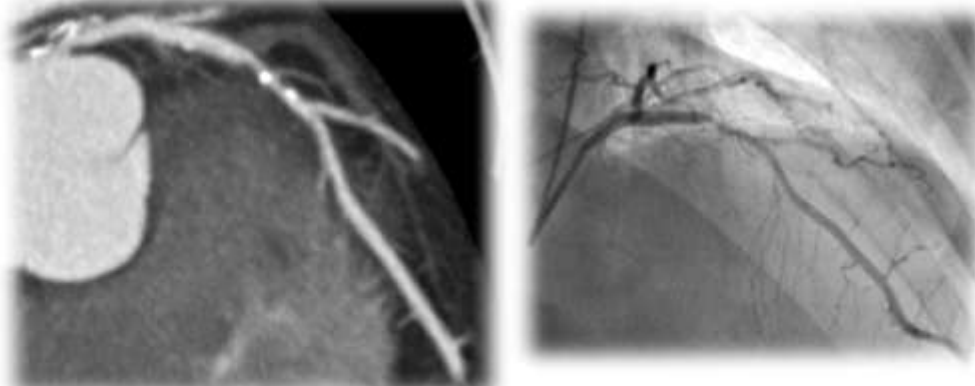
MAY BE FUNCTIONALLY SIGNIFICANT ^{1,2,3}



Optimal diagnostic approach to CAD



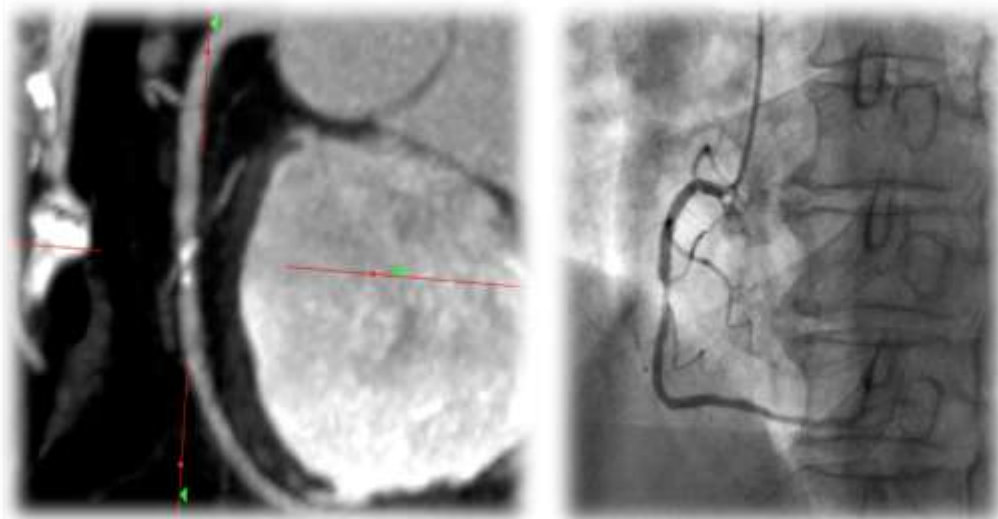
(1) Anatomic CAD Concordant with ICA



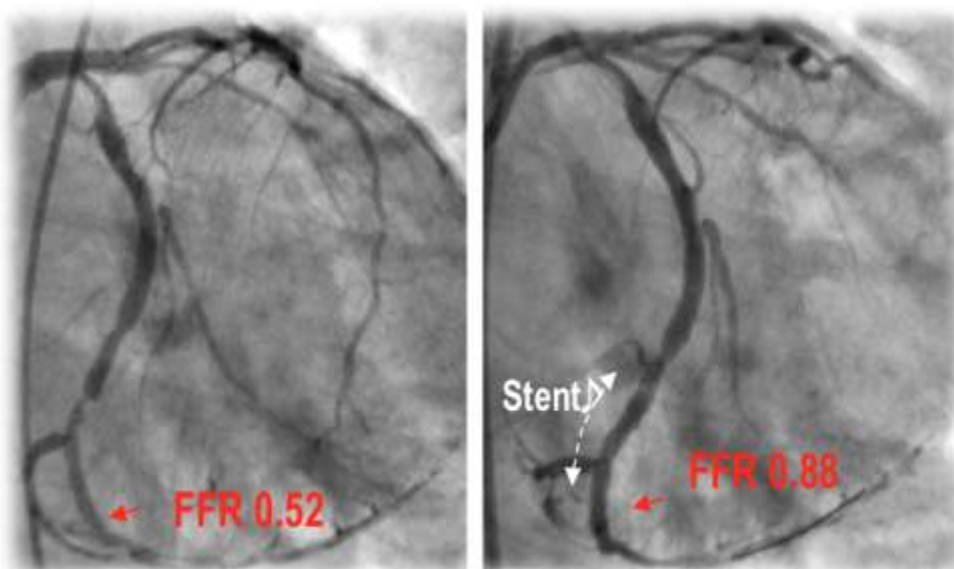
CCTA 50-69% stenosis

QCA %DS = 50.68%

(2) Effectively Prognosticate Outcomes



(3) Identify Lesion-Specific Ischemia



(4) Plan Revascularization Strategy

Conclusions

FDA approval 11/15

- FFR_{CT} superior to all modalities for dx of lesion-specific ischemia: 86% accuracy
- FFR_{CT} useful across all ranges of stenosis severity:
 1. Severe: 75% false positives
 2. Intermediate: ~50% prevalence, FFR_{CT} 95% NPV
 3. Non-obstructive (<50% stenosis): 17% ischemic
- Future of FFR_{CT} :
 1. Virtual stenting
 2. Virtual coronary bypass surgery
 3. Addl CFD variables (Wall shear stress, axial plaque force, particle residence time, FSI)
 4. Addl vascular territories