Precision Cardiovascular Care – Moving From Broad Guidelines to Patient-Specific Care: The Non-Invasive Evaluation for Stable Coronary Artery Disease – CTA as first line test

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Disclosures

Research Support: Jansen, Bayer, AstraZeneca, National Heart, Lung, & Blood Institute, Procyrion, Heartflow, Medtronic, Phillips-Volcano, Heartflow

Consulting/Advisory Board: AstraZeneca, Bayer Corporation, Janssen Research & Development, Saranas, Heartflow

Academic Affiliations: Duke University Medical Center, DCRI

The Challenge in Cardiology Practice

Patient Case - Mrs. M

- 58 years old with DM
- Lives independently
  - Shops, Cleans, works in bank
- Seen by PCP
  - Occasional Chest “ache” with walking at grocery store
  - Cramping in calves
- Referred to Duke Cardiology / Vascular Clinic for evaluation

Case 1

- A 58 year old woman referred to your office. The discomfort is characterized as:
- 3-4 out of ten in severity
- Described as sharp, with some mild pressure
- Nonpleuritic, localized under the left breast with some radiation to the shoulder.
- Has occurred with some housework but also occasionally at rest. Last episode while watching TV.
- When occurs with activity - relieves with rest

What would you do?

- How do you determine risk and identify disease?

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

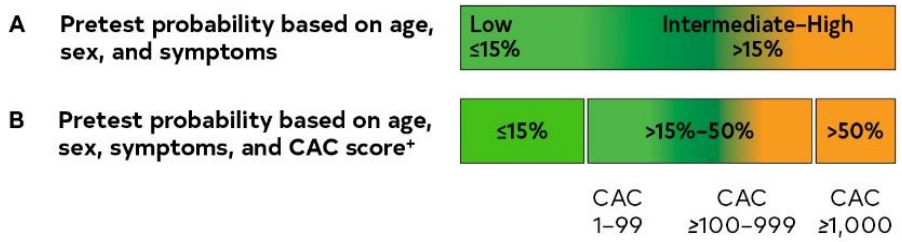
Figure 11. Pretest Probabilities of Obstructive CAD in Symptomatic Patients According to Age, Sex, and Symptoms.

Colors correspond to the Class of Recommendation in Table 1.

CAC indicates coronary artery calcium; and CAD, coronary artery disease.

Pretest Probabilities of Obstructive CAD in Symptomatic Patients.
(A) according to age, sex, and symptoms;
(B) according to age, sex, symptoms, and CAC

Age, y	Chest Pain		Dyspnea	
	Men	Women	Men	Women
30–39	≤4	≤5	0	3
40–49	≤22	≤10	12	3
50–59	≤32	≤13	20	9
60–69	≤44	≤16	27	14
70+	≤52	≤27	32	12



1. The Pretest Probability shown is for patients with anginal symptoms. Patients with lower risk symptoms would be expected to have lower PTP
2. The darker green and orange shaded regions denote the groups in which non-invasive testing is most beneficial (pre-test probability >15%). The light green shaded regions denote the groups with pre-test probability of CAD ≤15% in which the testing for diagnosis may be considered based on clinical judgement
3. If CAC available, can use to estimate pretest probability based on CAC Score

Adapted and modified from Juarez-Orozc ESC 201920, 1198–1207
+ Winther, S. et al. *J Am Coll Cardiol.* 2020;76(21):2421–32.

Question # 1

- In patients with intermediate pre-test probability of coronary artery disease - what cardiovascular test should be done to diagnose and risk stratify for coronary artery disease?

How do we perform – predicting obstructive coronary disease?

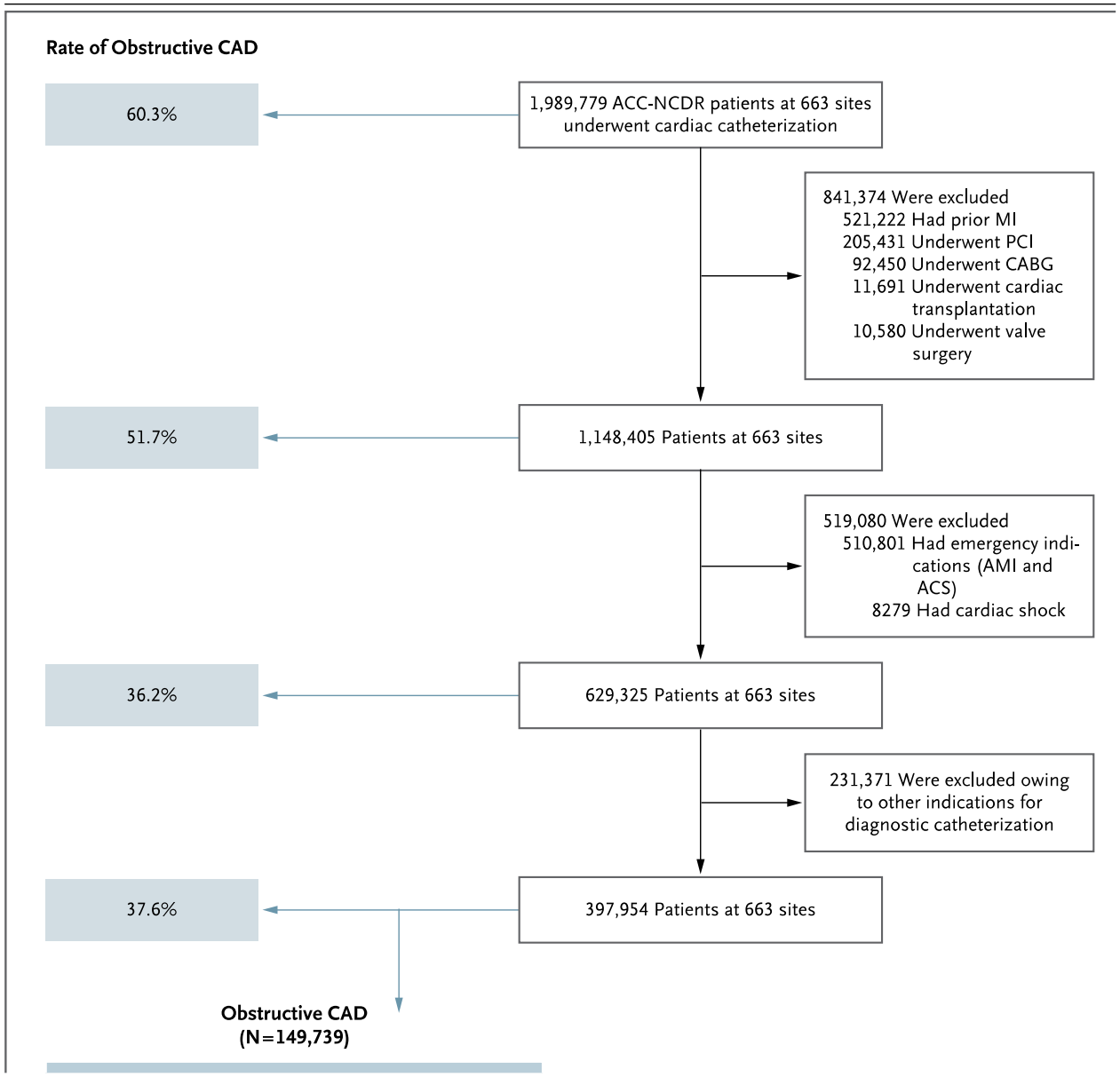
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

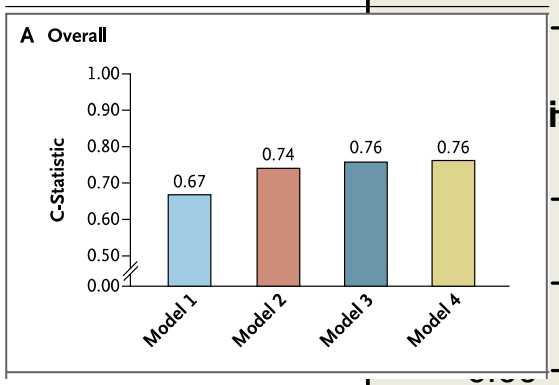
Low Diagnostic Yield of Elective Coronary Angiography

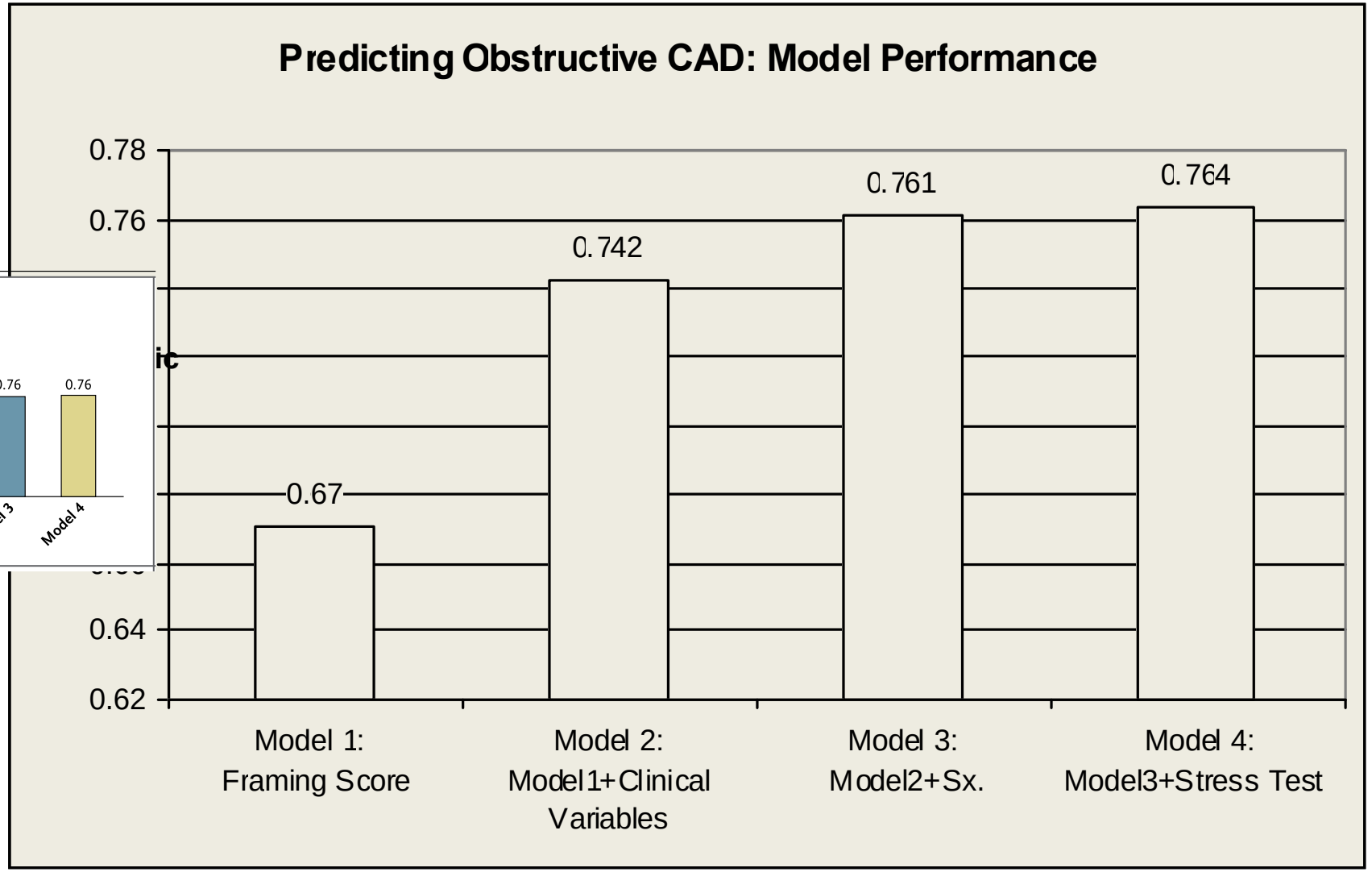
Manesh R. Patel, M.D., Eric D. Peterson, M.D., M.P.H., David Dai, M.S., J. Matthew Brennan, M.D., Rita F. Redberg, M.D., H. Vernon Anderson, M.D., Ralph G. Brindis, M.D., and Pamela S. Douglas, M.D.

- 38% Stenoses ≥50% LM or ≥ 70% epicardial
- 41% by any ≥ 50%
- 39% had all stenoses <20%



Value of pre-angiography information

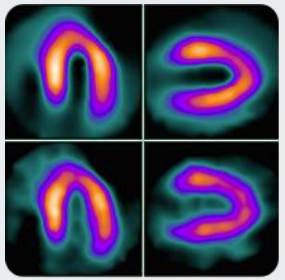




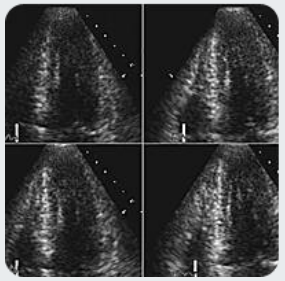
ACC-NCDR Study - Conclusions

- Current risk stratification including non-invasive testing used to inform decisions to perform angiography to identify obstructive CAD need significant improvement
- “Current System is broken”
  - Did not say we are doing too many heart catheterizations
  - Most efficient way may be more angiography (either non-invasive or invasive)
- Ideally want an accurate anatomic and functional evaluation
  - Cath + FFR
  - Heartflow – CTA

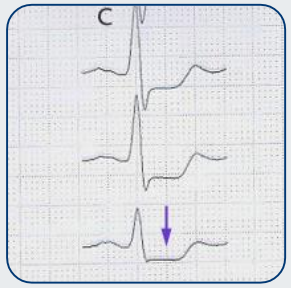
Current reality of non-invasive cardiac testing



SPECT



Stress Echo



Treadmill

No **lesion-specific** information provided

High rate of **false positives**

55% of patients sent for an elective ICA following a non-invasive test have **no obstructive CAD**[1]

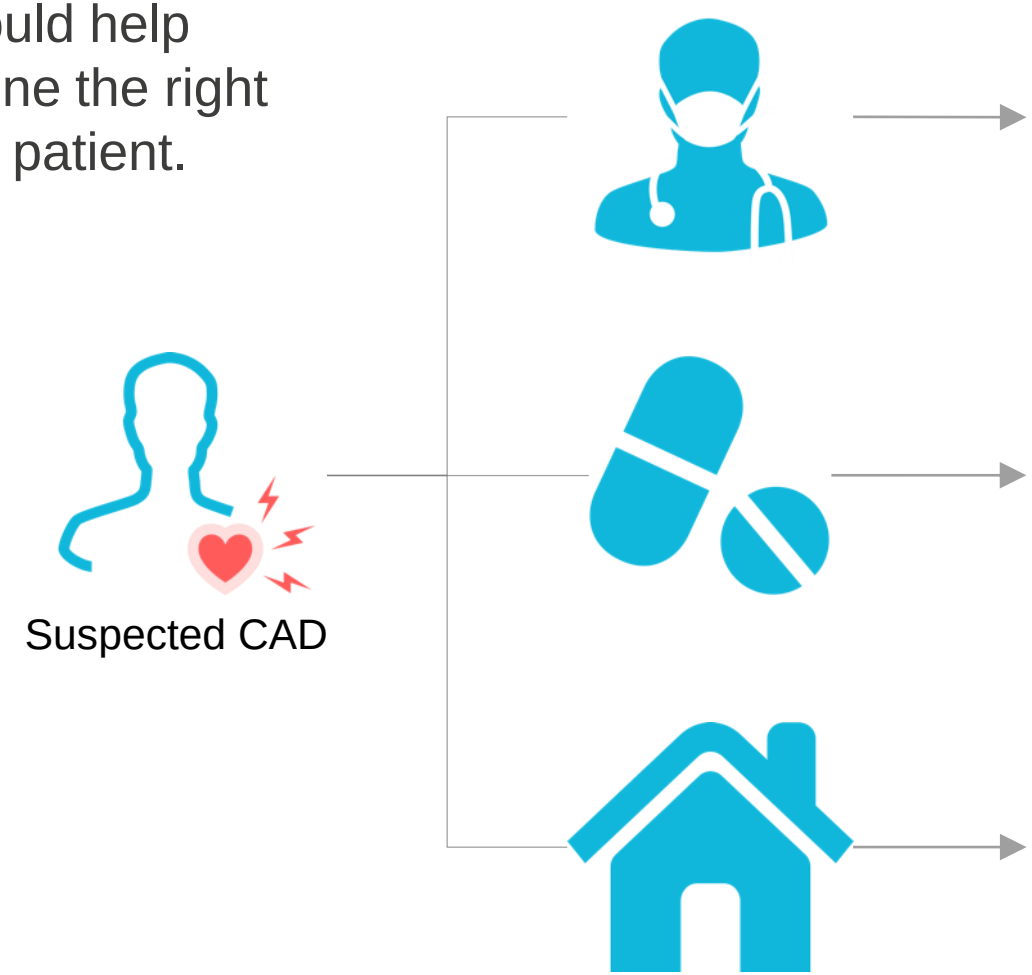
High rate of **false negatives**

20-30% of patients will have a false negative result for obstructive CAD from a non-invasive test[2]

1. Patel, et al. N Engl J Med 2010. Patel, et al. AHJ 2014. Danad, et al. JAMA Cardiology 2017.
2. Arbab-Zadeh, Heart Int 2012. Yokota, et al. Neth Heart J 2018. Nakanishi, et al. J Nucl Cardiol 2018.

Non-invasive cardiac testing

Cardiac tests should help clinicians determine the right pathway for each patient.



A finding of No CAD does not diminish the role of initiating or continuing primary prevention efforts

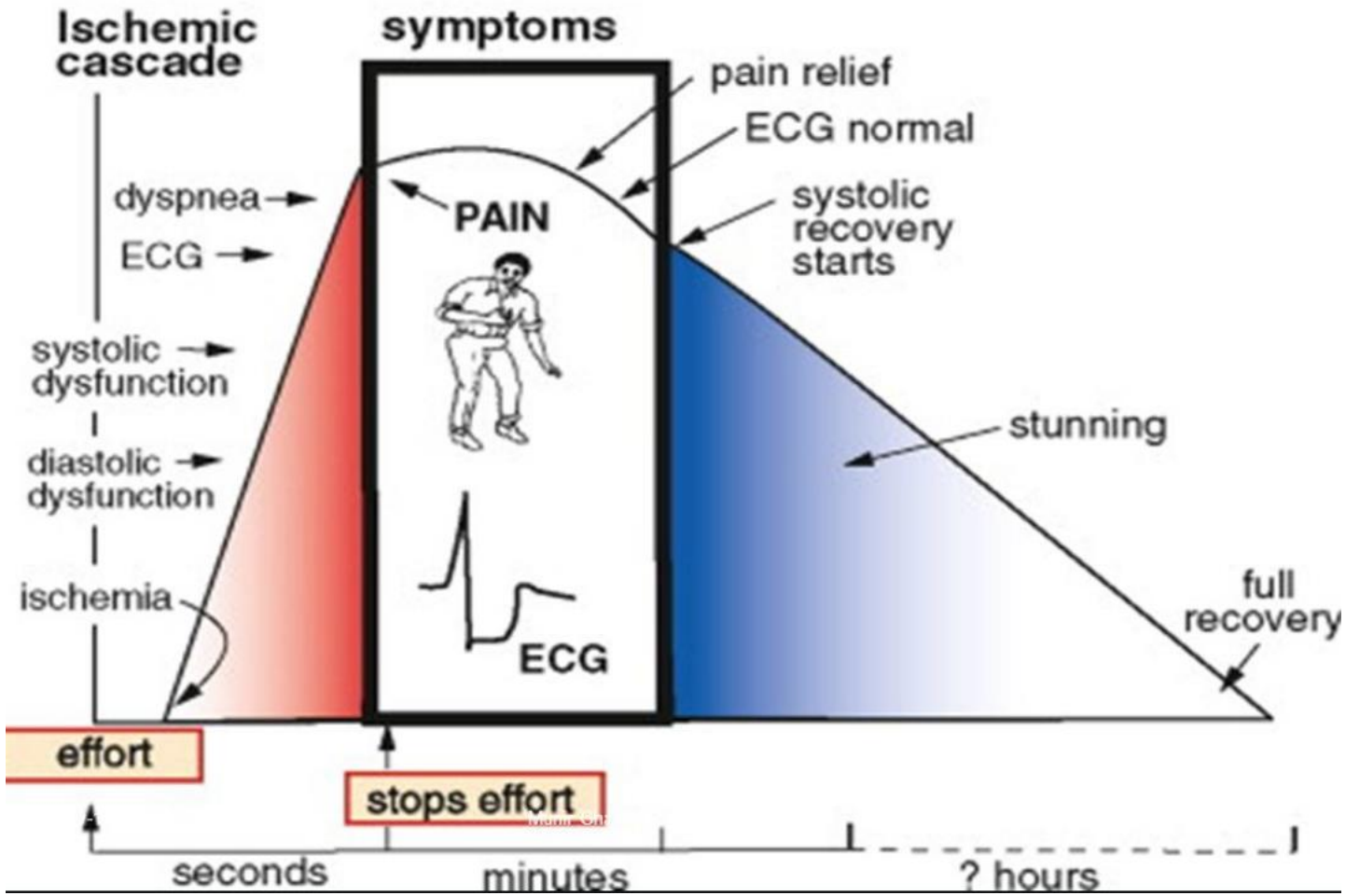
Question # 1

- In patients with intermediate pre-test probability of coronary artery disease - what cardiovascular test should be done to diagnose and risk stratify for coronary artery disease?

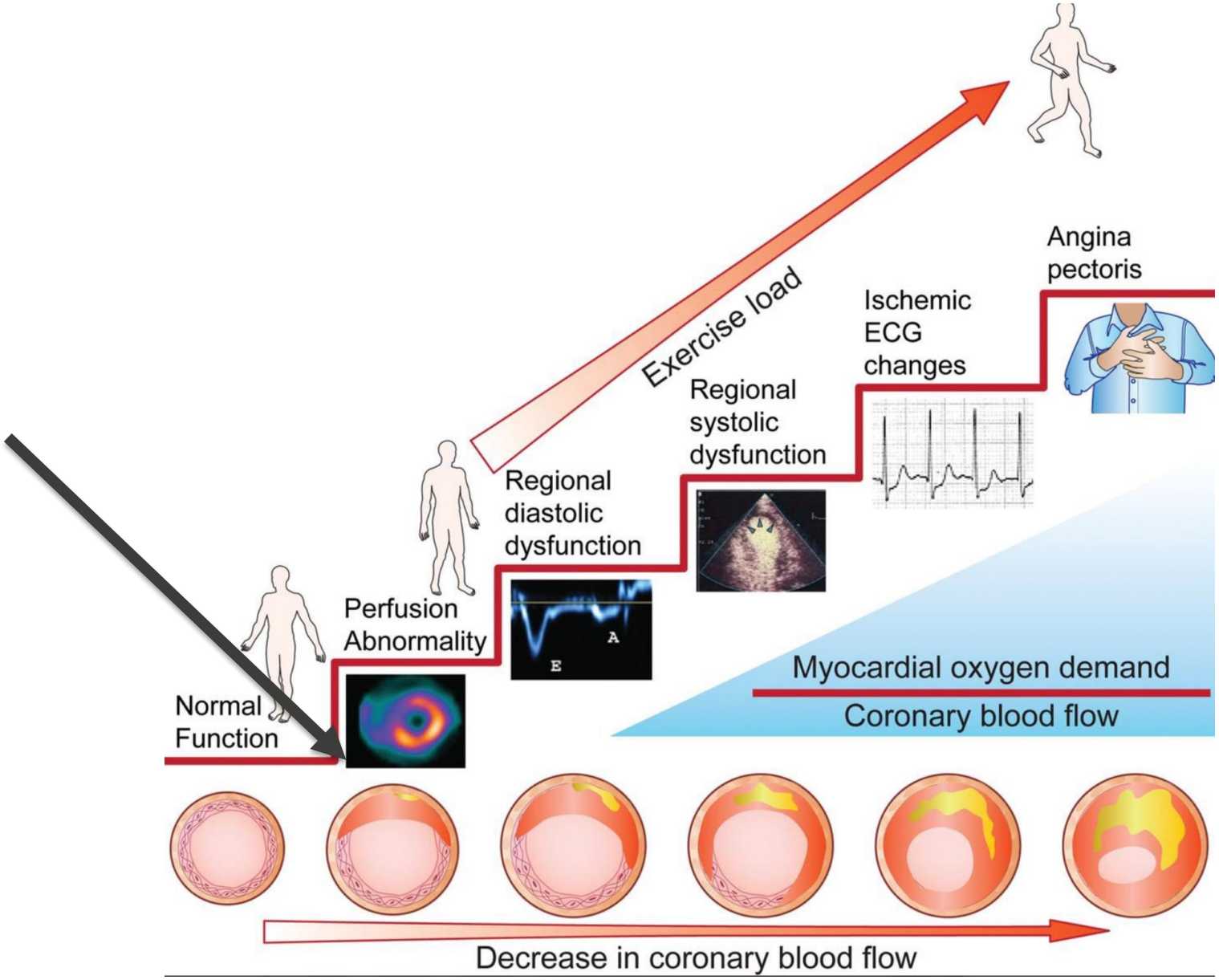
What is the classic teaching of ischemia and testing

Variable for DF pre-test risk consideration:
Age, Sex, and How Typical Anginal Symptoms are

Ischemic Cascade:
Reduced perfusion leading to metabolic abnormalities leading to diastolic then systolic dysfunction



Moving the paradigm – can we image with earlier disease

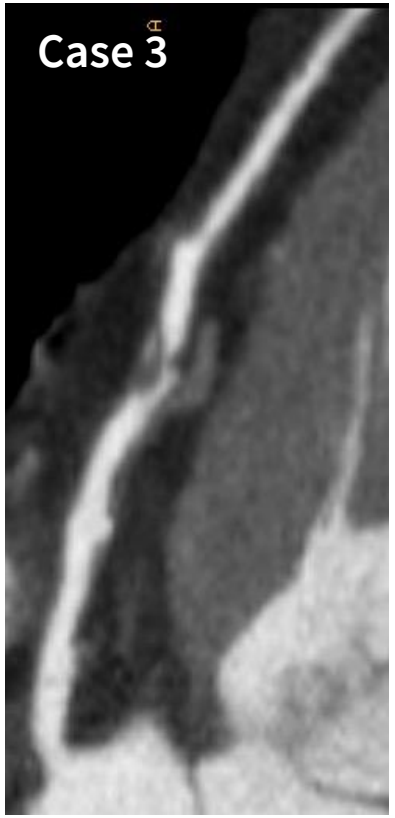


A earlier pathway starts with coronary CTA

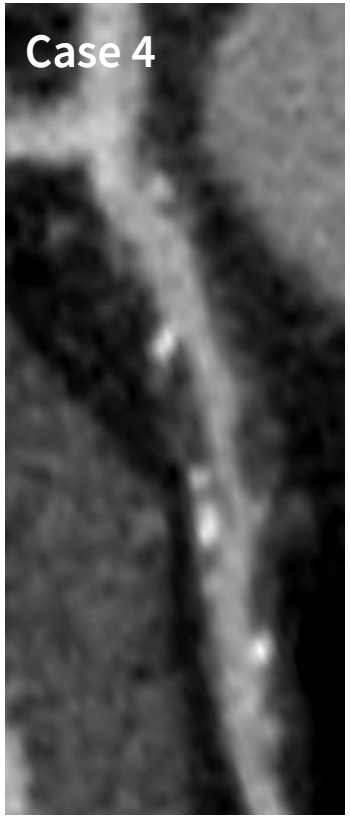
Coronary CTA offers CAD visualization to inform treatment decisions

No identifiable anatomic disease

Minimal disease; possible OMT



Disease with unknown functional impact



Complex high disease burden

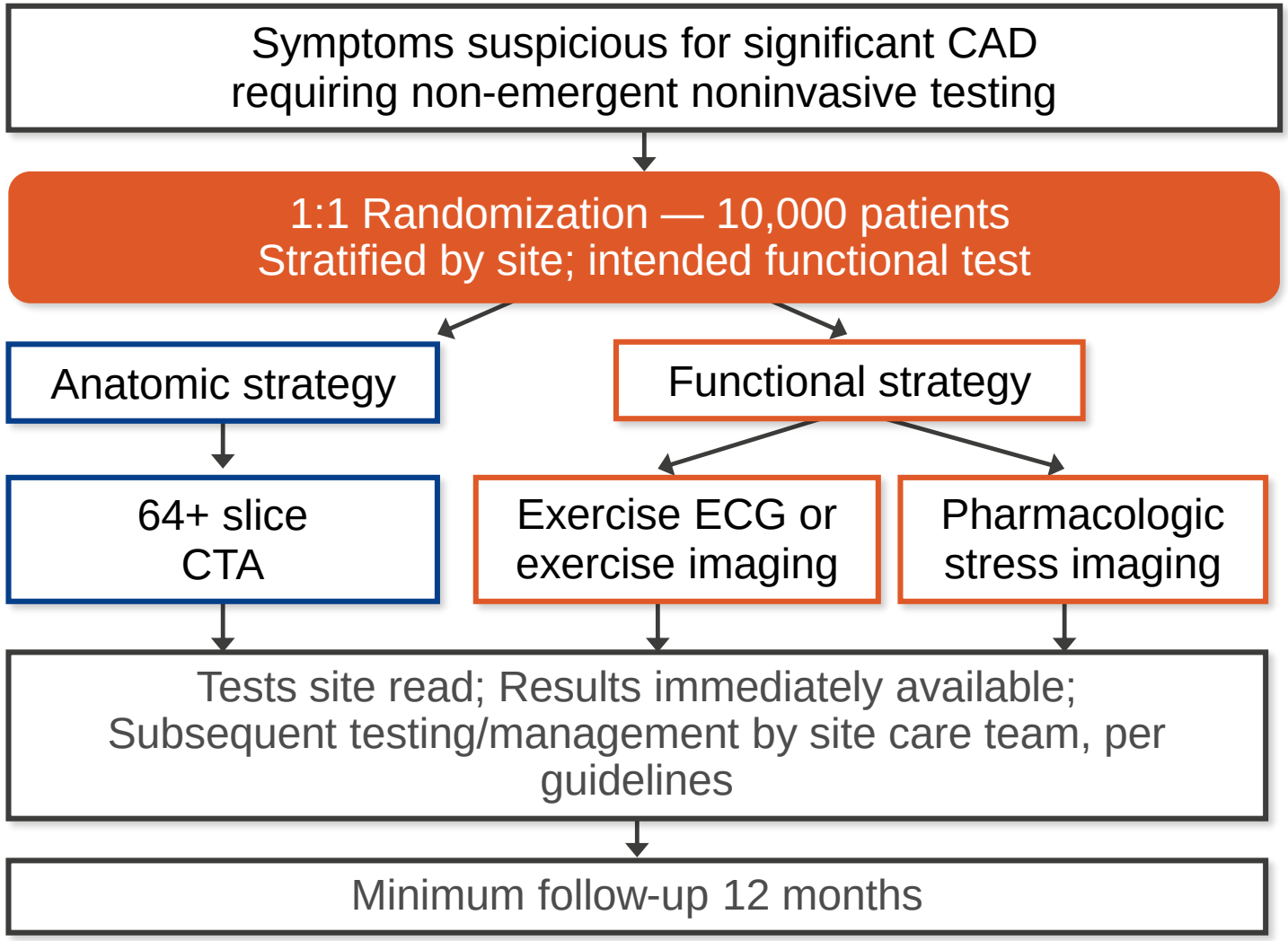
Diagnostic Performance of CCTA:

Four (4) Prospective Multicenter Studies

	Sensitivity	Specificity	PPV	NPV
ACCURACY	**94**	83	48	**99**
N=230, Stable Chest Pain; No known CAD; No exclusion criteria; CAD prevalence 13%				
Europe	**99**	64	85	**97**
N=360, Acute and Stable Chest Pain; No known CAD; CAD prevalence 68%				
MEDIC	**95**	91	71	**99**
N=415 (83), No known CAD; 20-80% pretest LK of CAD				
CorE64	85	90	91	83
N=291, Stable Chest Pain; Known / No Known CAD; Exclude CACS >600; CAD prevalence 56%				

Source: Budoff et al. J Am Coll Cardiol 2008; Miller et al. N Eng J Med 2008; Meijboom et al. J Am Coll Cardiol 2009

PROMISE Trial Design



NHLBI funded

Baseline Characteristics

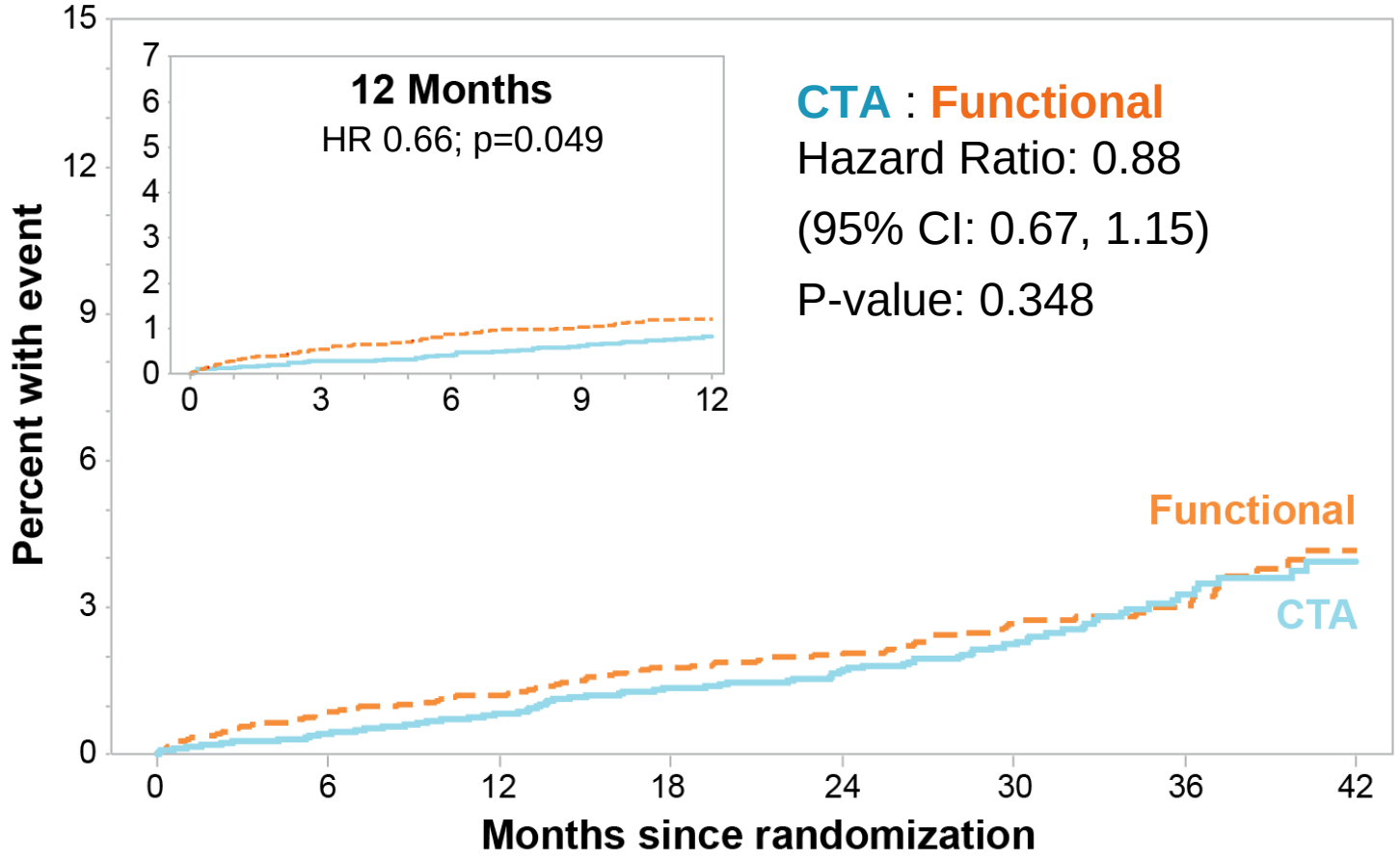
		CTA (n=4996)	Functional (n=5007)
Demographics	Age — mean ± SD, yrs	60.7 ± 8.3	60.9 ± 8.3
	Female sex — %	52	53
	Non-white race	16	15
Risk factors	Hypertension — %	65	65
	Diabetes — %	21	22
	Dyslipidemia — %	67	68
	Family hx premature CAD — %	33	32
	Current or past smoking — %	51	51
1°symptom	Chest pain or DOE — %	88	88
Anginal type	Typical or atypical — %	89	89
Pretest probability CAD	Diamond–Forrester/CASS — mean %	53.4	53.2

Secondary Endpoint:
Catheterization Without Obstructive CAD ≤90 days

	CTA (n=4996)	Functional (n=5007)	P value
Invasive catheterization without obstructive CAD — N (%)	**170 (3.4)**	**213 (4.3)**	**0.022**
Invasive catheterization	609 (12.2%)	406 (8.1%)	
With obstructive CAD (% of caths)	439 (72.1%)	193 (47.5%)	
Revascularization	311 (6.2%)	158 (3.2%)	
CABG	72	38	

promise

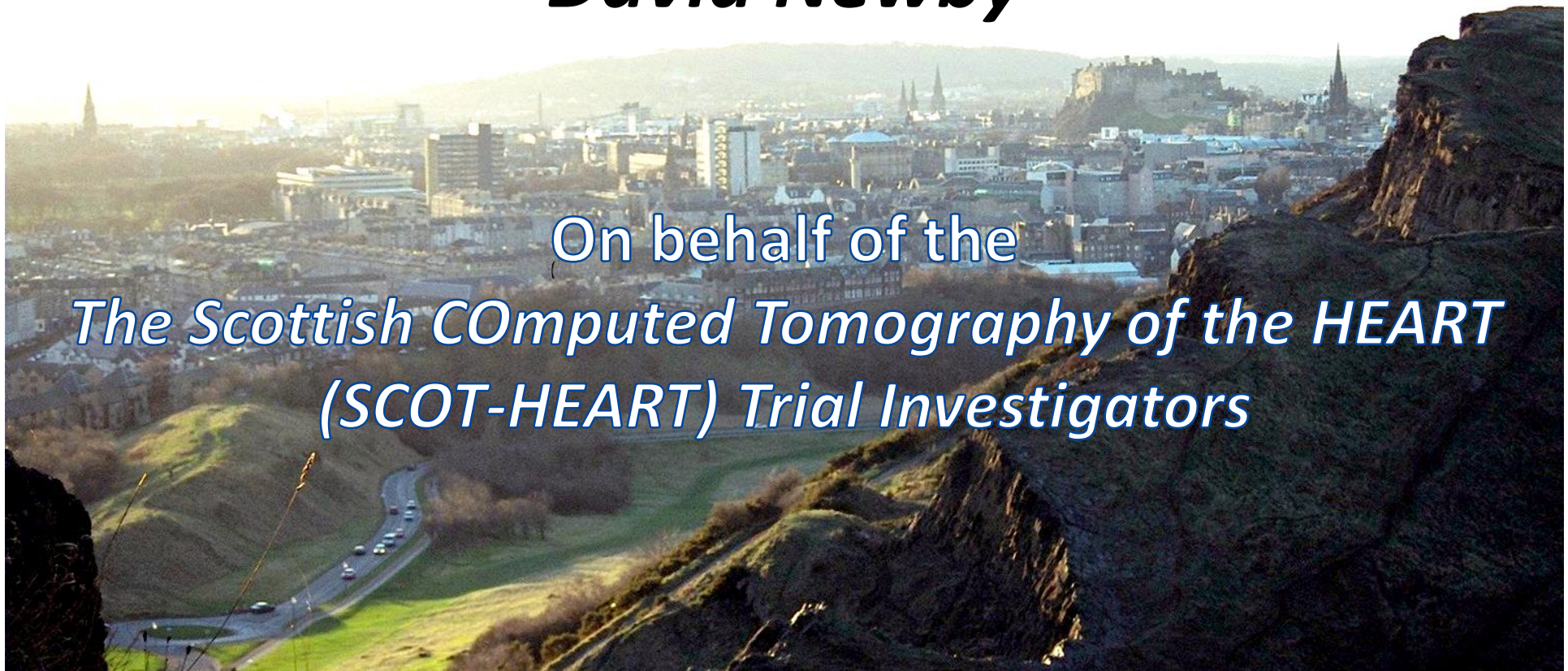
Secondary Endpoint:
Death or Non-fatal MI



# at risk	Baseline (0)	6 Mo.	12 Mo.	18 Mo.	24 Mo.	30 Mo.	36 Mo.	42 Mo.
CTA	4996	4739	4409	3599	2686	1732	918	276
Functional	5007	4563	4148	3365	2415	1540	846	262

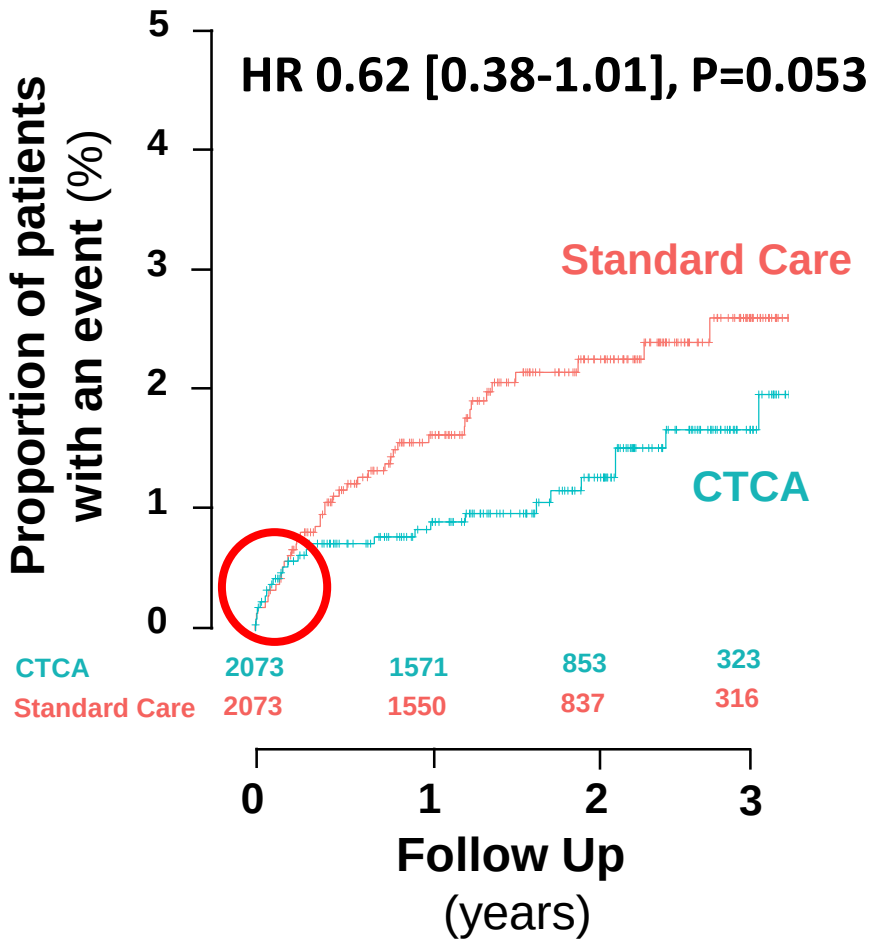
Computed Tomography Coronary Angiography in Patients with Suspected Angina due to Coronary Heart Disease

David Newby

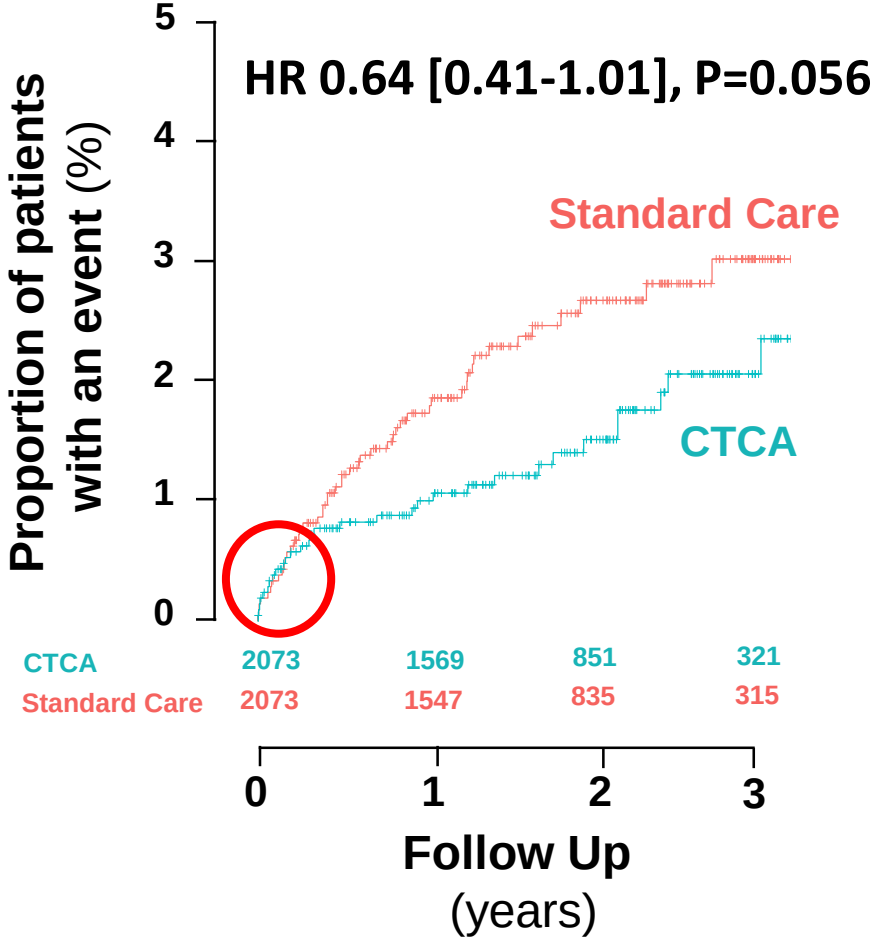


CTCA and Clinical Outcome: *1.7 Years of Follow-up*

CHD Death and Non-Fatal MI

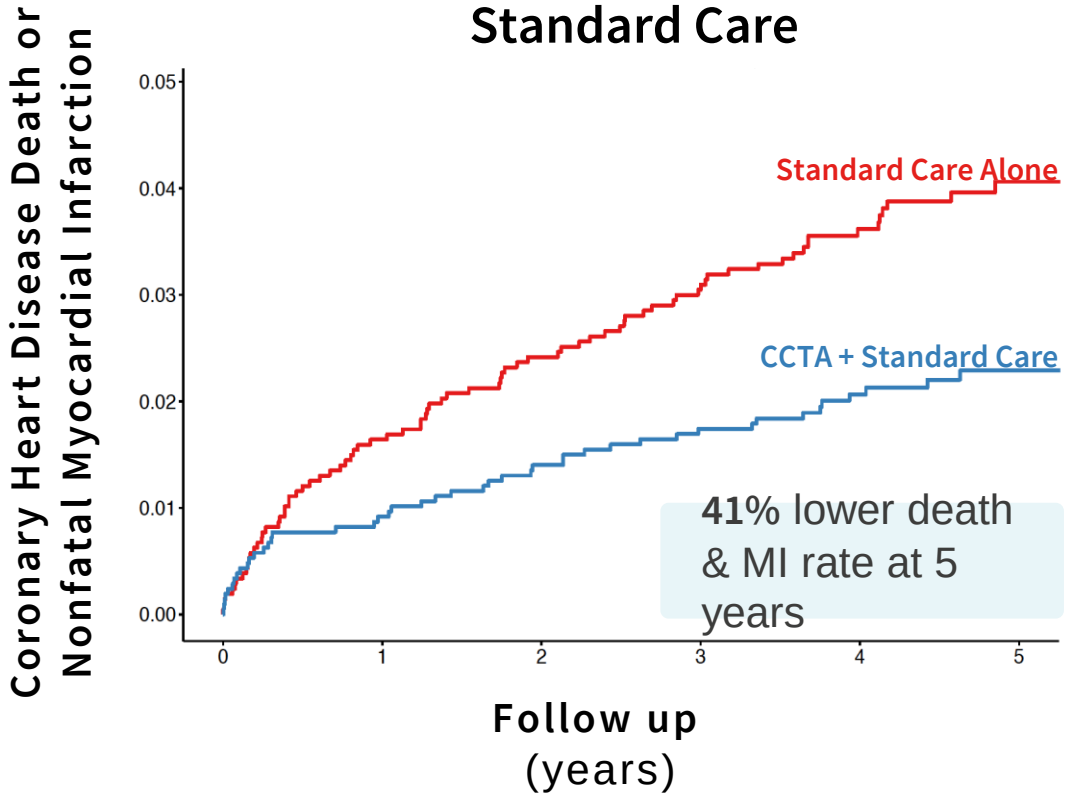


CHD Death, Non-Fatal MI and Non-fatal Stroke



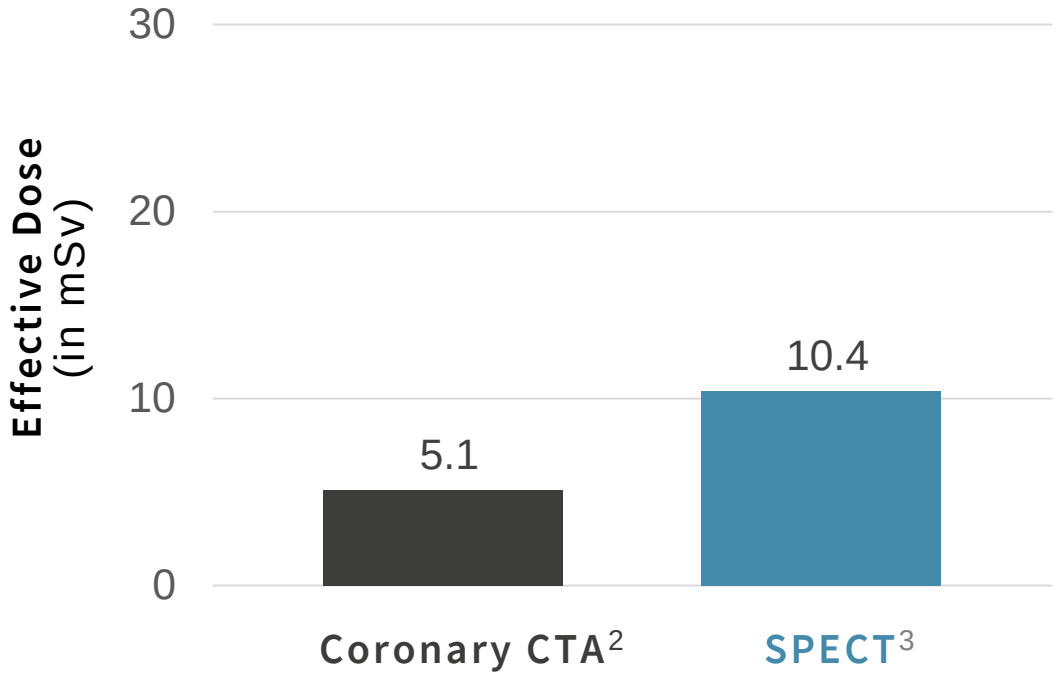
Anatomic compared to standard of Care

Improved Long-term Outcomes: Coronary CTA + Standard Care



Lower Radiation than SPECT: Coronary CTA

(PROTECTION VI[2])

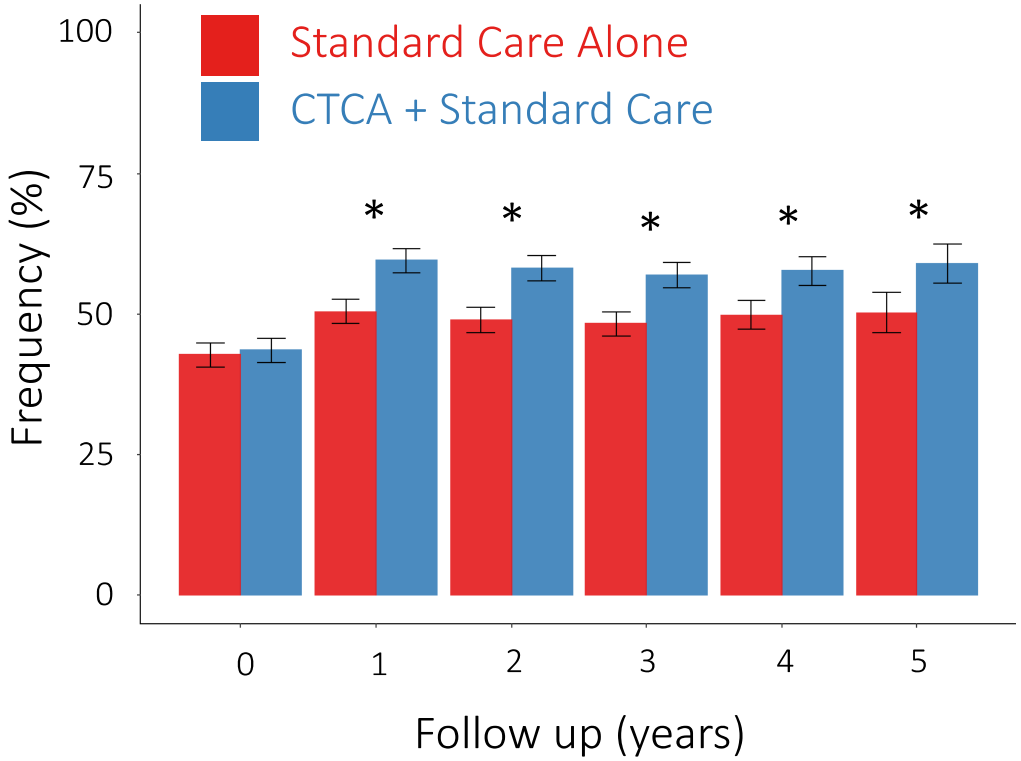


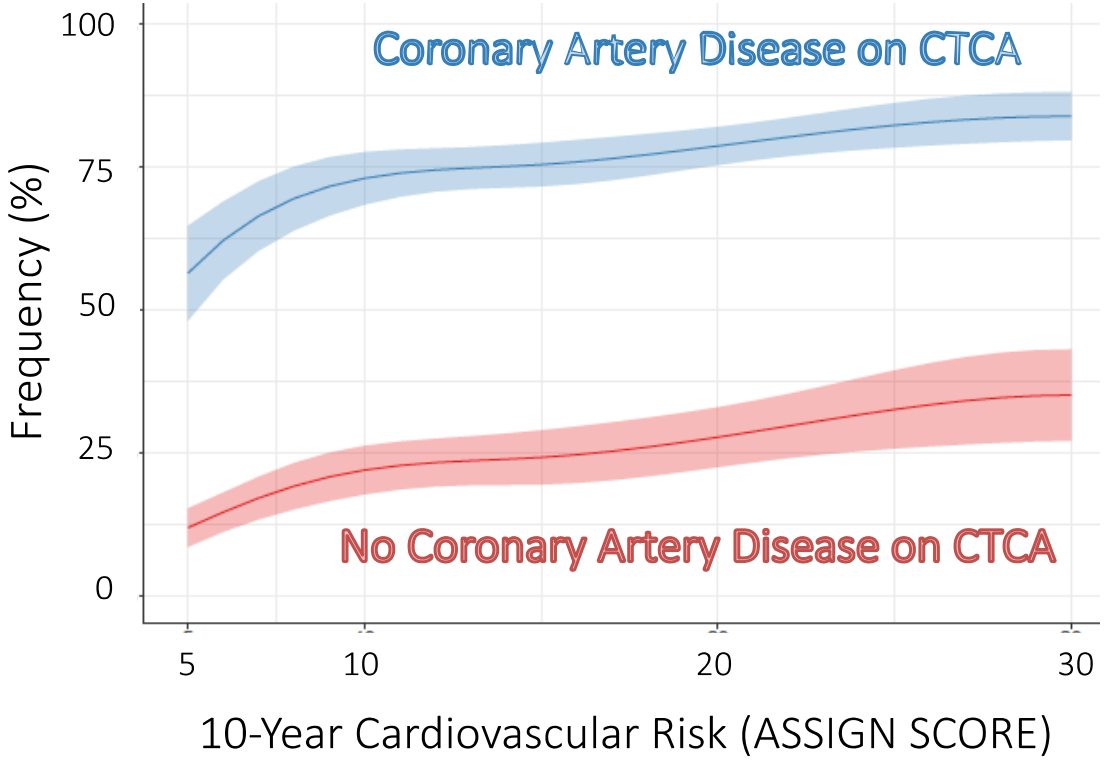
1. Newby, et al. N Engl J Med 2018. | 2. Stocker, et al. Euro Heart J 2018. | 3. Einstein, et al. Euro Heart J 2015.

Anatomic Imaging – might lead to more OMT

The right patient gets the right treatment: Statin therapy use

(SCOT-HEART)





*P<0.0001

Newby, et al. N Engl J Med 2018.

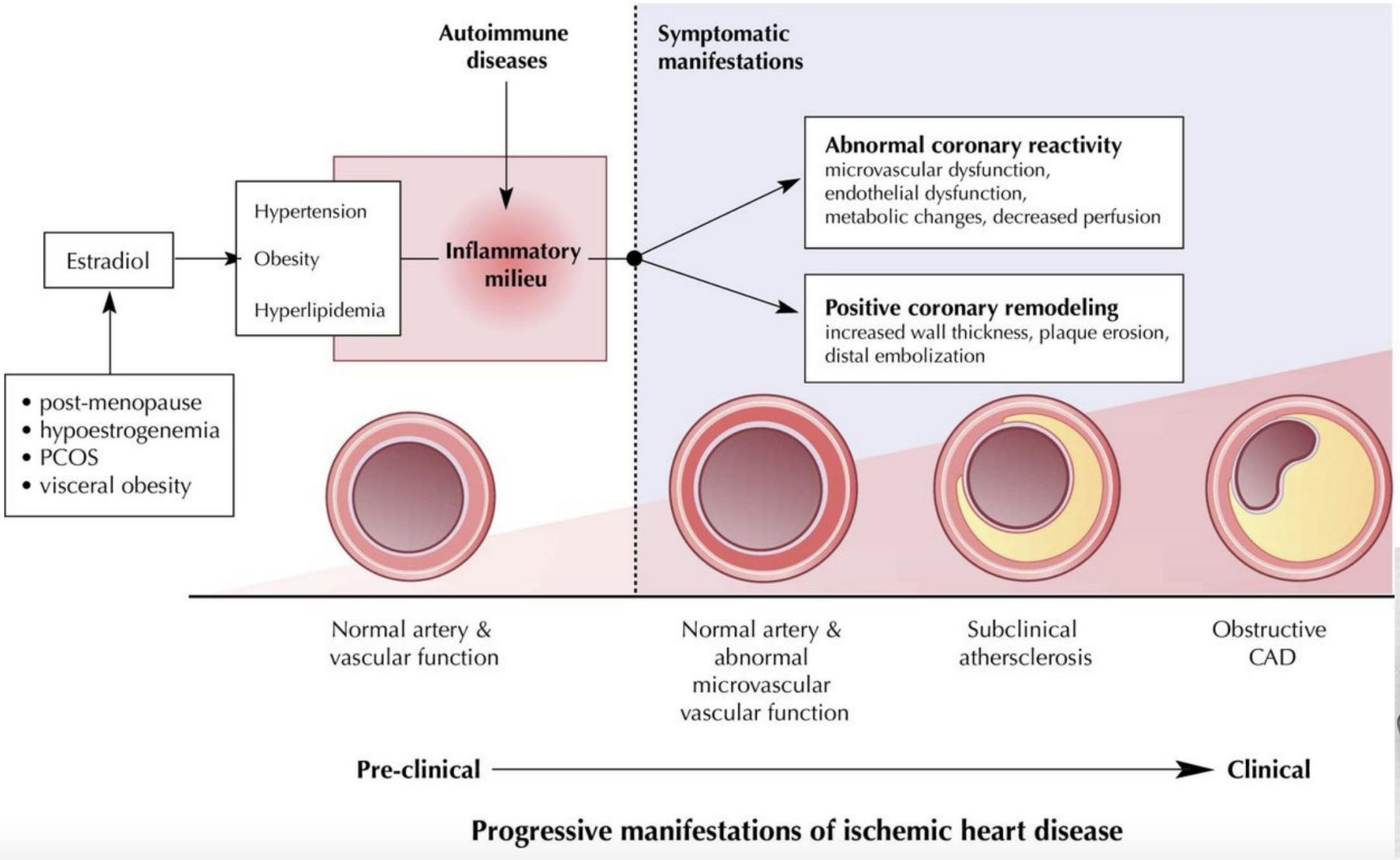
Back to my Patient: Women with Ischemic Heart Disease

Journal of the American College of Cardiology
Volume 54, Issue 17, October 2009
DOI: 10.1016/j.jacc.2009.04.098

STATE-OF-THE-ART PAPER

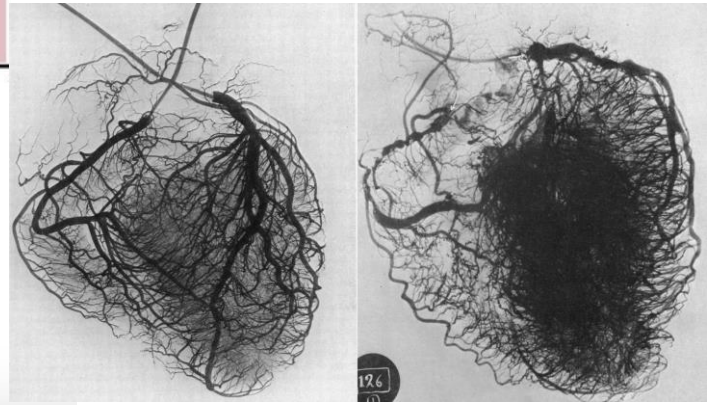
Women and Ischemic Heart Disease
Evolving Knowledge

Leslee J. Shaw, Raffaelle Bugiardini and C. Noel Bairey Merz



Progressive manifestations of ischemic heart disease

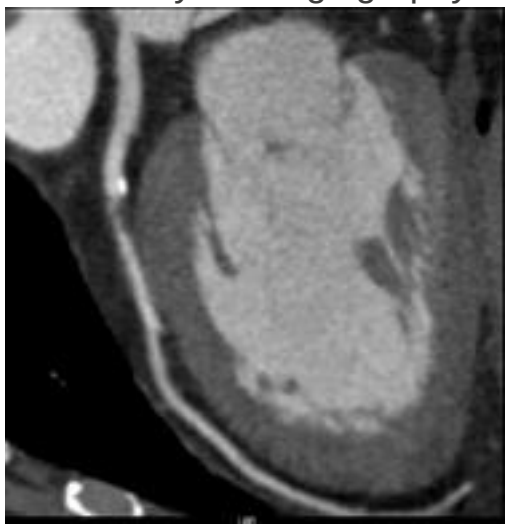
Many years of vascular disease in the vessel wall that we are not evaluating and treating



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

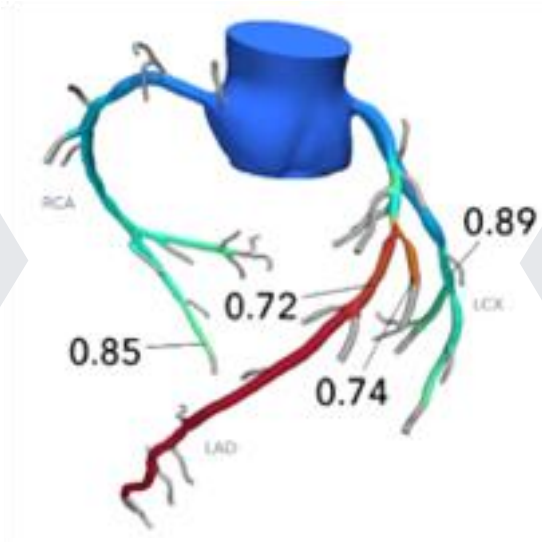
Anatomical Testing

Coronary CT Angiography



Anatomical and Functional

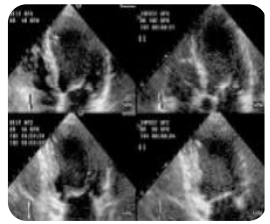
FFR_{CT}



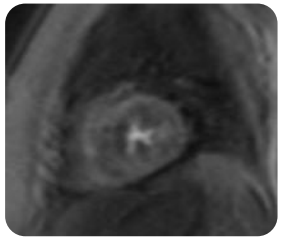
Functional Testing

Treadmill ECG

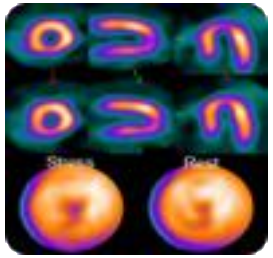
Stress Echo



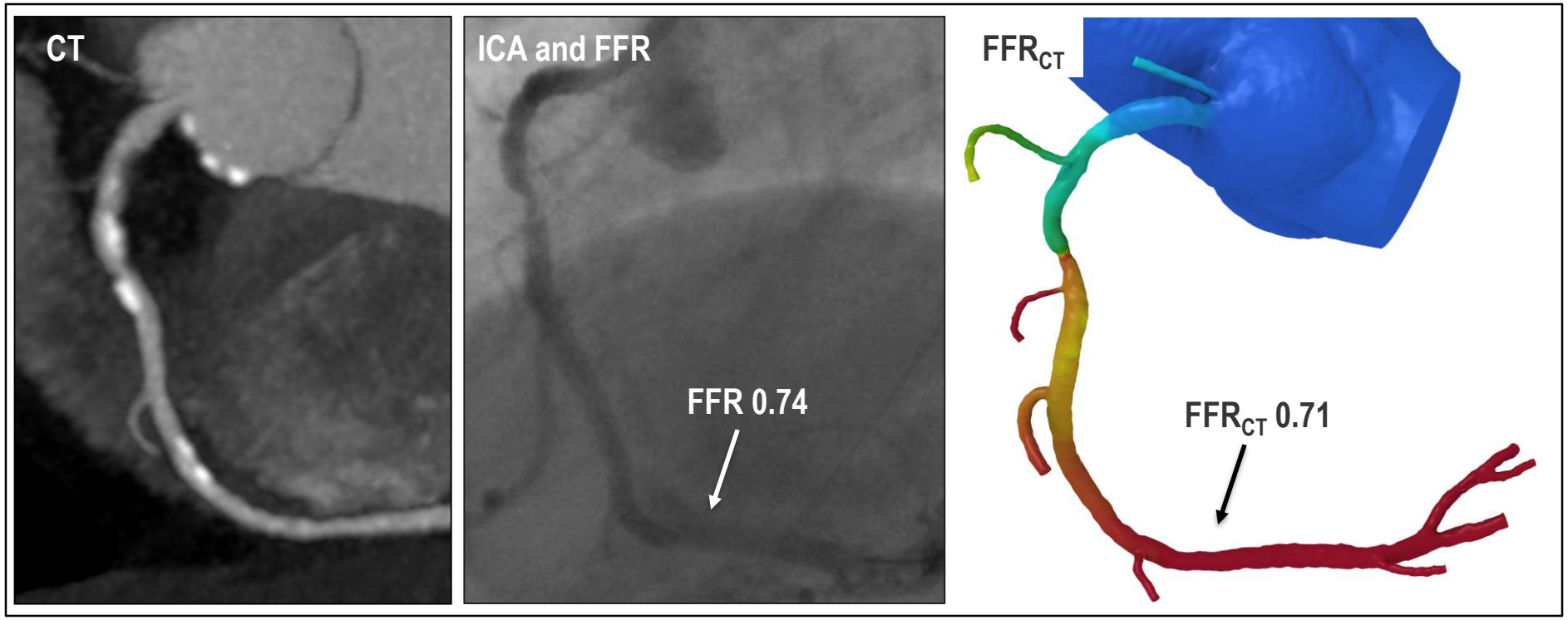
Stress MRI



SPECT



FFR_{CT}: Intermediate Stenosis



31-49% stenosis
CT Core Lab

50-69% stenosis
QCA Core Lab

FFR 0.74
= Lesion-specific ischemia

FFR_{CT} 0.71
= Lesion-specific ischemia

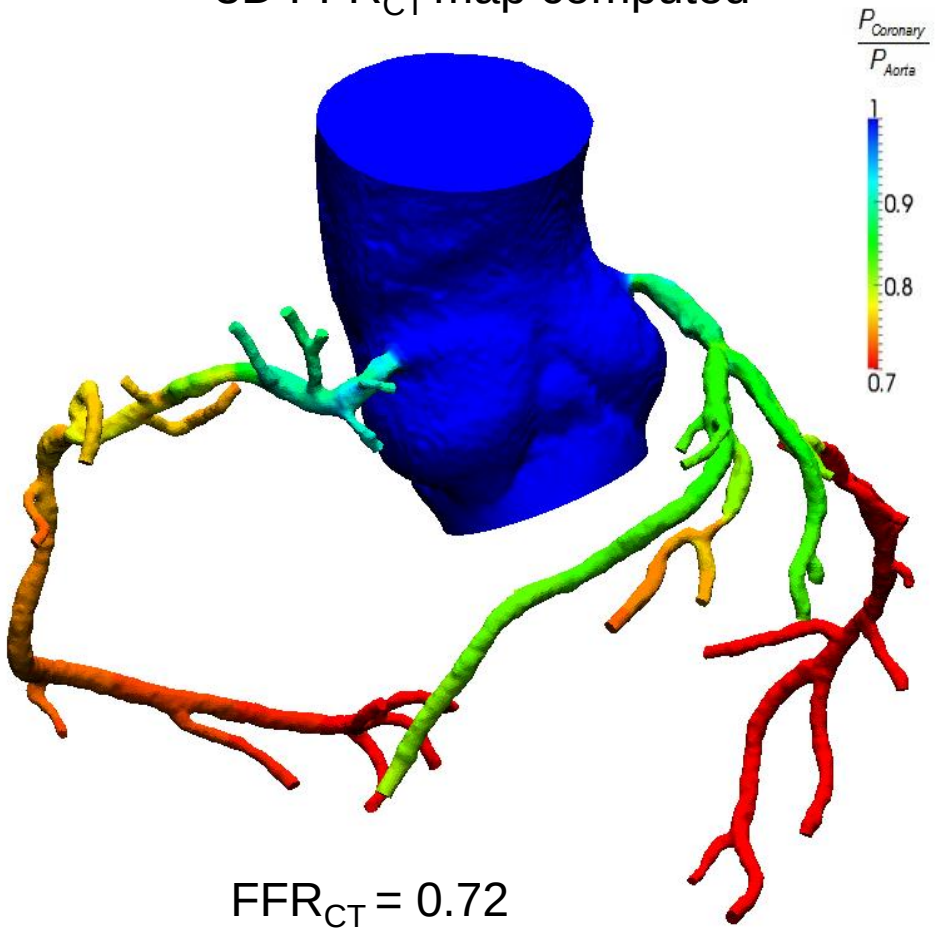
Source: Min et al. JAMA 2012

DeFACTO
Determination of Fractional Flow Reserve by Anatomic Computed Tomographic Angiography

FFR can now be derived from CT

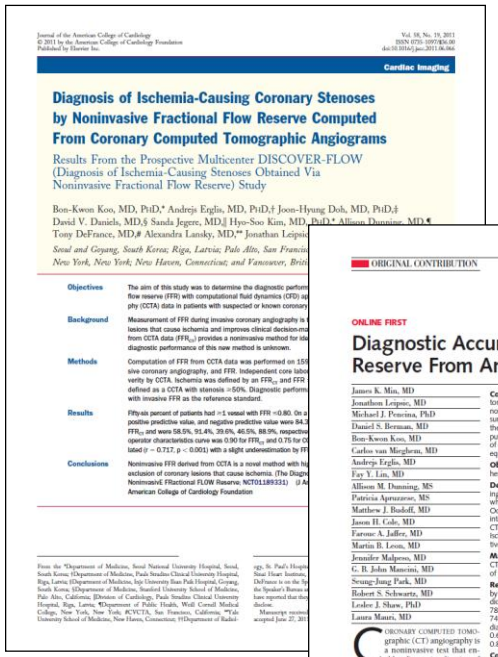
1. From typical CCTA
2. No radiation
3. No Δ image protocols
4. No medications

3D FFR_{CT} map computed



FFR_{CT} = 0.72
(can select any point on model)

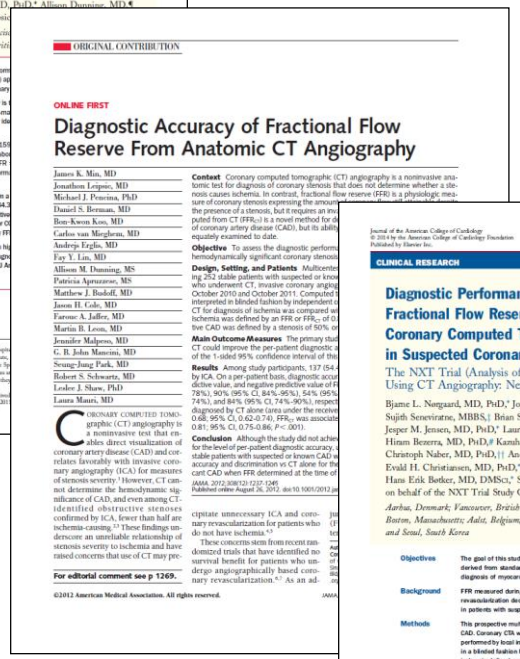
HeartFlow FFR_{CT} Clinical Trial Data is Substantial



Diagnosis of Ischemia-Causing Coronary Stenoses by Noninvasive Fractional Flow Reserve Computed From Coronary Computed Tomographic Angiograms

Results From the Prospective Multicenter DISCOVER-FLOW (Diagnosis of Ischemia-Causing Stenoses Obtained Via Noninvasive Fractional Flow Reserve) Study

- **DISCOVER-FLOW**
  - Completed 2011
  - N=103 patients



ORIGINAL CONTRIBUTION

Diagnostic Accuracy of Fractional Flow Reserve From Anatomic CT Angiography

- **DeFACTO**
  - Completed 2012
  - N=252 patients

CLINICAL RESEARCH

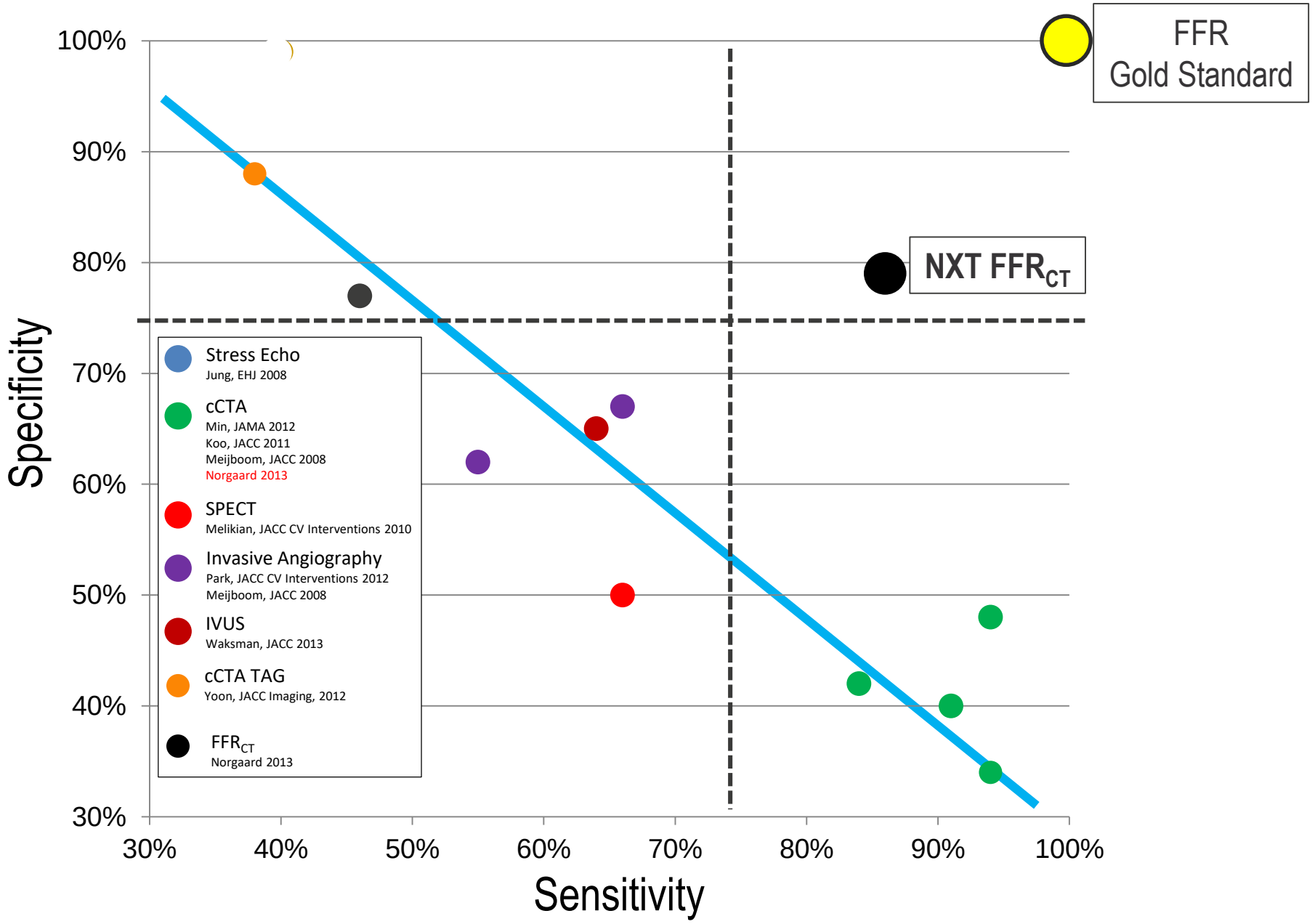
Diagnostic Performance of Noninvasive Fractional Flow Reserve Derived From Coronary Computed Tomography Angiography in Suspected Coronary Artery Disease

The NXT Trial (Analysis of Coronary Blood Flow Using CT Angiography: Next Steps)

- **NXT**
  - Completed 2013
  - N=254 patients
  - 10 Worldwide Sites
    - Europe
    - Australia
    - Japan
    - Korea

3 major trials directly comparing FFR_{CT} to FFR in more than 600 patients

Diagnostic performance of non-invasive imaging vs. FFR



PLATFORM – FFR-CT into Clinical Practice

European Heart Journal
doi:10.1093/eurheartj/ehv444

FASTTRACK
ESC Hot Line

Clinical outcomes of fractional flow reserve by computed tomographic angiography-guided diagnostic strategies vs. usual care in patients with suspected coronary artery disease: the prospective longitudinal trial of FFRct: outcome and resource impacts study

Pamela S. Douglas[1]*, Gianluca Pontone[2], Mark A. Hlatky[3], Manesh R. Patel[1], Bjarne L. Norgaard[4], Robert A. Byrne[5], Nick Curzen[6], Ian Purcell[7], Matthias Gutberlet[8], Gilles Rioufol[9], Ulrich Hink[10], Herwig Walter Schuchlenz[11], Gudrun Feuchtner[12], Martine Gilard[13], Daniele Andreini[2], Jesper M. Jensen[4], Martin Hadamitzky[5], Karen Chiswell[1], Derek Cyr[1], Alan Wilk[14], Furong Wang[14], Campbell Rogers[14], and Bernard De Bruyne[15], On Behalf of the PLATFORM Investigators†

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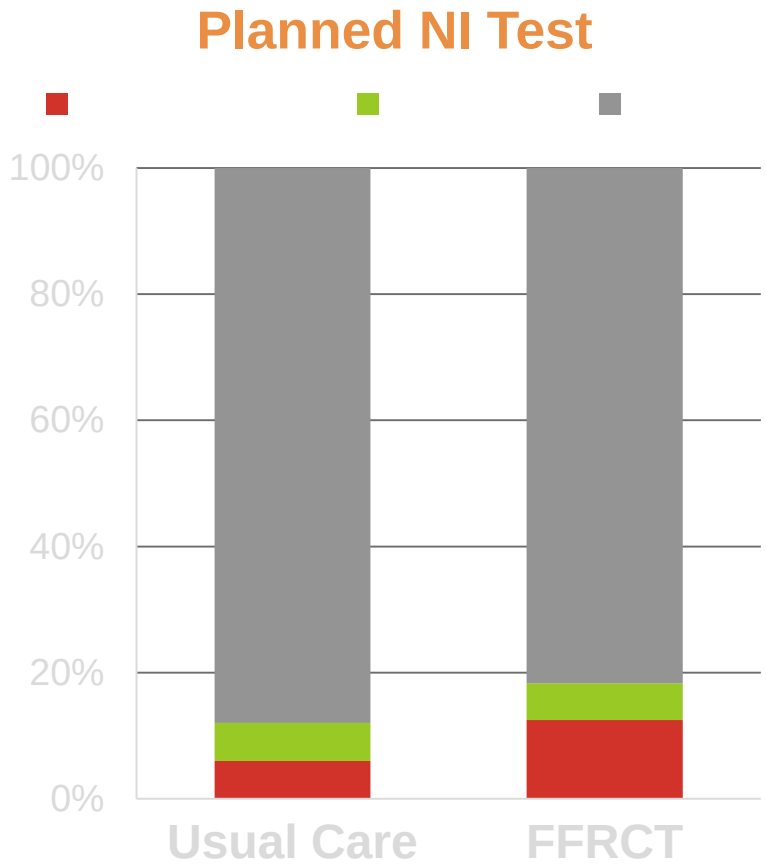
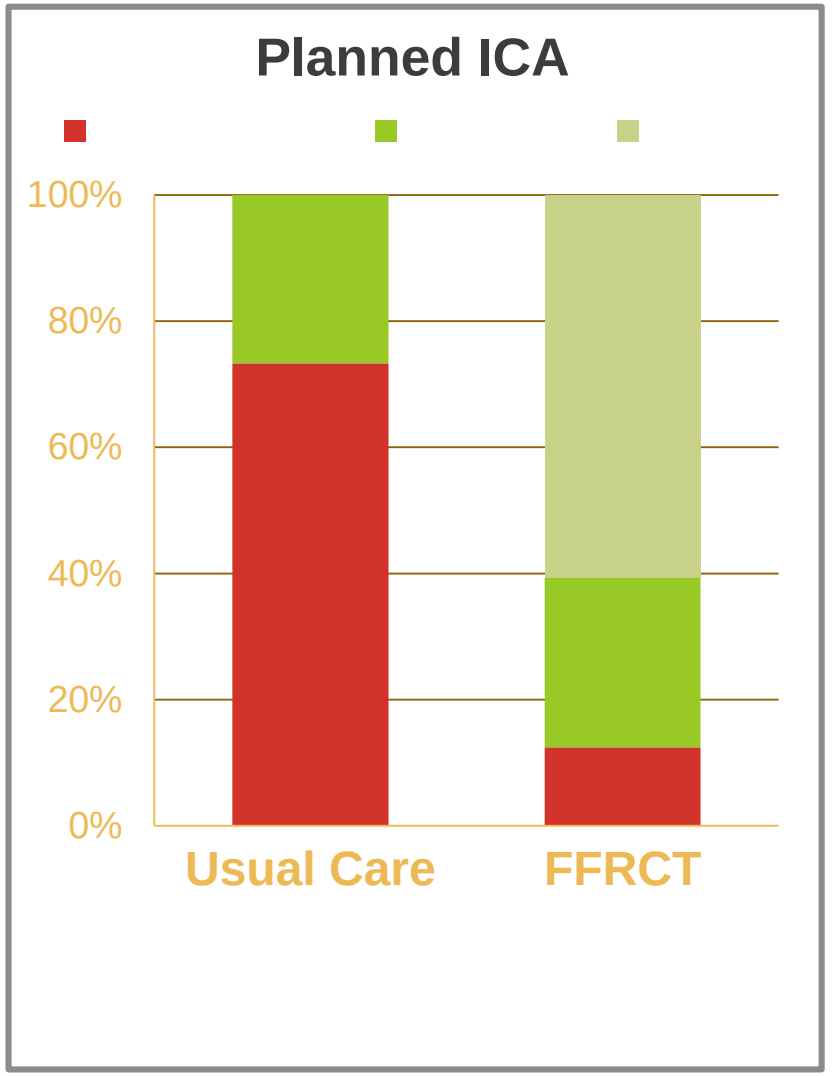
doi: 10.1093/eurheartj/ehv444
eurheartj.oxfordjournals.org

Primary Endpoint

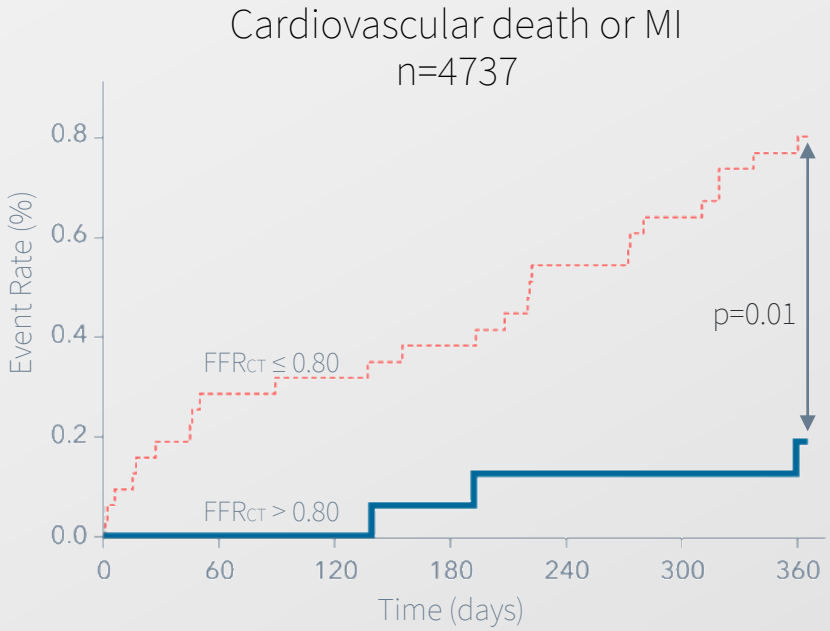
Invasive Catheterization w/o Obstructive CAD



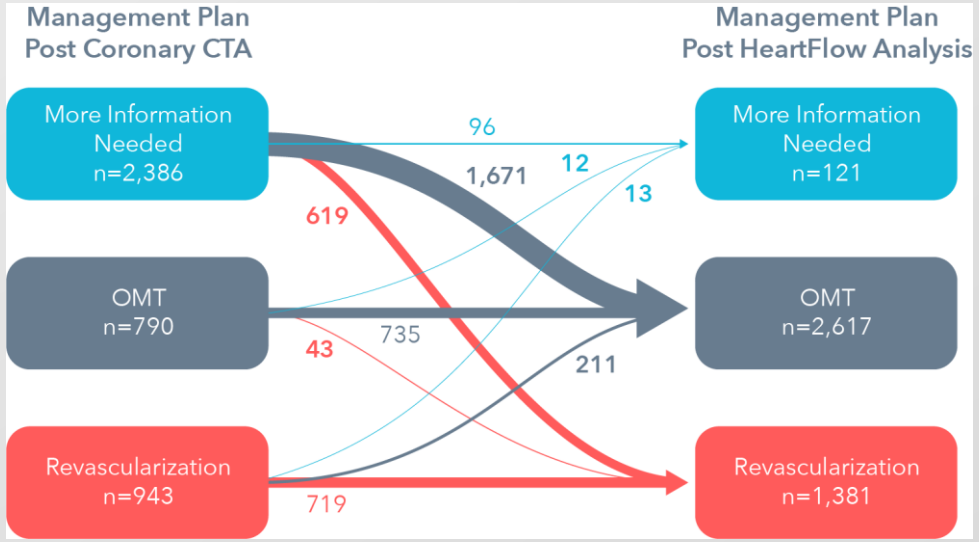


ADVANCE Registry:
Clear clinical impacts of FFRCT in real-world use

The 1-year outcomes of the ADVANCE Registry confirmed the HeartFlow Analysis helps physicians precisely stratify their patients and deliver more personalized care



Risk Identification: Patients with a negative HeartFlow Analysis (FFRCT >0.80) were significantly less likely to experience MI or cardiovascular-related death than those with a positive HeartFlow Analysis (FFRCT ≤0.80).



Actionable Information: 2 out of 3 patient management plans were altered after physicians had access to the information from a HeartFlow Analysis.

Efficiency: 72.3% of patients with a positive HeartFlow Analysis (FFRCT ≤0.80) who were sent for ICA underwent revascularization.

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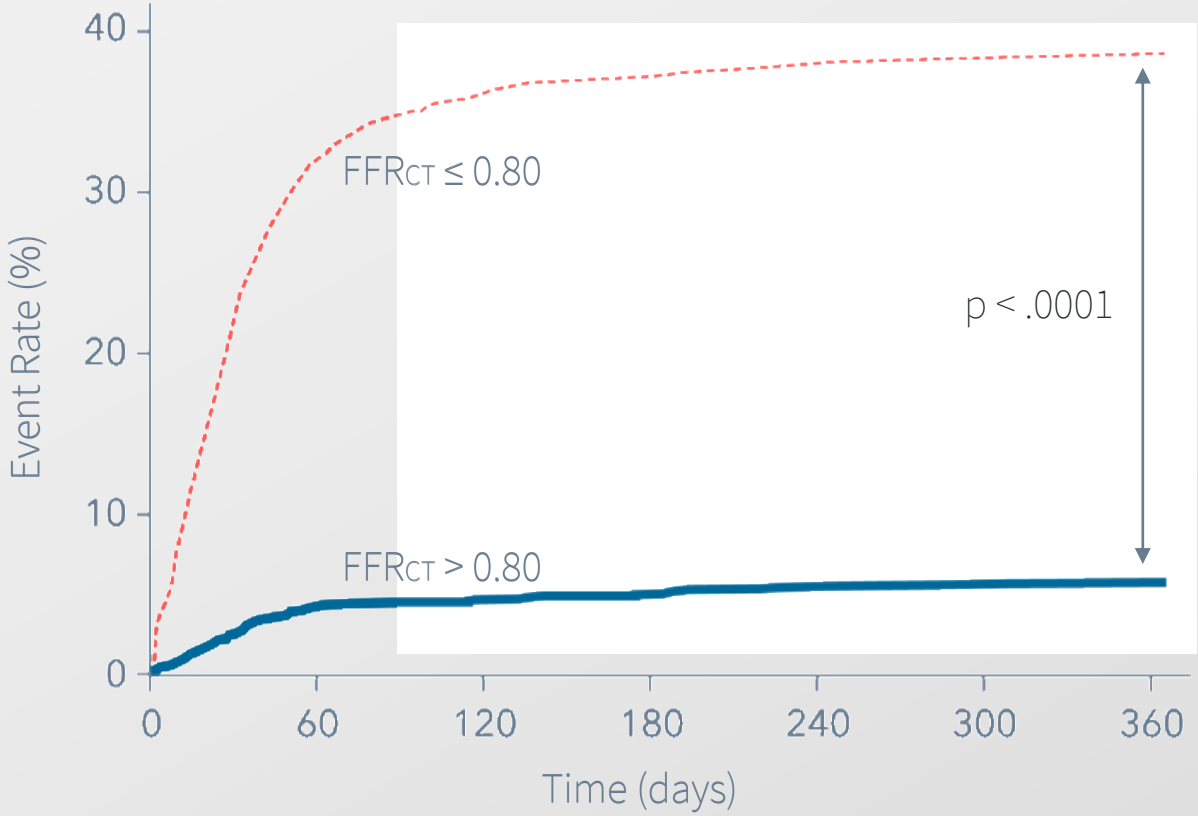
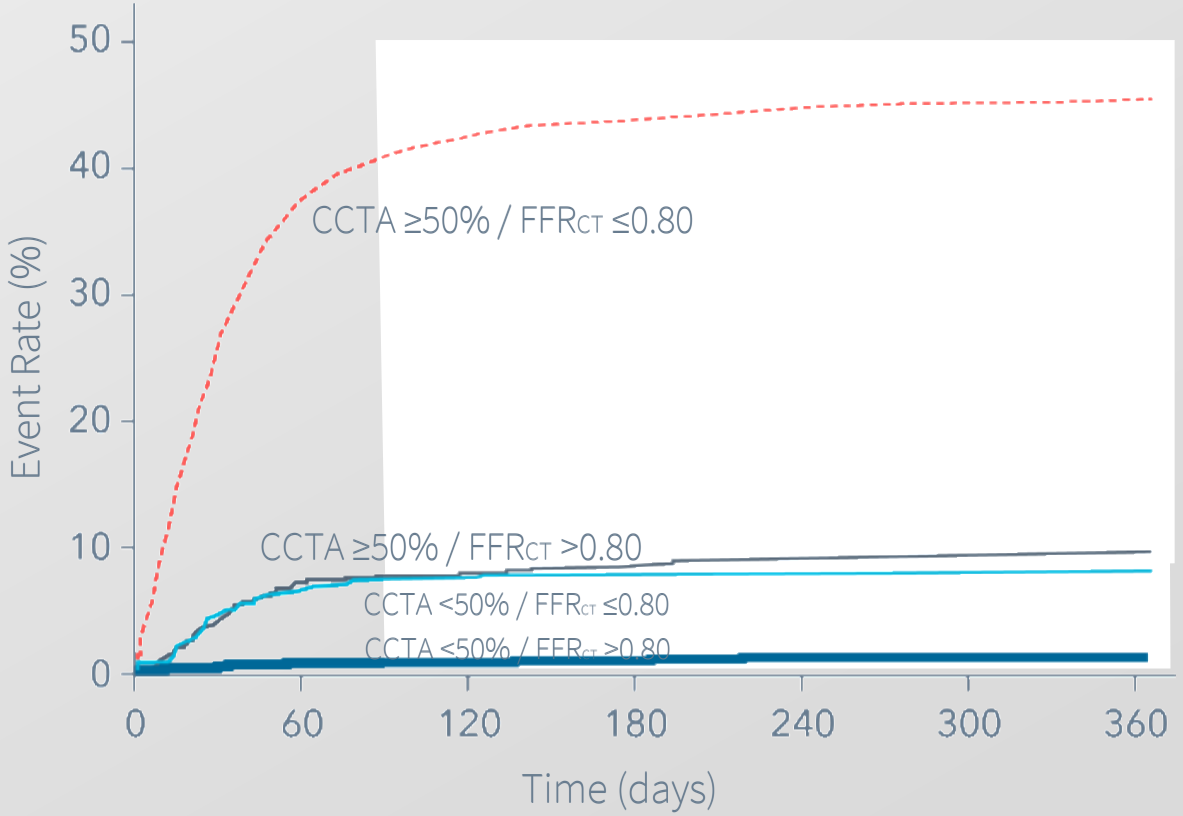
Fairbairn, et al. Euro Heart J 2018. Patel, et al. JACC CV Imaging 2019. 5083 patients enrolled across 38 sites in the EU, Japan, and North America.

ADVANCE 1 year:
Revascularization as a function of FFRCT and anatomic stenosis

Durable Impact: Independent of the extent of CAD shown on the CCTA, when FFRCT values are > 0.80 providers overwhelmingly opt for a non-invasive approach, and that decision is durable (i.e. initial deferral of invasive management is highly unlikely to result in later return for revascularization). In these patients, cardiovascular outcomes are extremely good over time.





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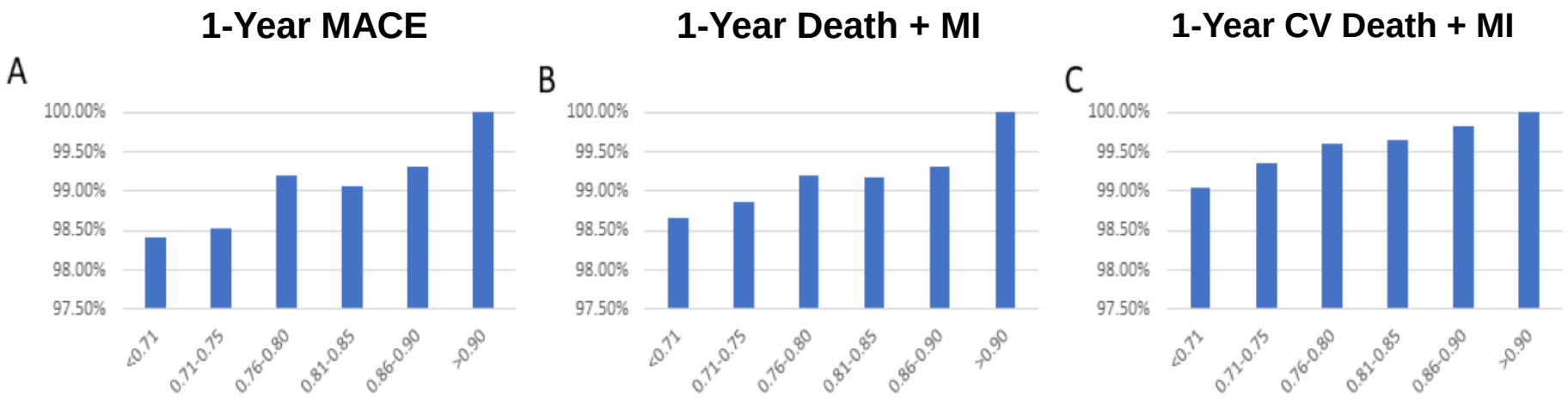
Clinical Outcomes through 1 Year: Stratified by FFR_{CT} (n=4737)

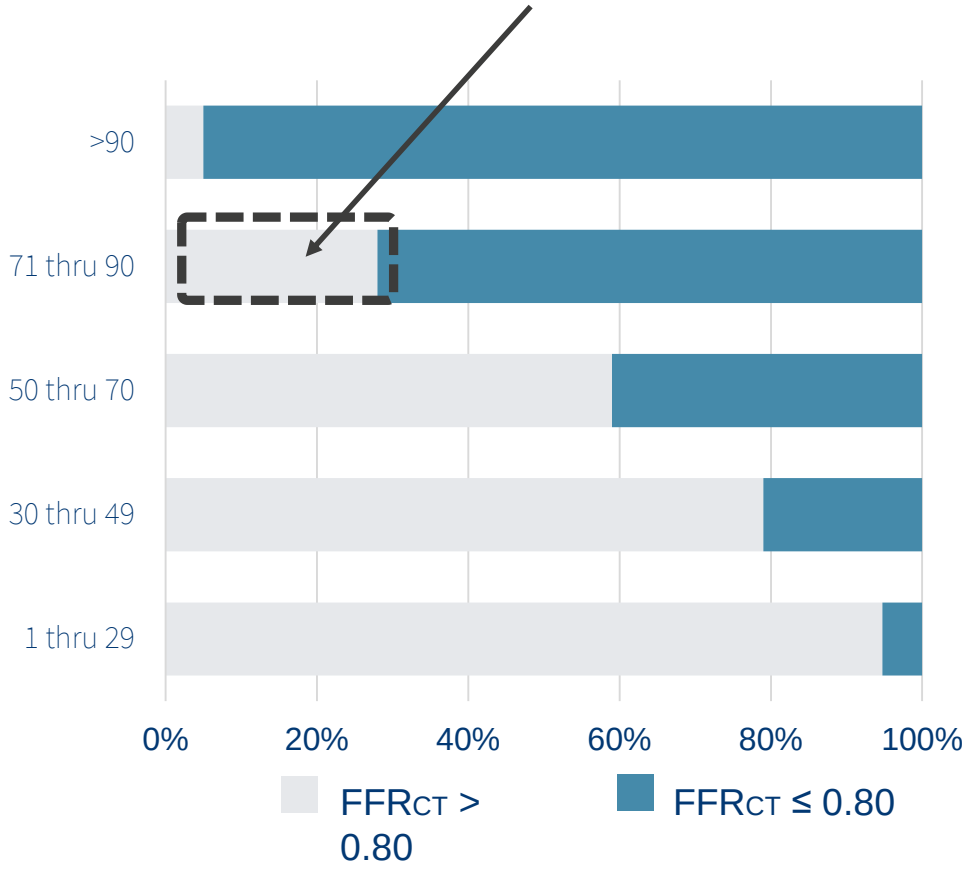


Distribution of event-free survival by categorical FFR_{CT} values for: **(A)** MACE, **(B)** Death and MI, **(C)** Cardiovascular death and MI.

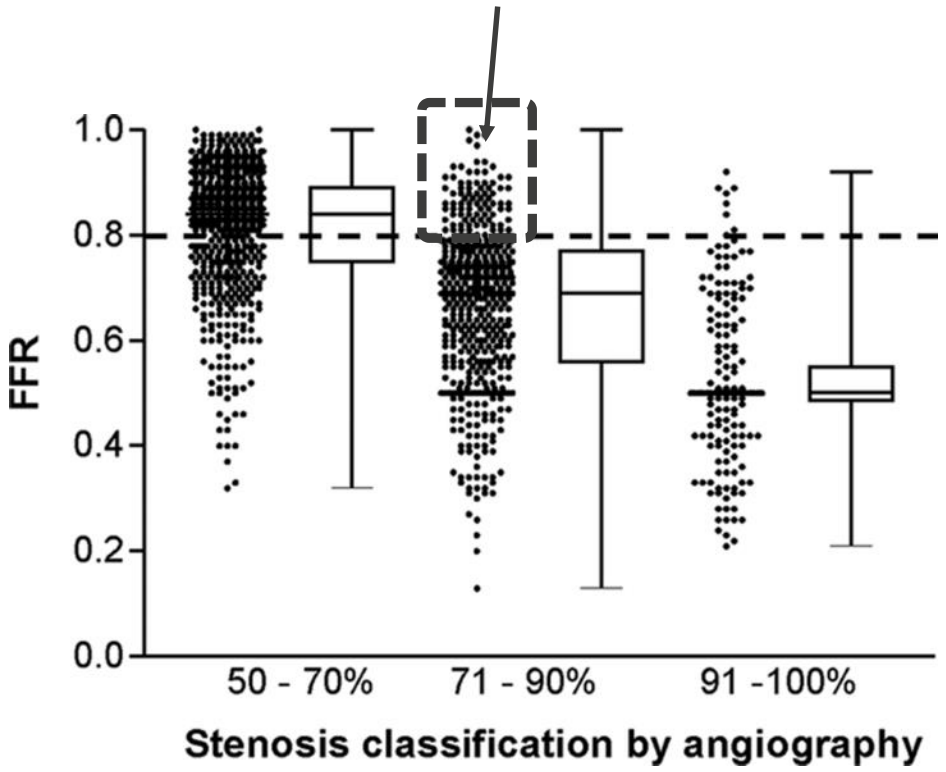
Patel, M JACC imaging March. 2019

Anatomy & Function: Frequent real-world discordance

28% of CT stenosis >70% are FFR_{CT} negative[1]



20% of ICA stenosis >70% are FFR negative[2]



1. *ADVANCE 1000 Patient Analysis*, Kitabata, et al. ACC 2017. | 2. *FAME*, Tonino, et al. JACC 2010; 55:2816-21.

Where are we going to get more precise?

Prediction of Risk

Age [enter value between 45 and 92]

69

Sex

- ○ Male
- ◉ Female

Racial/Ethnic Minority

- ◉ No
- ○ Yes

Ever Smoked Tobacco

- ◉ Never
- ○ Ever

Diabetes

- ◉ No
- ○ Yes

Dyslipidemia

- ○ No
- ◉ Yes

Family History of Premature CAD

- ○ No
- ◉ Yes

28%

Predicted Probability of No Risk

The likelihood of being 'No Risk' [a normal diagnostic test and no clinical events (Death, MI, or Hospitalization due to Unstable Angina) within 25 months] in a patient with the reported constellation of risk factors is: 28%

What type of non-invasive test are you considering for your patient?

- ◉ CCTA
- ○ Functional Stress Test

View Event Rate Results from Selected Test

Test Results:

Normal (No CAD):

19.0%

Abnormal (CAD present):

81.0%

Severely Abnormal (2 or more vessel disease (>=70%) or >=50% in left main stenosis or >=70% proximal LAD stenosis):

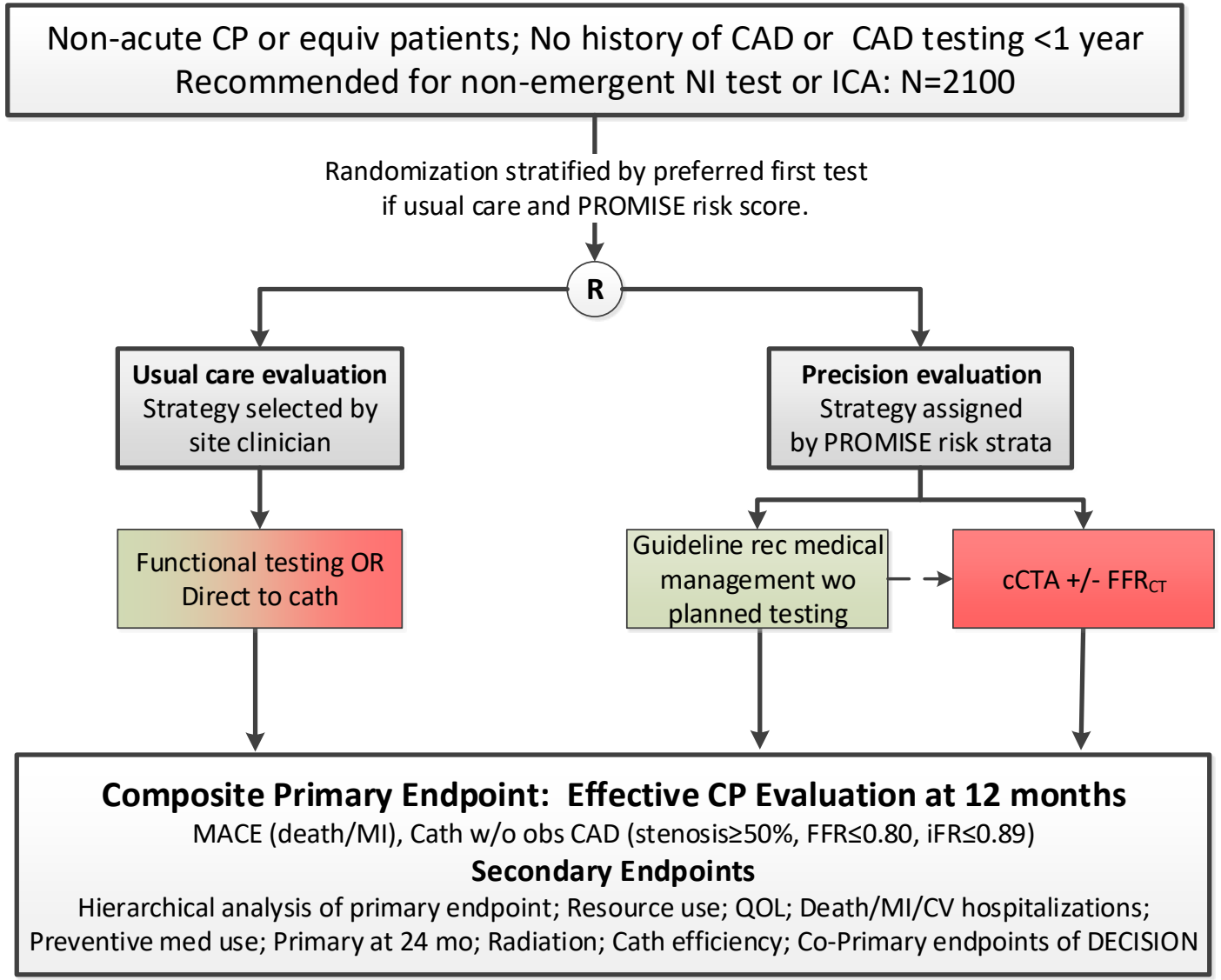
8.4%

Clinical Outcomes:

Cardiovascular Death/MI:

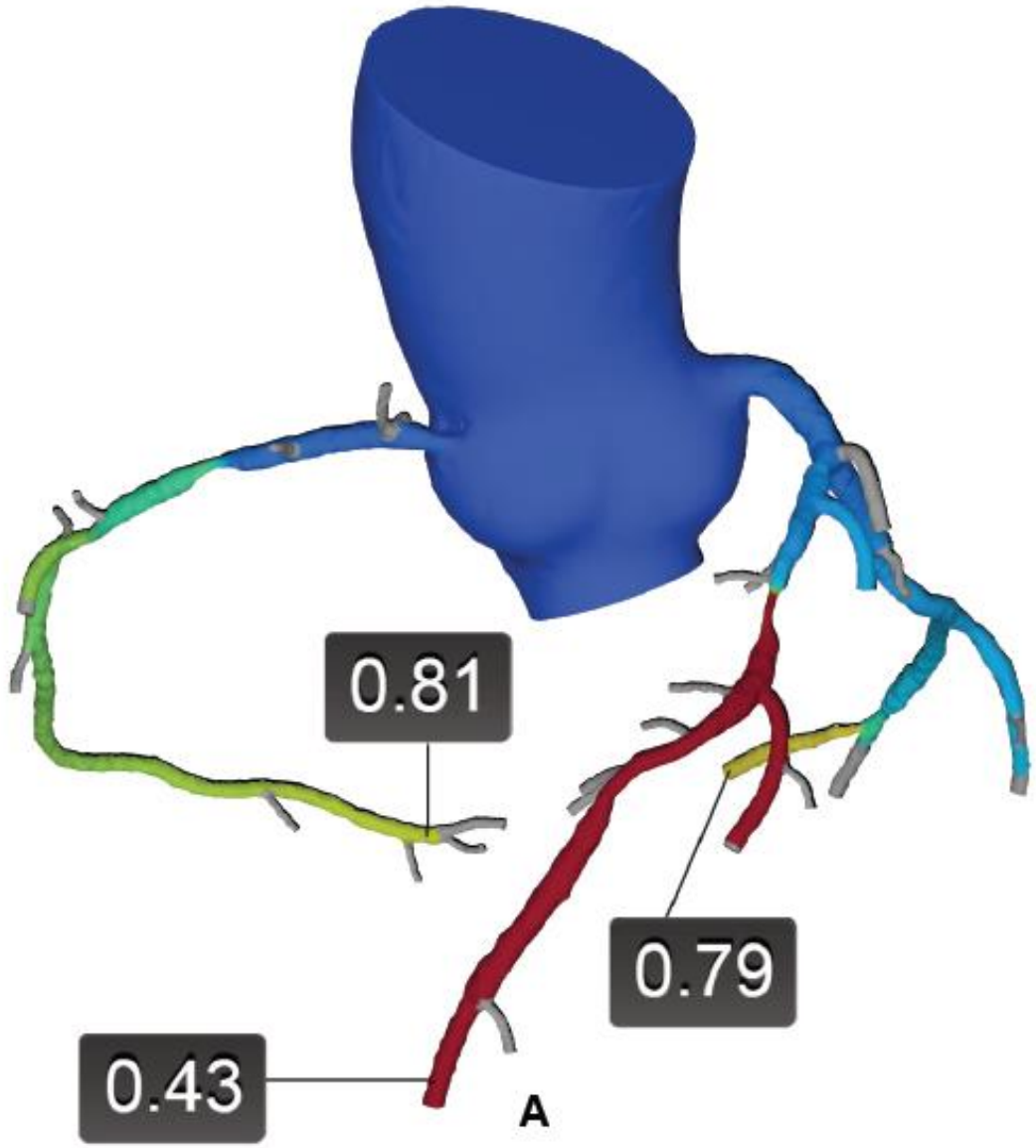
1.3%

PRECISE Trial Design



New Ways of Caring for a Patient

Pre-procedure planning



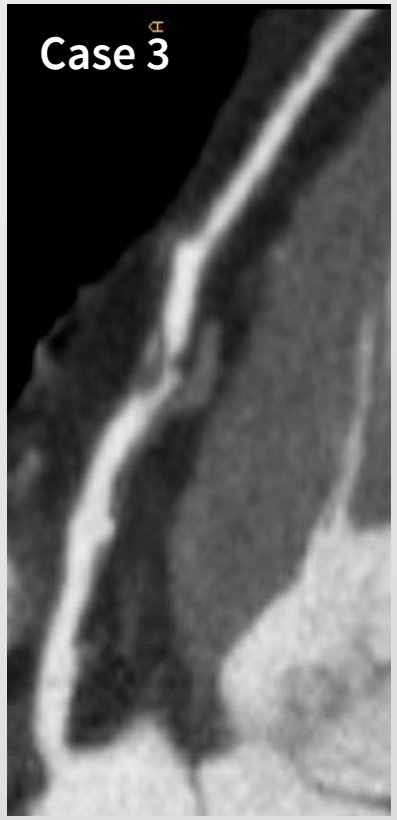
Choosing coronary CTA

Coronary CTA answers the clinically relevant questions

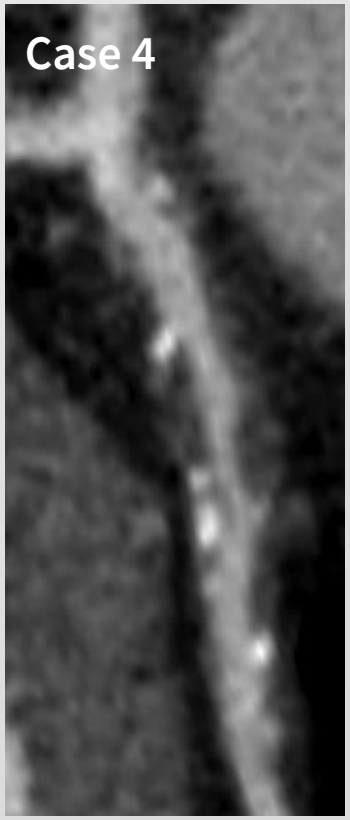
1. Does my patient have coronary artery disease?

No identifiable anatomic disease

Identifiable disease



Identifiable disease



Identifiable disease

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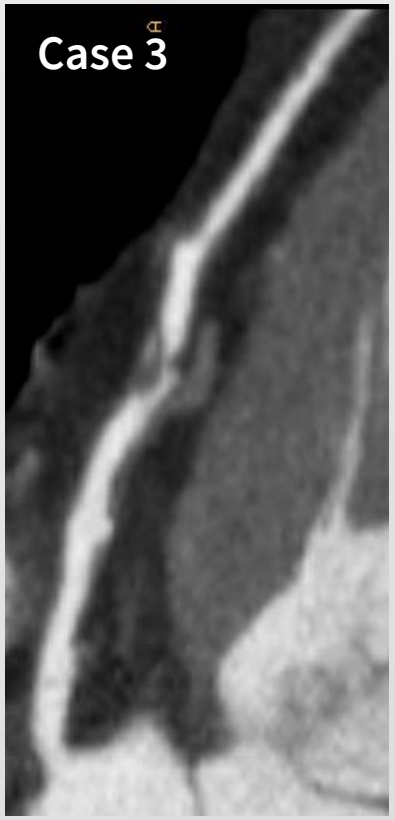
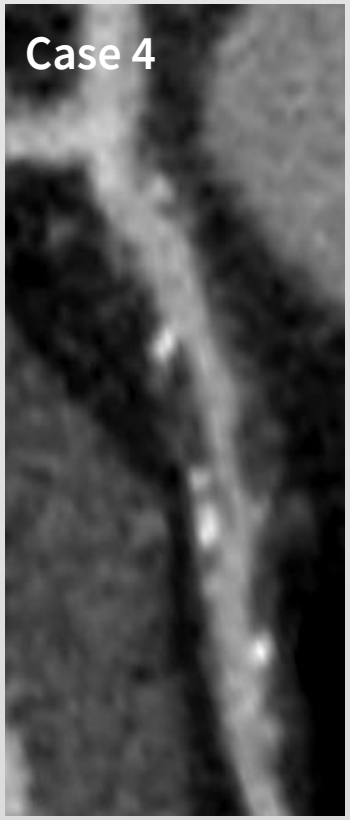
Coronary CTA answers the clinically relevant questions

2. How severe is my patient's disease?

Minimal disease, possible OMT



Disease with unknown functional impact

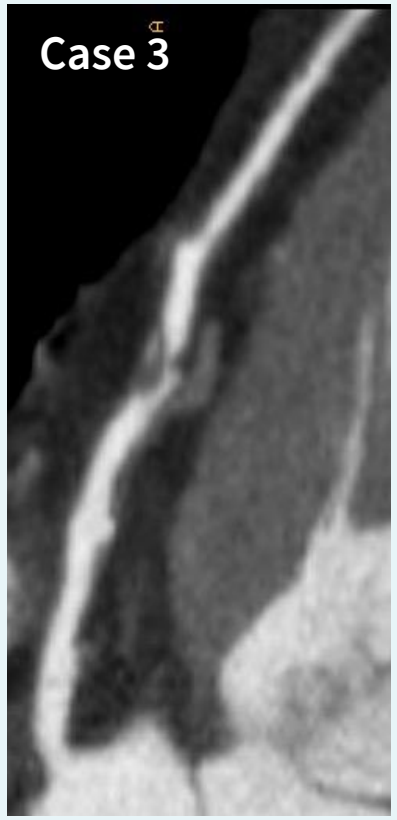


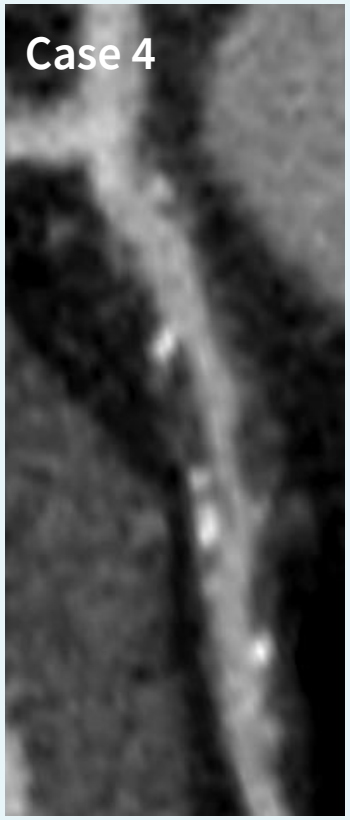
Complex, high disease burden

Coronary CTA answers the clinically relevant questions

3. What can be done to treat my patient's disease?

Minimal disease, possible OMT





Inform clinical decisions that may involve ICA, PCI, and CABG

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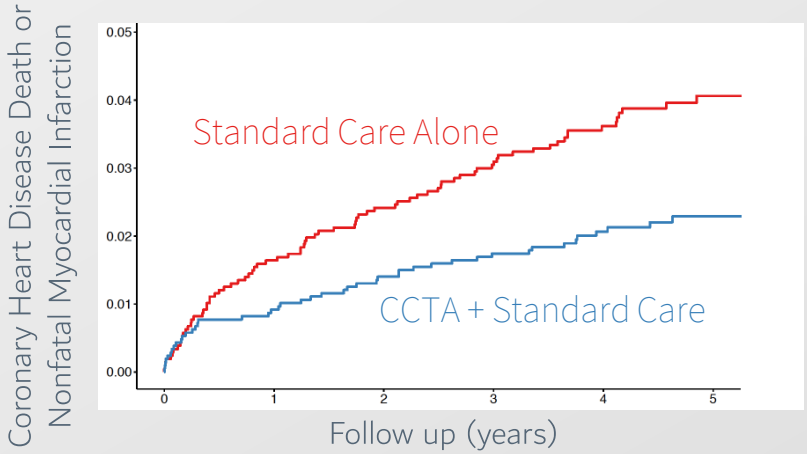
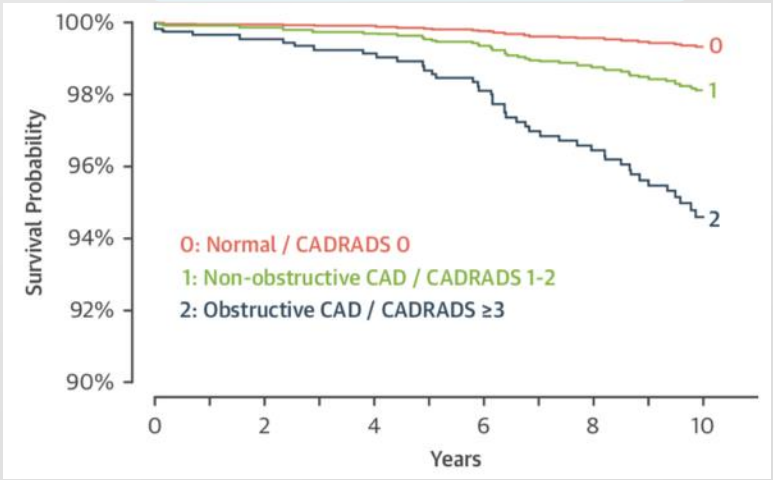
Evidence supports coronary CTA as a primary test for suspected CAD

1. Significantly better long-term outcomes than usual care testing
2. Better negative predictive value confirming it is safe to send patients home
3. Lower radiation than other non-invasive tests

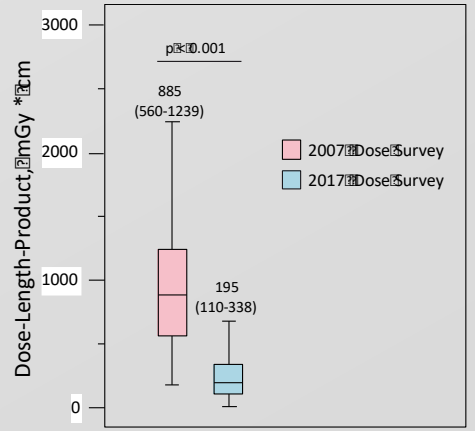
Better outcomes in multi-center RCT w/5-year follow up[1]



Better negative predictive value through 10-year follow up[2]



Major reductions in radiation over 10 years of experience worldwide[3]



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1. Newby, et al. N Engl J Med 2018. | 2. Finck, et al. JACC: Cardiovascular Imaging 2018. | 3. Stocker, et al. Euro Heart J 2018.

Evidence supports coronary CTA as a primary test for suspected CAD

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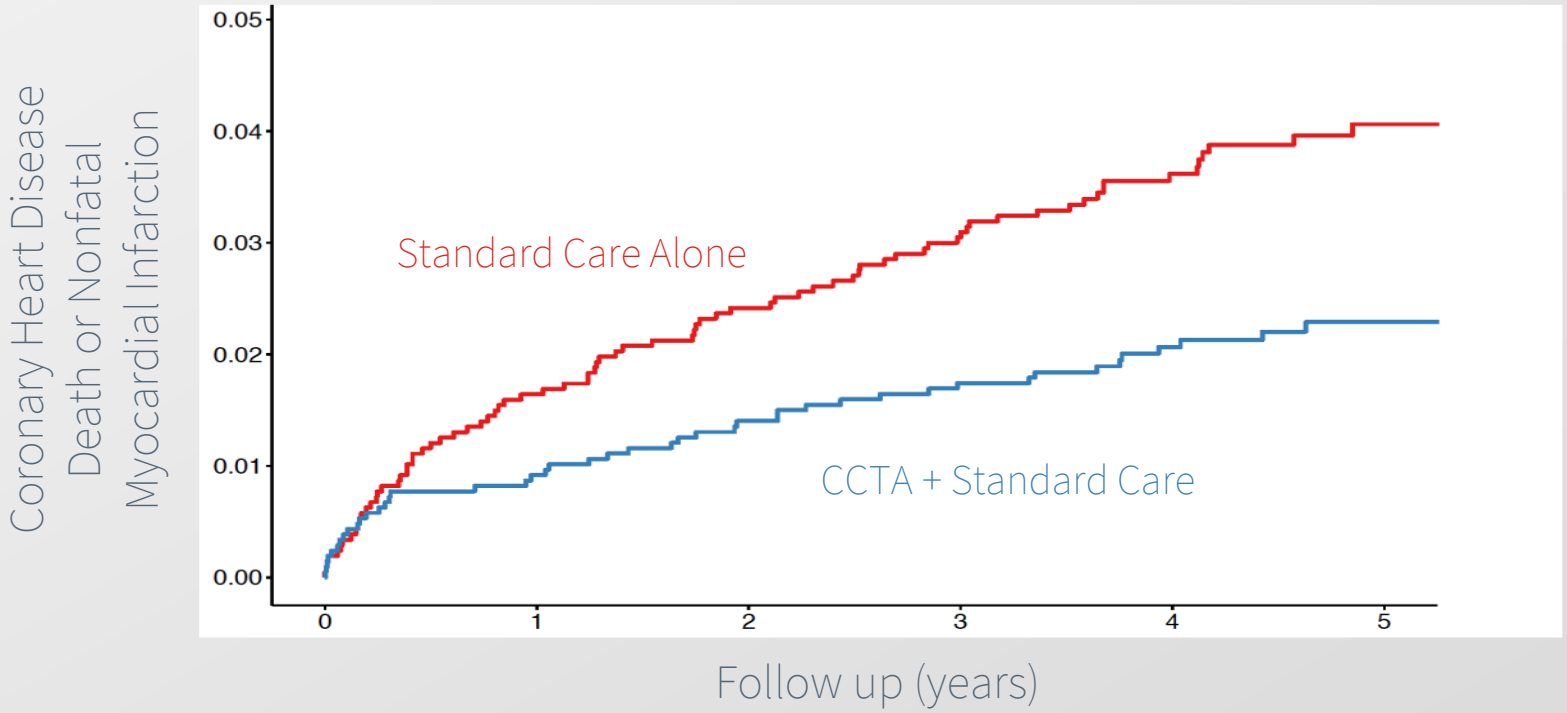

41% lower death & MI rate in CCTA group than in standard care group at 5 years (SCOT-HEART, NEJM 2018)

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Newby, et al. N Engl J Med 2018.

Evidence supports coronary CTA as a primary test for suspected CAD

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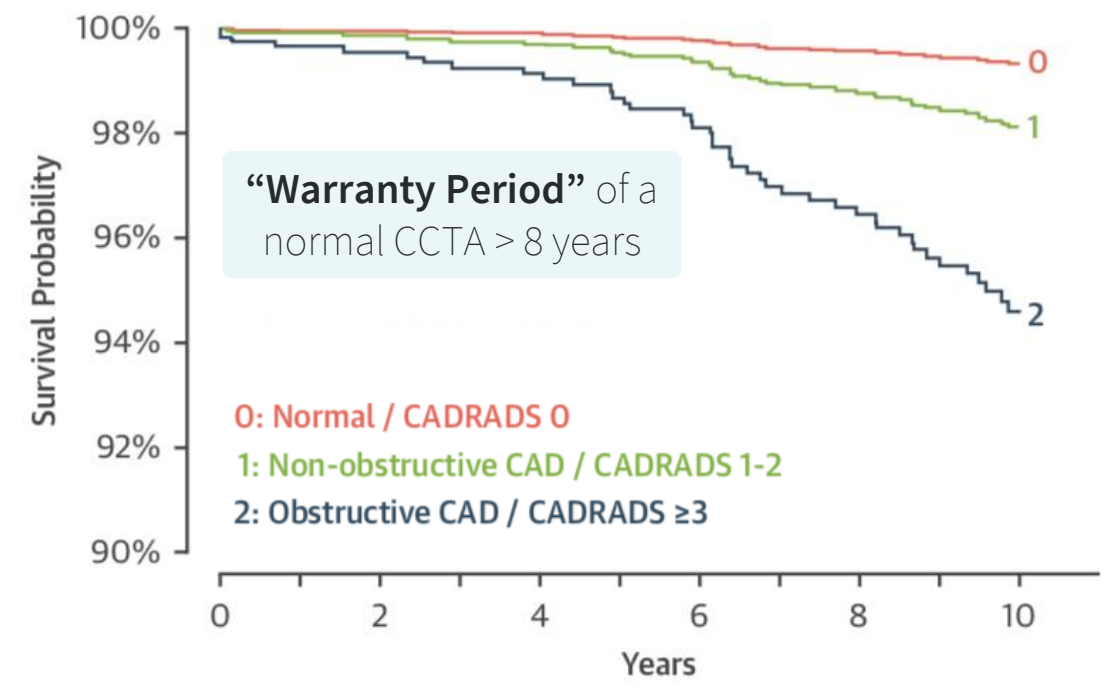
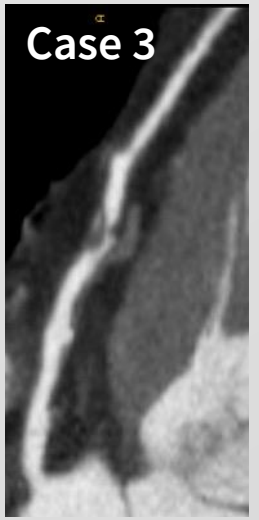
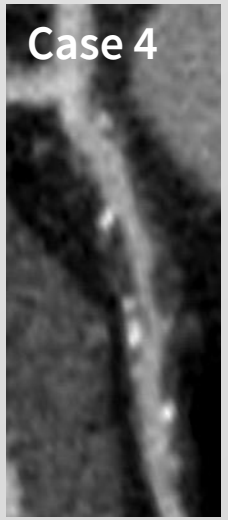


CADRADS 0

CADRADS 1-2



CADRADS 3



CADRADS ≥3

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Finck, et al. JACC: Cardiovascular Imaging 2018.

Evidence supports coronary CTA as a primary test for suspected CAD

1. Significantly better long-term outcomes than usual care testing
2. Better negative predictive value confirming it is safe to send patients home
3. Lower radiation than other non-invasive tests

Lower radiation

- 78% reduction in the past 10 years
- ~50% lower than an average SPECT
- Median dose of 2.7 mSv

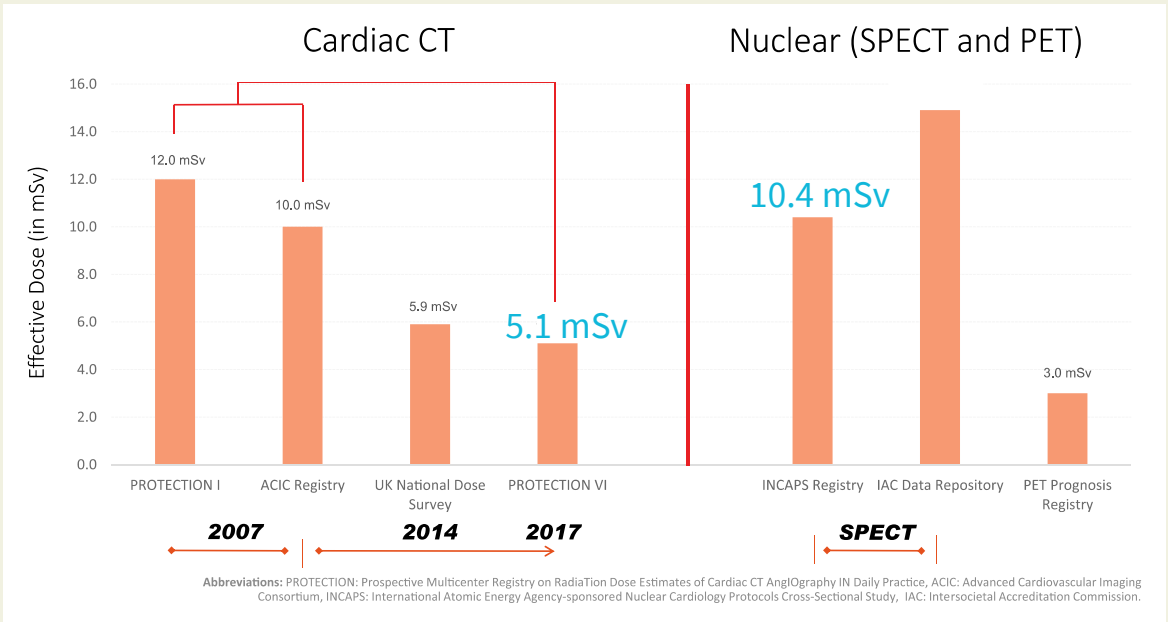

Figure 1 Worldwide radiation dose practices from contemporary multicenter registries of CT and nuclear imaging in the evaluation of coronary artery disease.

73474022 v1

Stocker, et al. Euro Heart J 2018.

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

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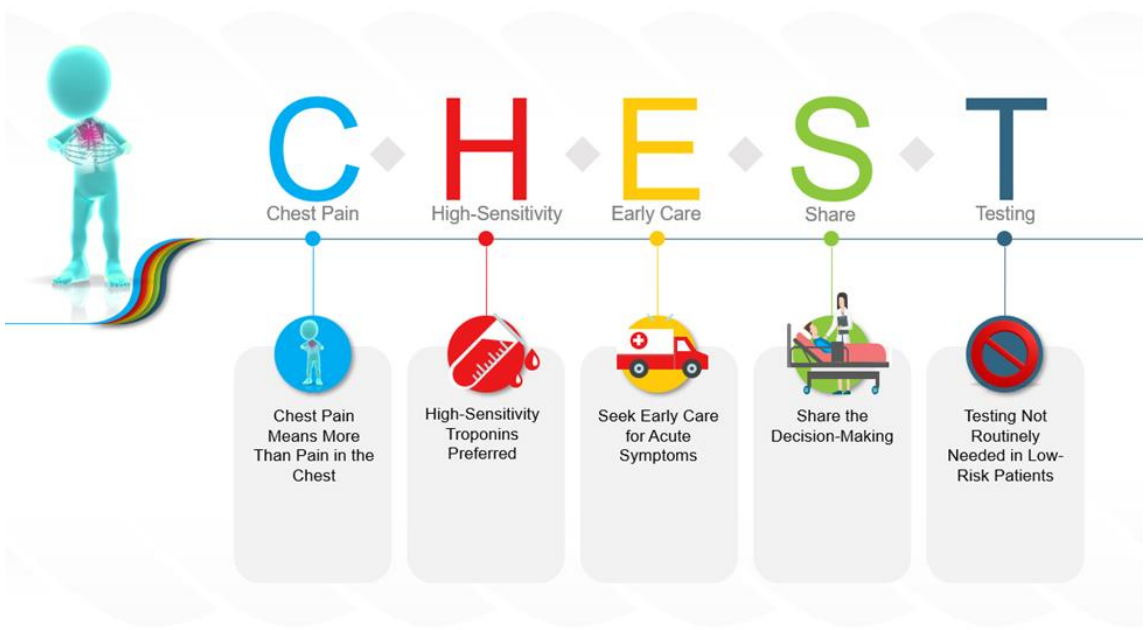
Figure 1. Take-Home Messages for the Evaluation and Diagnosis of Chest Pain



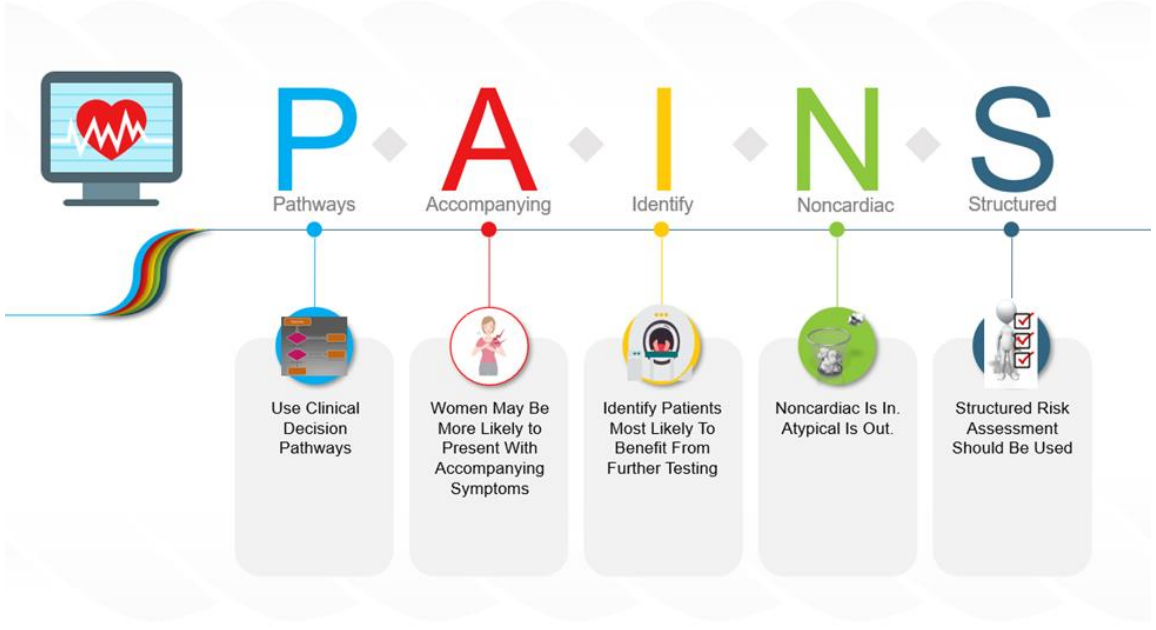
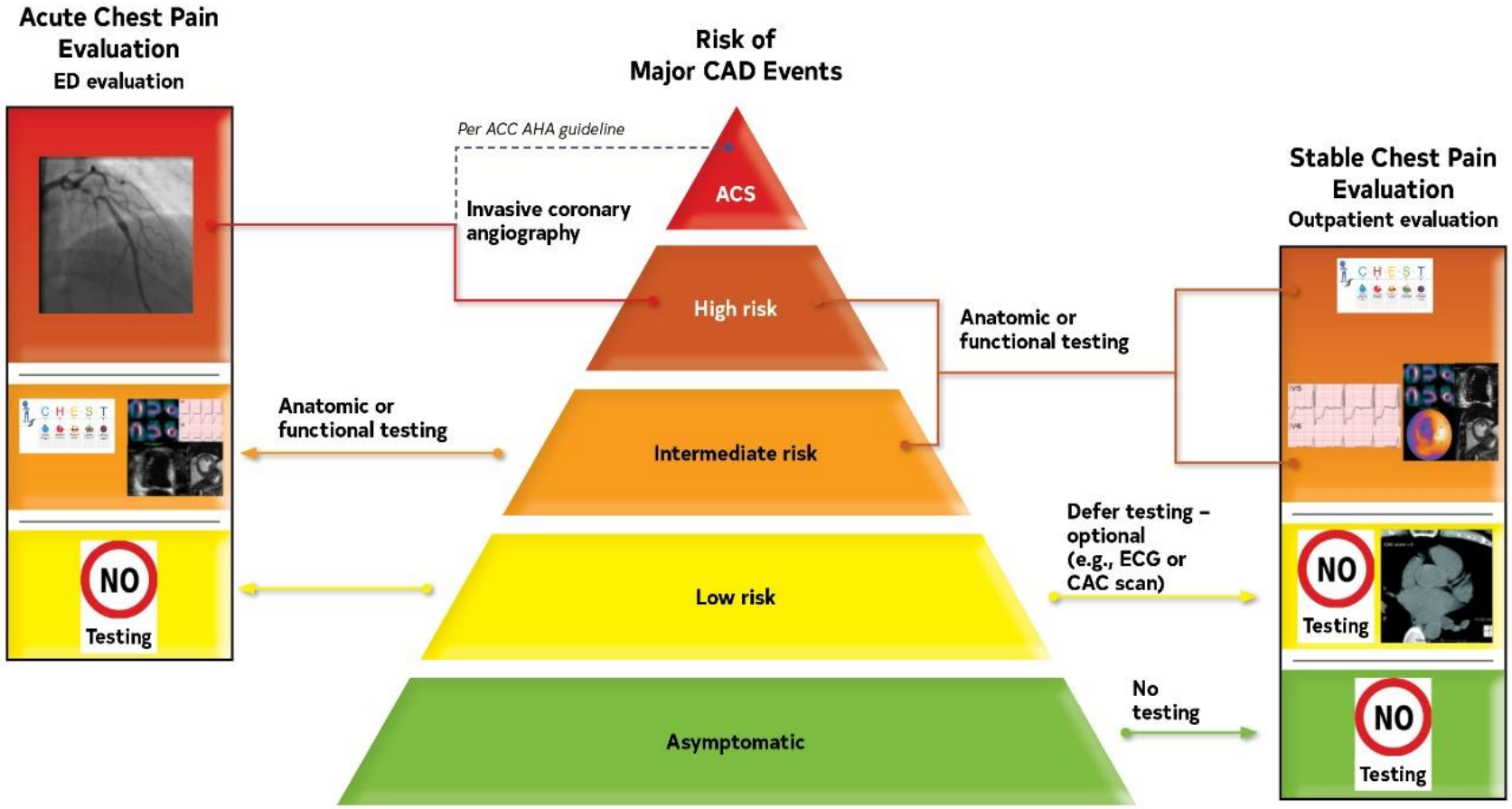


Figure 5. Chest Pain and Cardiac Testing Considerations.



The choice of imaging depends on the clinical question of importance, to either a) ascertain the diagnosis of CAD and define coronary anatomy or b) assess ischemia severity among patients with an expected higher likelihood of ischemia with an abnormal resting ECG or those incapable of performing maximal exercise.
ACS indicates acute coronary syndrome; CAC, coronary artery calcium; CAD, coronary artery disease; and ECG, electrocardiogram.
Please refer to Section 4.1.
For risk assessment in acute chest pain: See Figure 9.
For risk assessment in stable chest pain: See Figure 11.

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.**

Conclusions

- Significant evolving data for CCTA and FFR-CT
- Much to be learned about delivery
- More Science coming
  - Ongoing trial PRECISE (SOC vs. Risk based testing with CTA first/ Also CCTA prior to cath)
- Getting it into practice with procedure planning

Thank you