FFR_{CT} Guidance for the Diagnosis and Treatment of Suspected CAD

The DECISION Trial

Gregg W. Stone, MD
Columbia University Medical Center
New York-Presbyterian Hospital
Cardiovascular Research Foundation

Disclosures

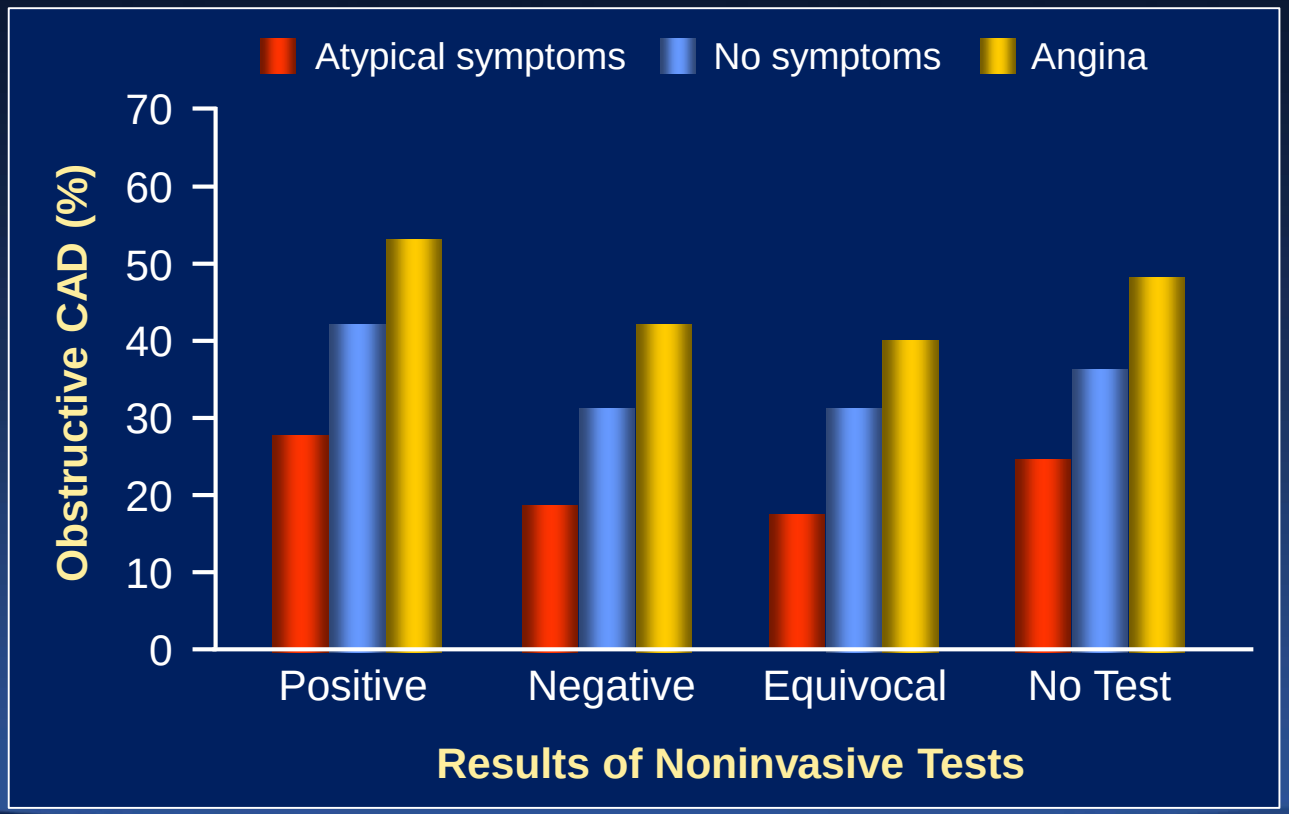
Consultant to HeartFlow

Background: Most Patients with Suspected CAD Undergoing Cath Do Not Have Obstructive CAD

Cath performed in 398,978 pts at 663 US hospitals between 1/2004 - 4/2008 for suspected CAD; median age 61 yrs, 53% men, 26% diabetes, 79% HTN.

Obstr. CAD (DS ≥50% in LM or ≥70% in non-LM) in 149,739 pts (37.6%).

Non-invasive testing was performed in 83.9% of pts.



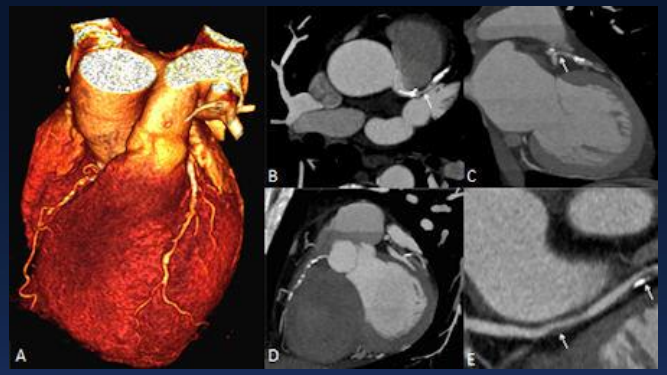
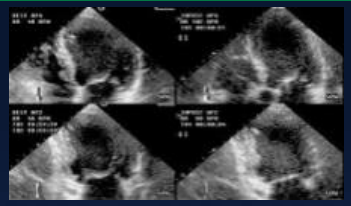
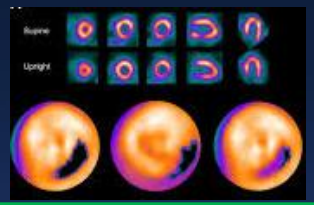
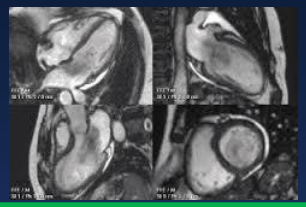
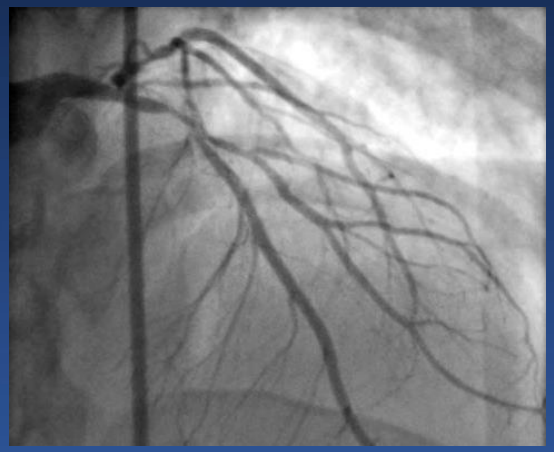
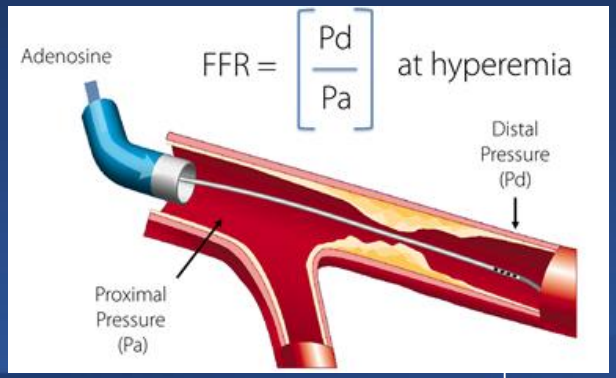
39.2% of pts had normal cors (DS <20% in all vessels)

Pts with a + NI test were moderately more likely to have obstr CAD than those who did not undergo any testing (41.0% vs. 35.0%; adj OR 1.28; 95% CI, 1.19 to 1.37), and more than those with equivocal neg test results (41.3%, vs. 27.1% vs. 28.3%, respectively)

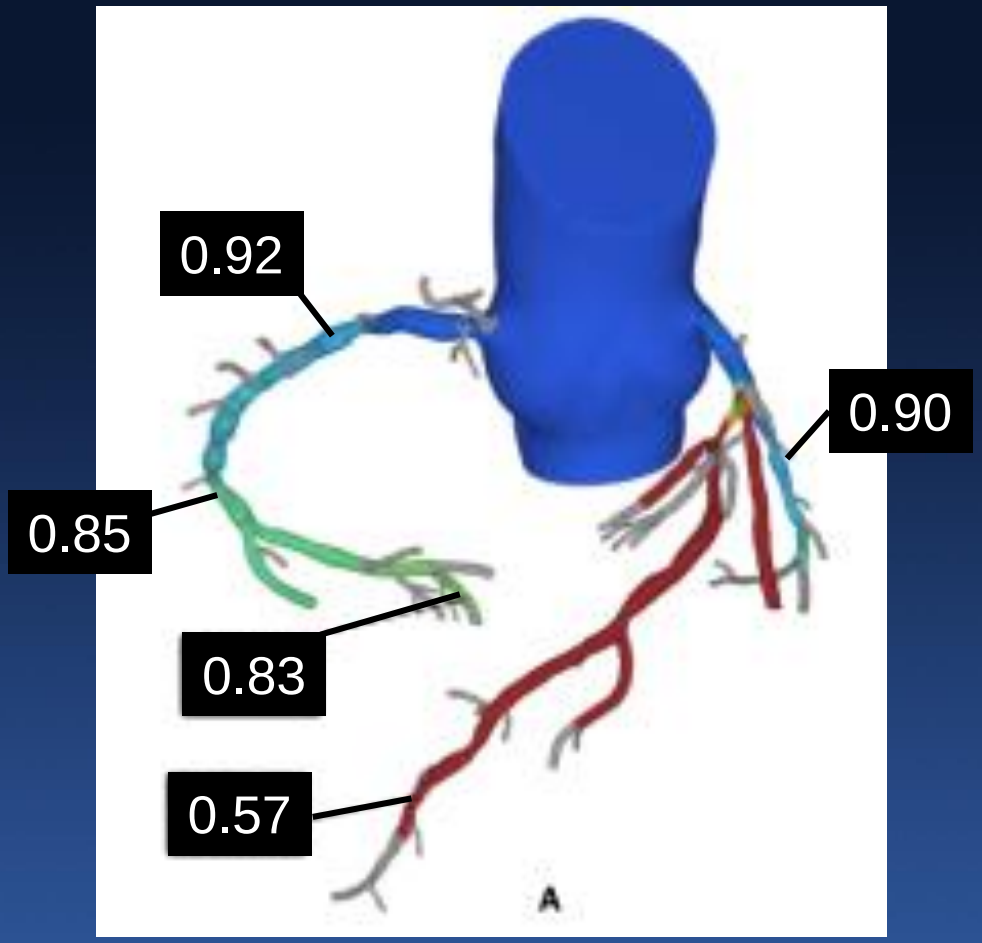
More Background

- Heart Team decision-making is recommended for complex CAD
  - However, detailed angiographic anatomy and lesion-specific physiologic significance is not usually known until after invasive coronary angiography
  - Pts and docs prefer ad hoc PCI when feasible – it is difficult to “take pts off the table” to hold these discussions
- Since FFR/iFR is usually done at the time of PCI, stent decisions are usually made “on the fly”
  - Assessing serial lesions/diffuse disease can be particularly challenging – yes, mistakes can be made

Identifying Anatomically and Functionally Significant CAD

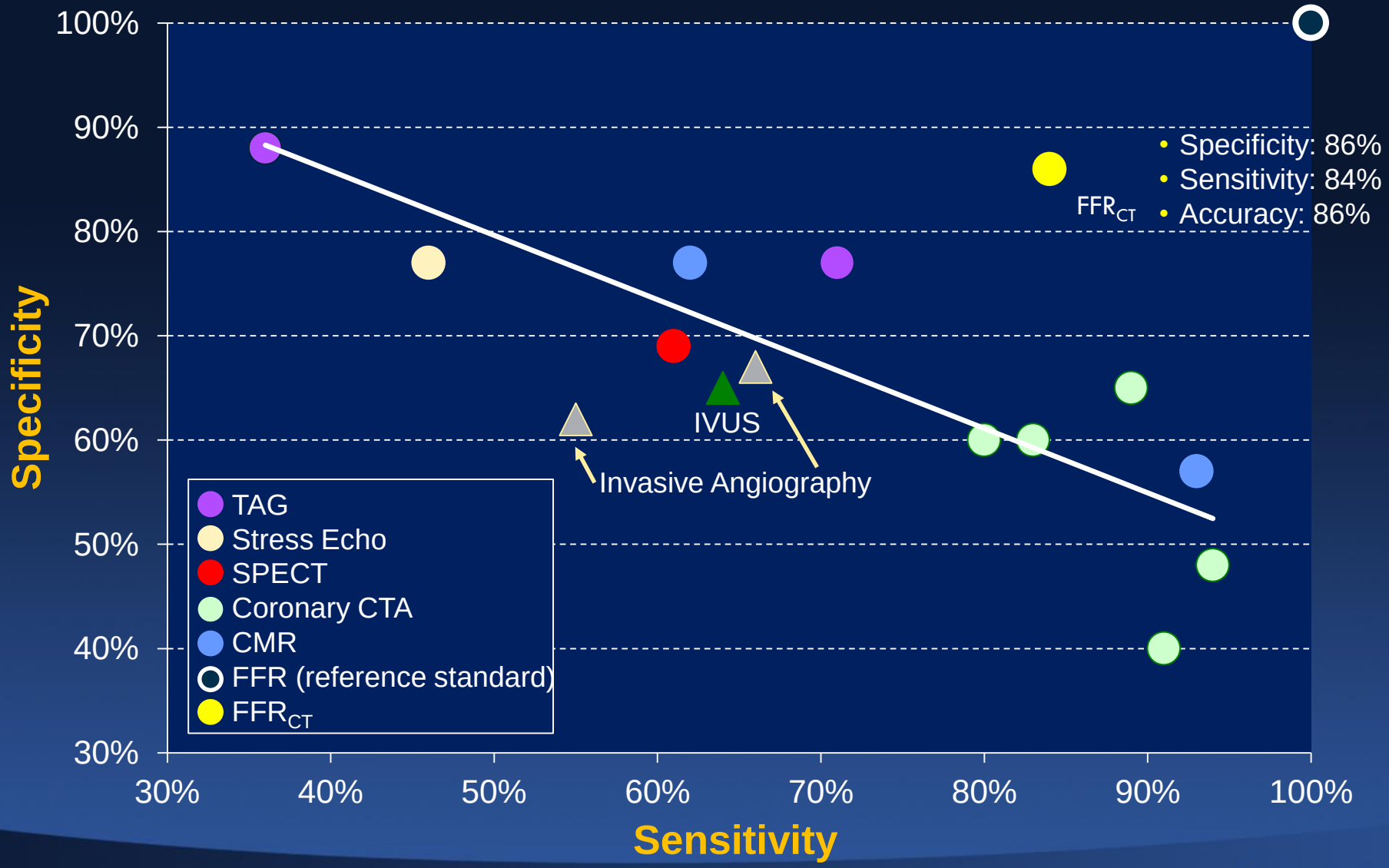
	Anatomy Identify obstructive CAD	**Function** Identify vessel-specific ischemia
Non-Invasive		   
Invasive		**Function** Identify lesion-specific ischemia 

Identifying Anatomically Vessel-Specific and Lesion-Specific Functionally Significant CAD with a Single Non-invasive Test



FFR_{CT} Accuracy (from NXT)

Performance of coronary diagnostic tests vs. FFR



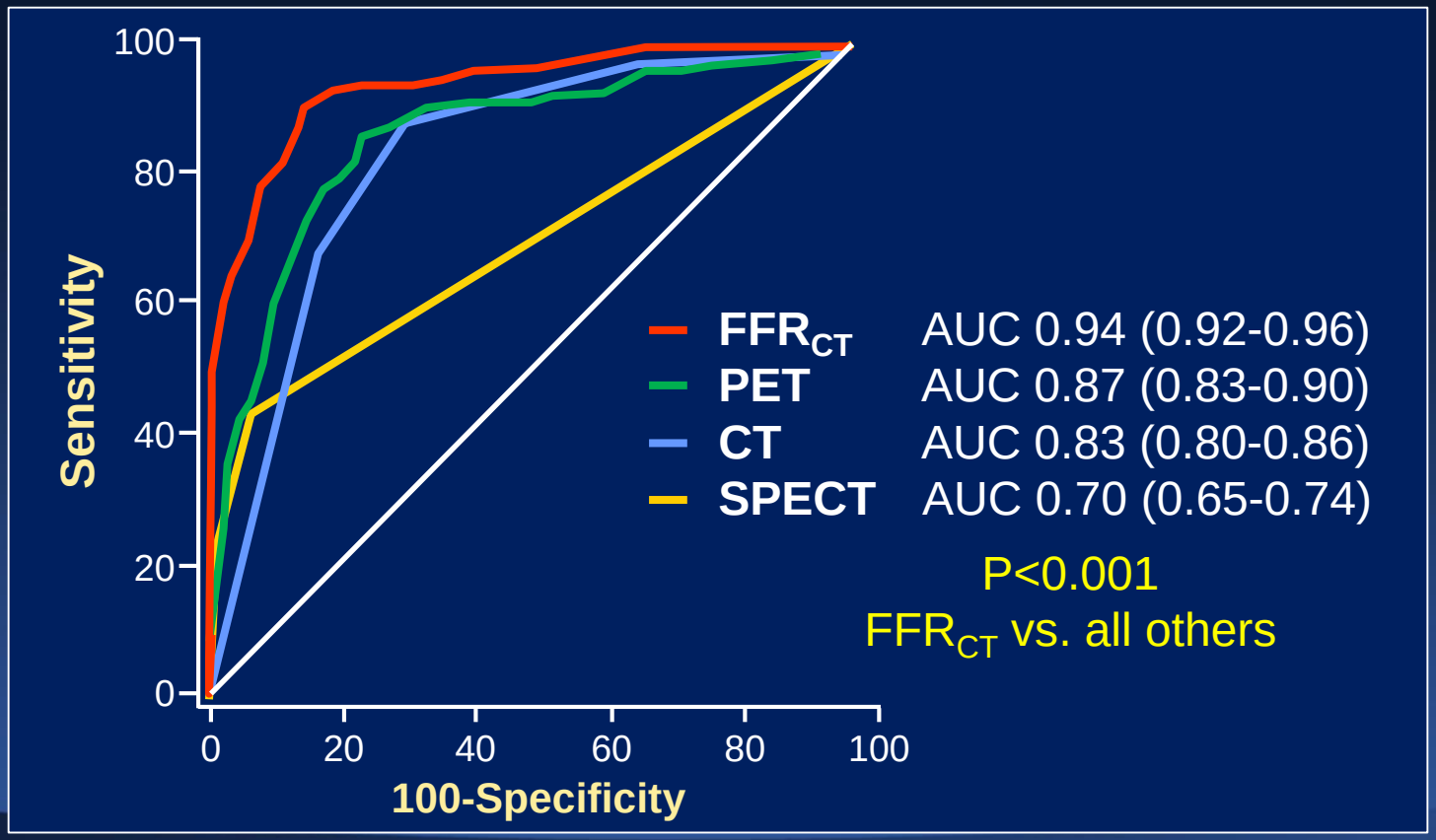
Adapted from Nørgaard B et al. Euro Radiology 2015;25:2282-90

PACIFIC: 208 pts underwent CTA, SPECT, PET, and routine 3-vessel invasive FFR

FFR_{CT} was analyzable in 180 pts (87%)

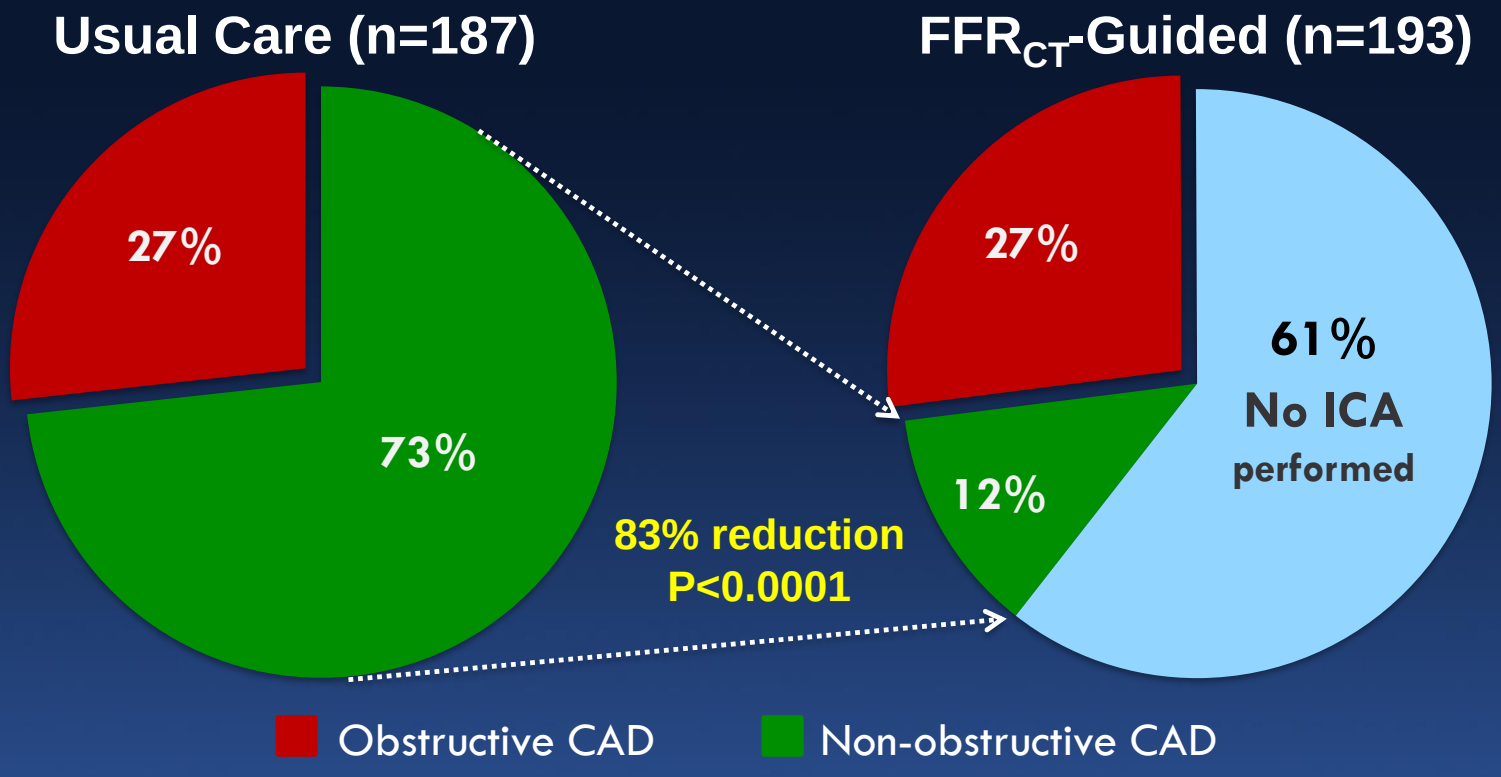
FFR ≤0.80 in 81 pts (45%); FFR_{CT} ≤0.80 in 114 pts (63%)

Sensitivity, specificity and accuracy vs. invasive FFR



PLATFORM: Invasive Arm

584 pts with new onset CP were prospectively assigned to usual testing (n=287) or FFR_{CT}-guided testing (n=297) in different time periods. Local site decided ICA would be performed in 380 pts.



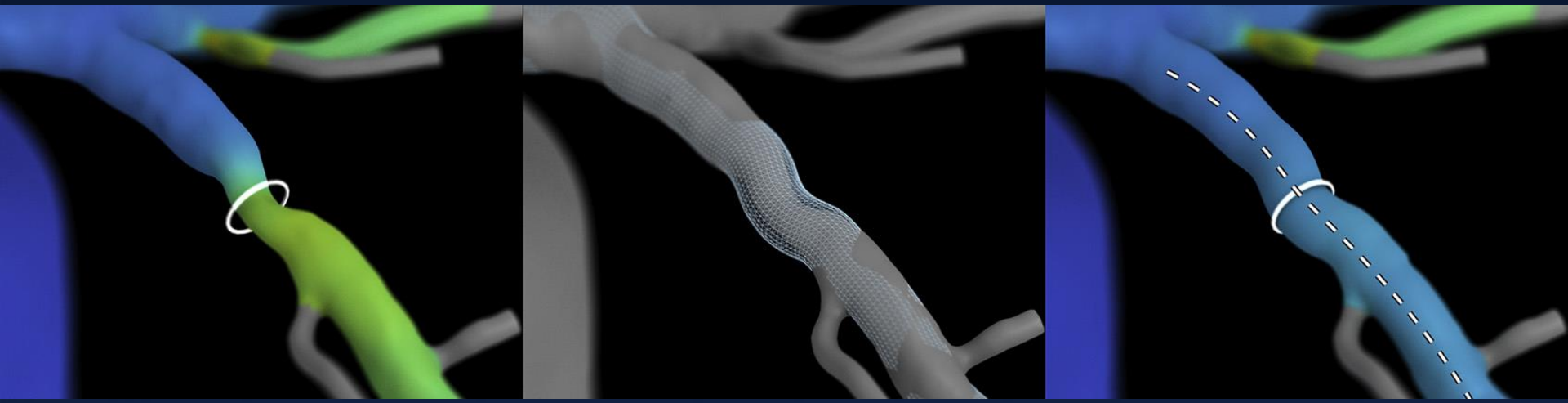
Primary endpoint was catheterization without obstructive CAD:
73.4% with Usual Care vs. 12.4% with FFR_{CT} Guidance, P<0.0001

PLATFORM Invasive: 1-Year Outcomes

	Usual Care (n=187)	FFR_{CT} Guidance (n=193)	P value
MACE	2 (1.1%)	2 (1.0%)*	0.99
- Death	1 (0.5%)	0 (0%)	
- Non-fatal MI	1 (0.5%)	1 (0.5%)	
- Hosp w/urg revasc	0 (0%)	1 (0.5%)	
Cum. Radiation, mSv	10.4 ± 6.7	10.7 ± 9.6	0.21
Total costs, mean (FFR_{CT} = $0)	$12,145	$8,127	<0.0001
Total costs, mean (FFR_{CT} = $1400**)	$12,145	$8,975	<0.0001

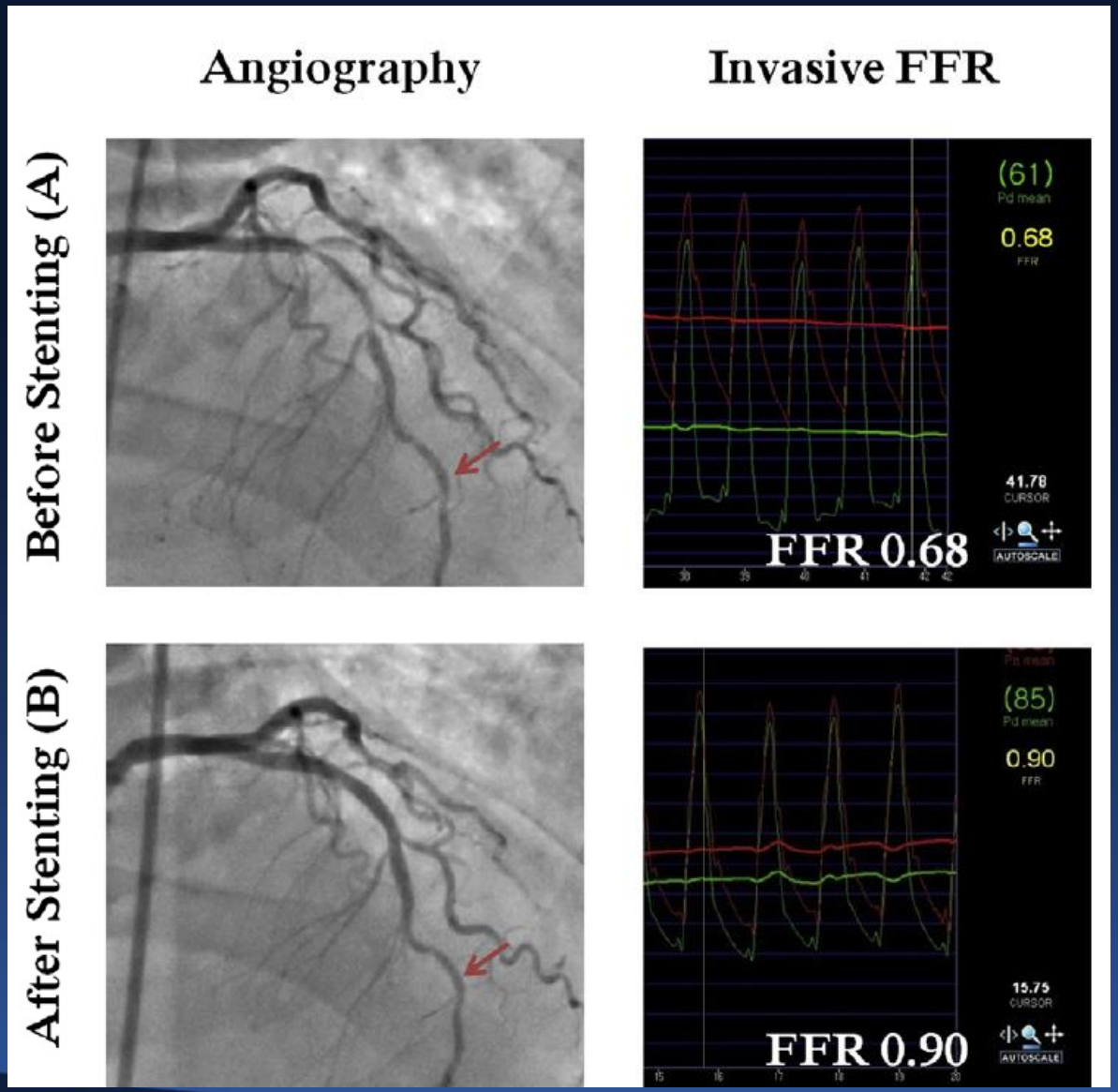
*Among 117 pts whose planned ICA was cancelled on the basis of FFR_{CT}, only 4 underwent ICA during 1-year FU, and MACE = 0%. **Current ASP

FFR_{CT} Planner Application: Virtual Stenting



Geometry of the diseased segment on the original computational model is virtually remodeled to enlarge the radius of the lumen according to the proximal and distal reference area to mimic the effects of a stent. Computational analysis of coronary pressure and flow is repeated to determine post-treatment FFR_{CT} blinded to invasive FFR results.

FFR_{CT} Planner Application: Virtual Stenting



Kim KH et al. JACC Intv 2014;7:72-8

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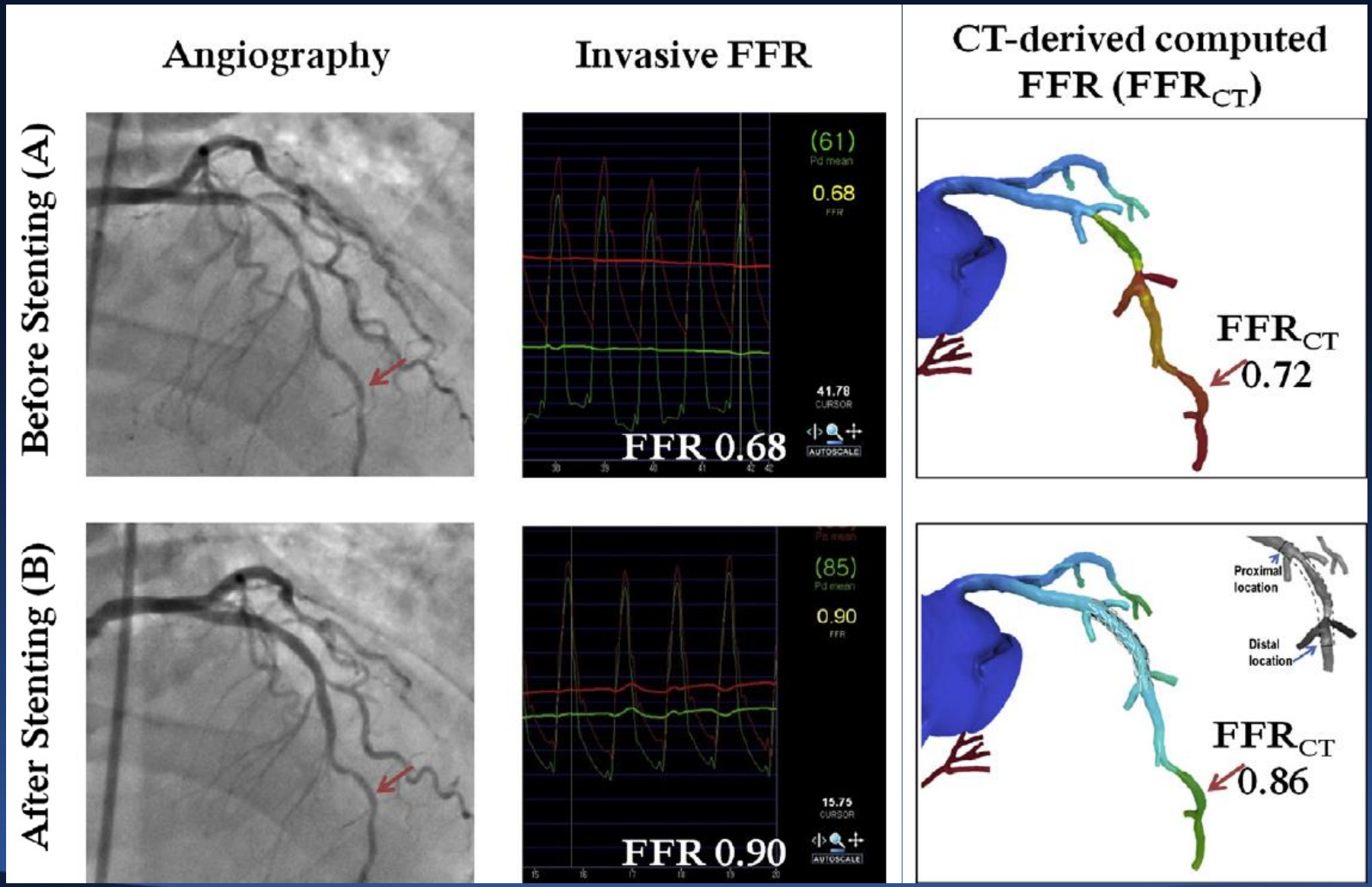
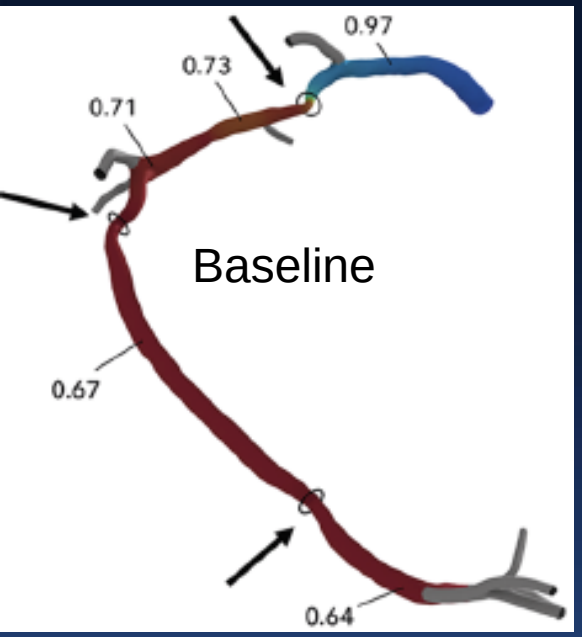


Interactive FFR_{CT} Planner to Guide Stenting

Baseline FFR_{CT} highly positive
4 stenting strategies evaluated



Sonck J et al. EuroIntervention 2018;14:924-925

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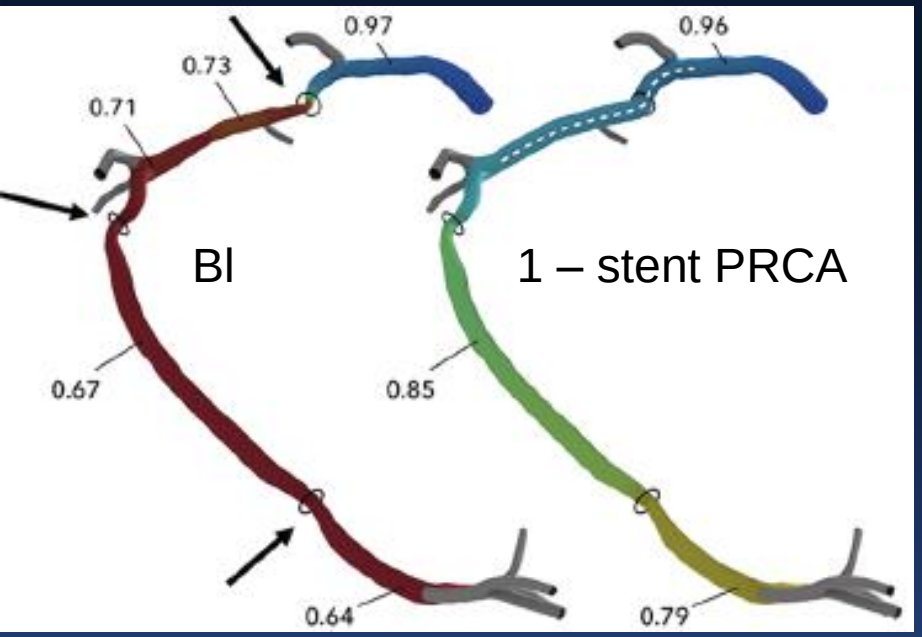

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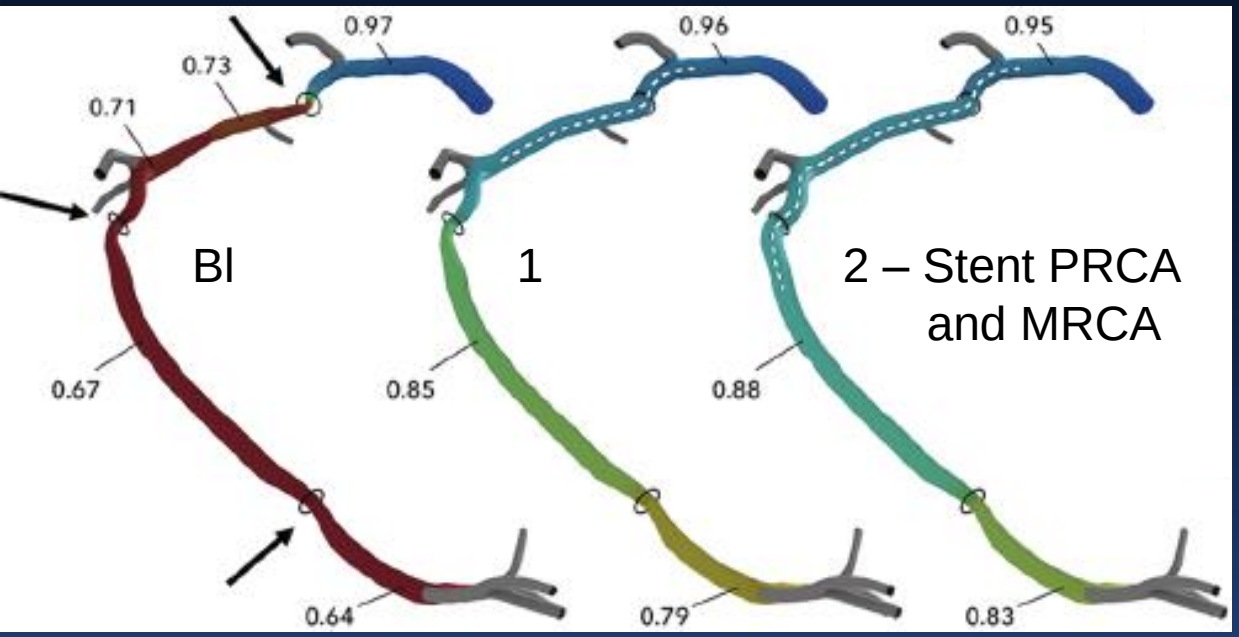

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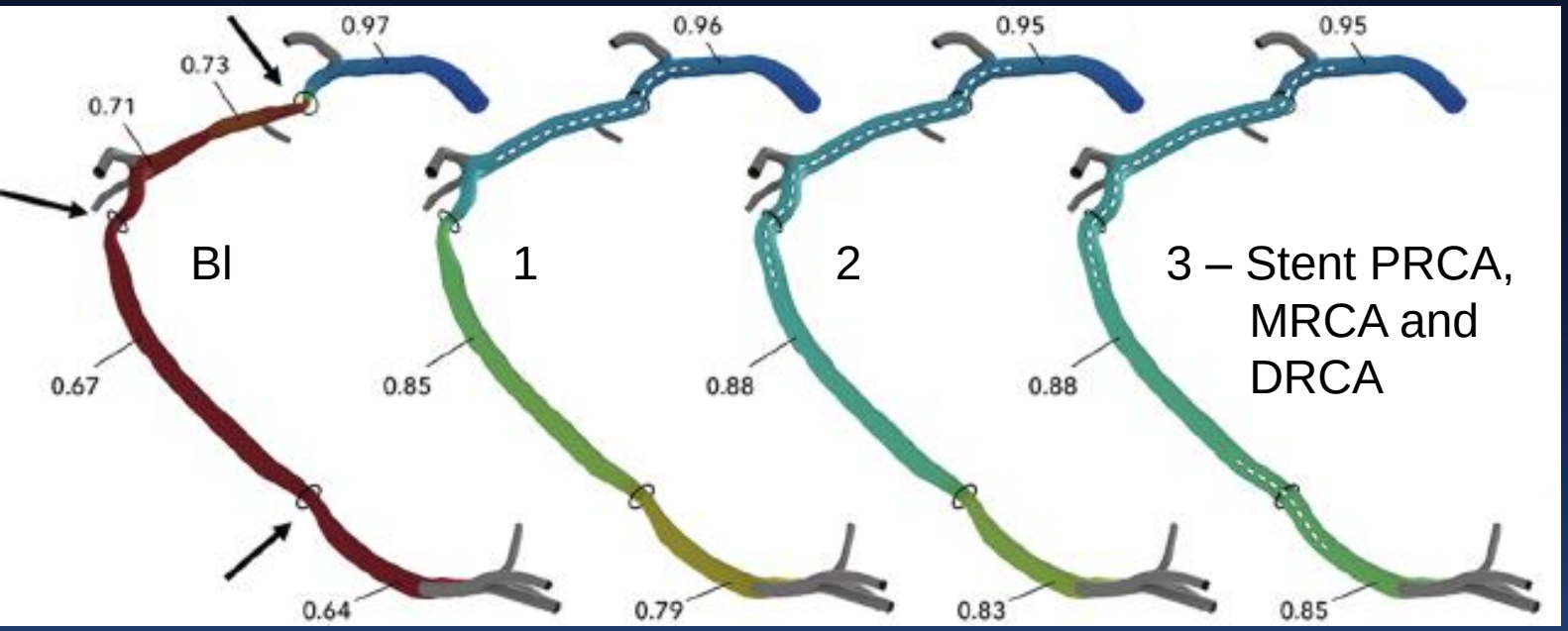

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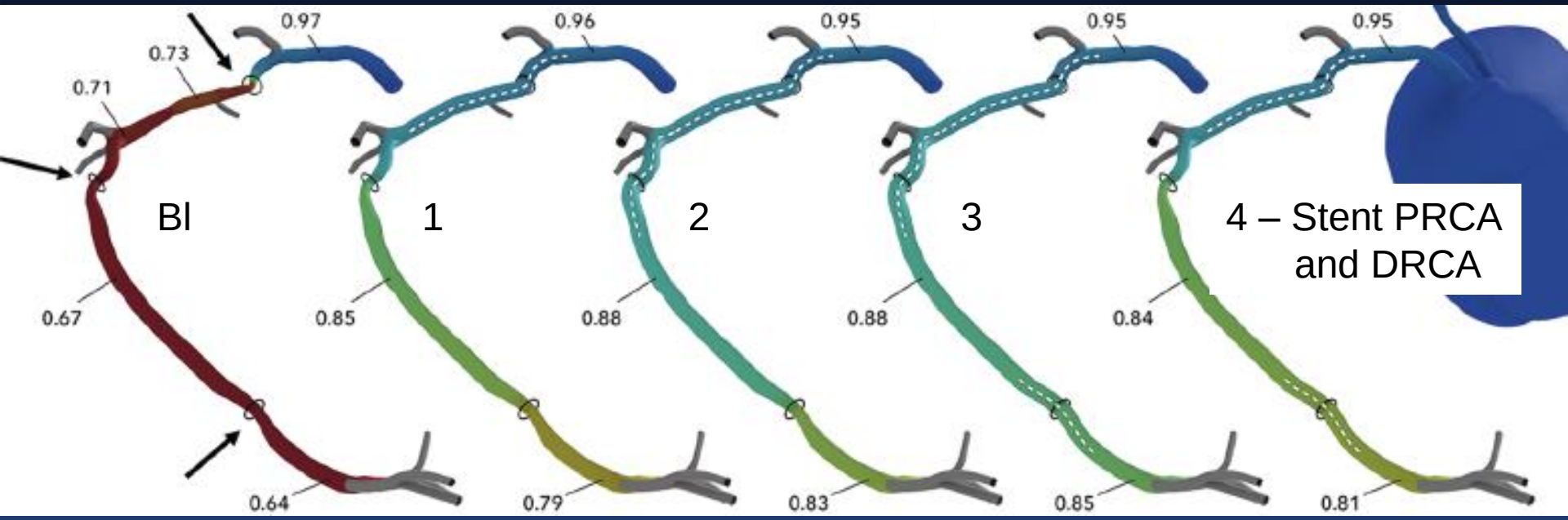

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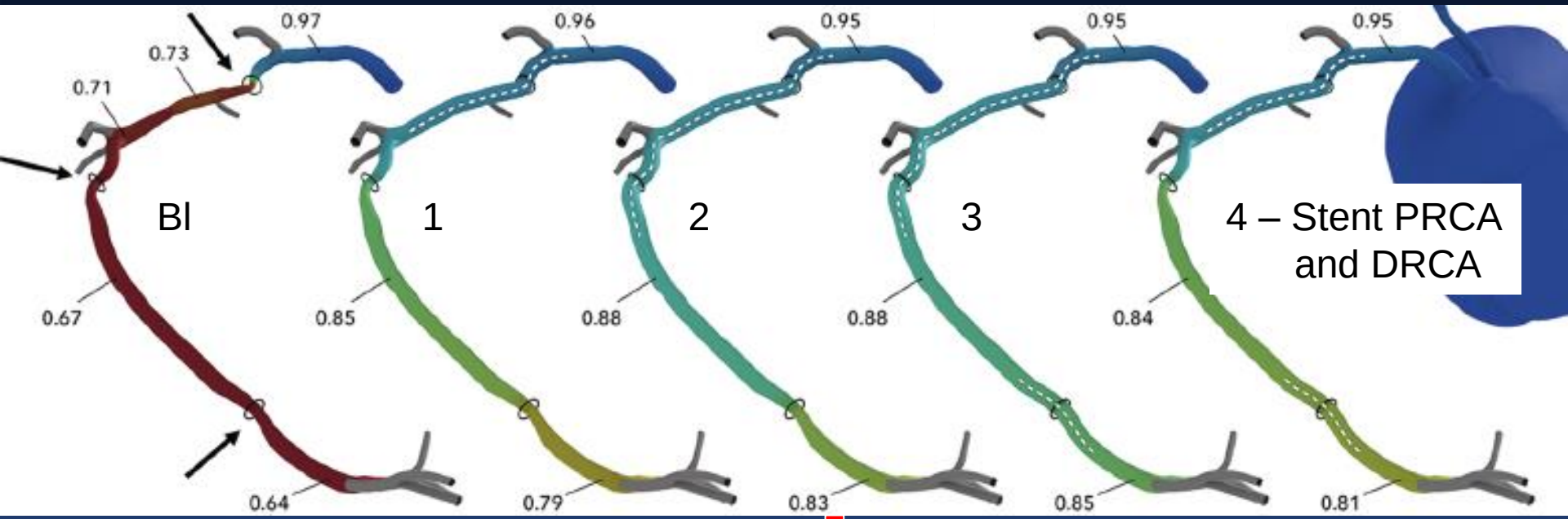
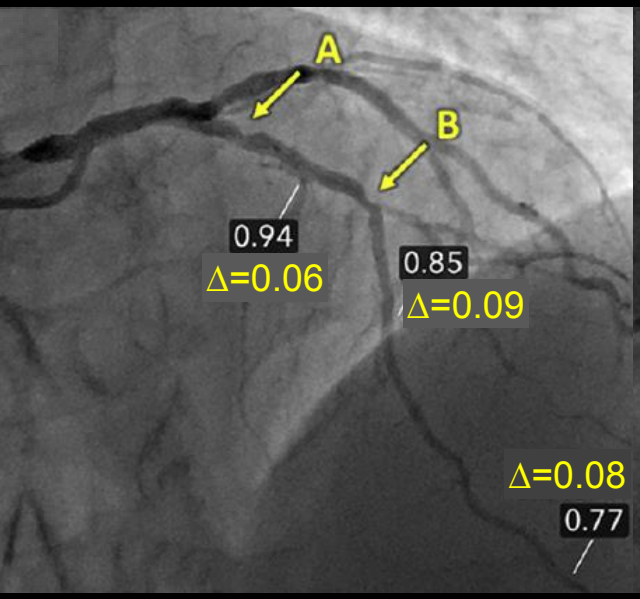
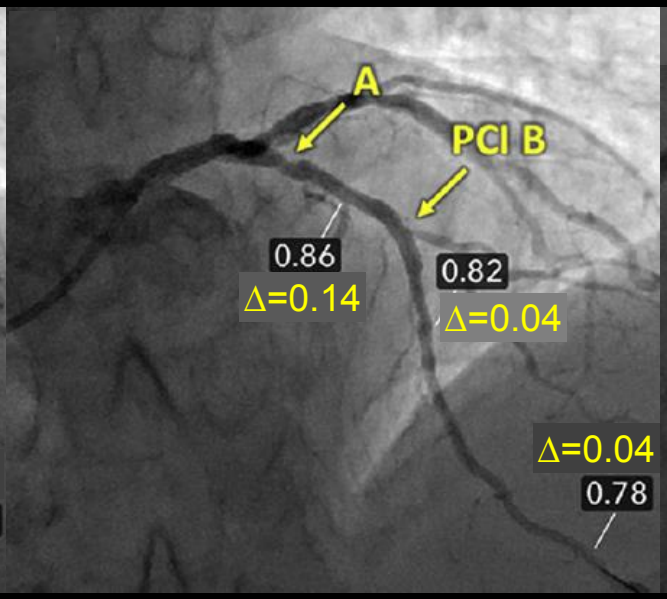


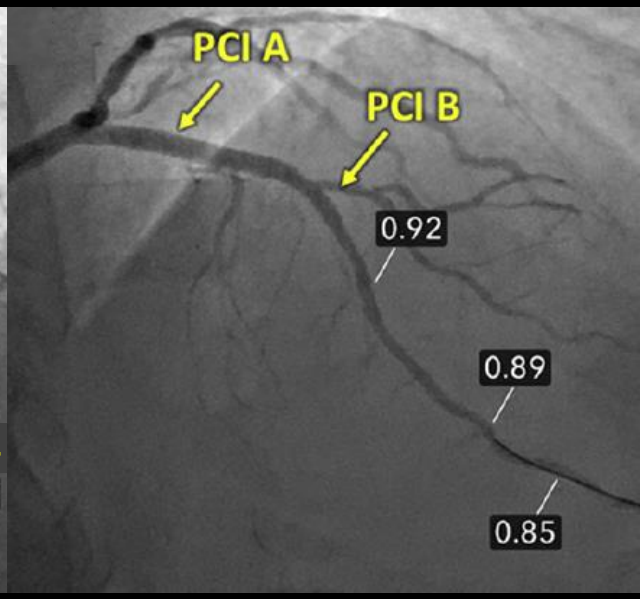
Recommended

Sonck J et al. EuroIntervention 2018;14:924-925

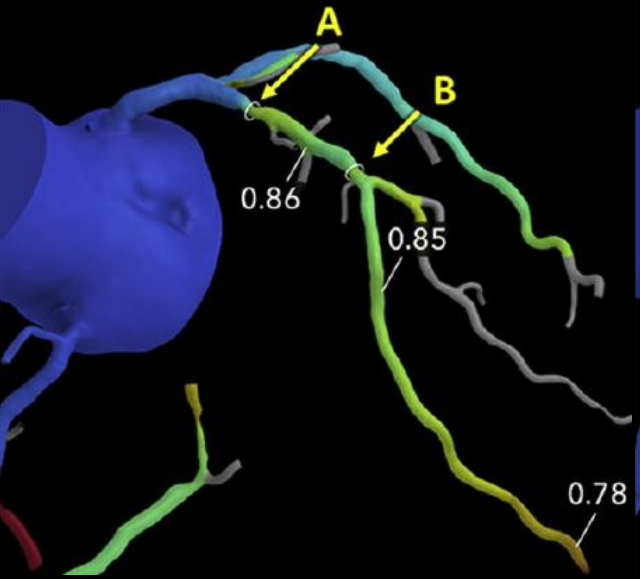
FFR_{CT} Planner Superior to FFR? Case report



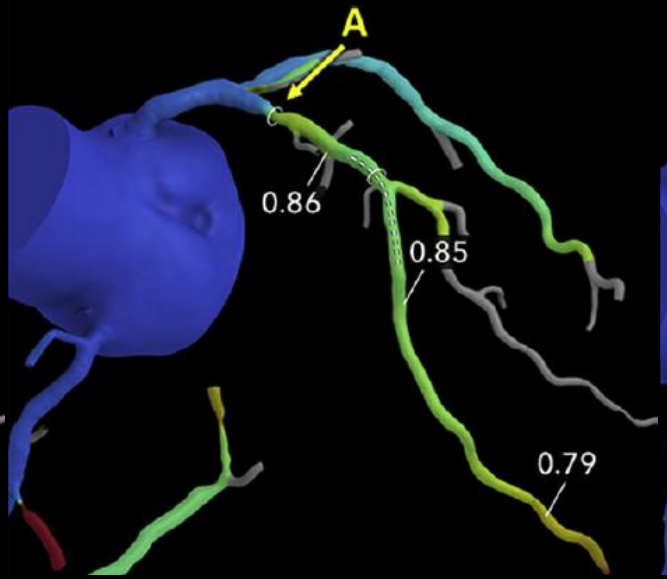




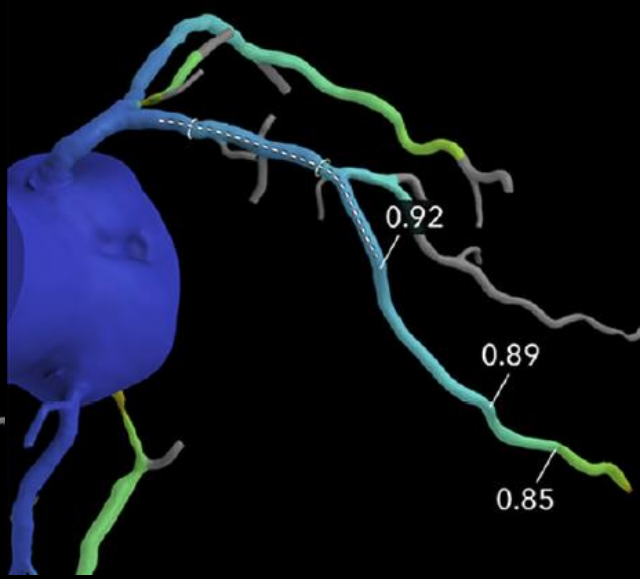
Baseline



After stent lesion B



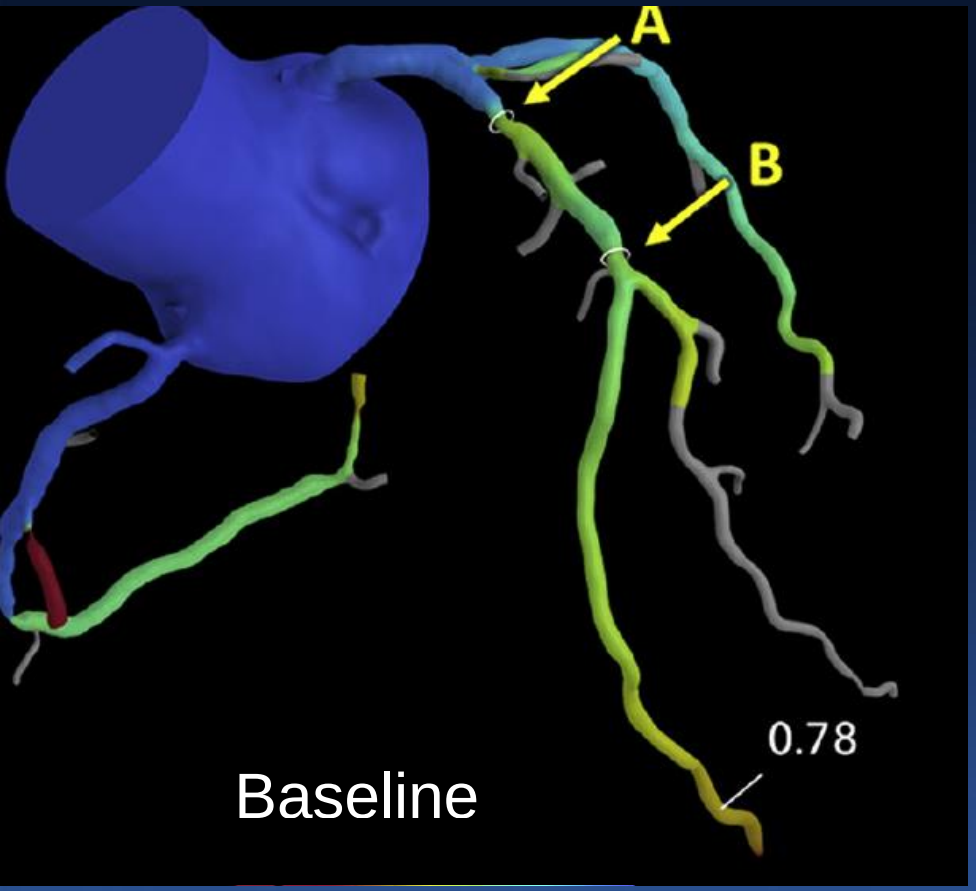
After stent lesion A



FFR_{CT} Planner Superior to FFR?

Better strategy:

Stent lesion A only



Ihdayhid AR et al. JACC Int 2017

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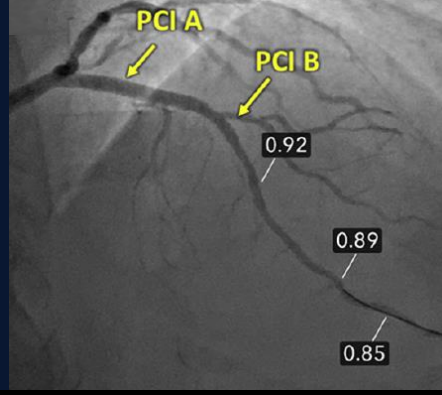
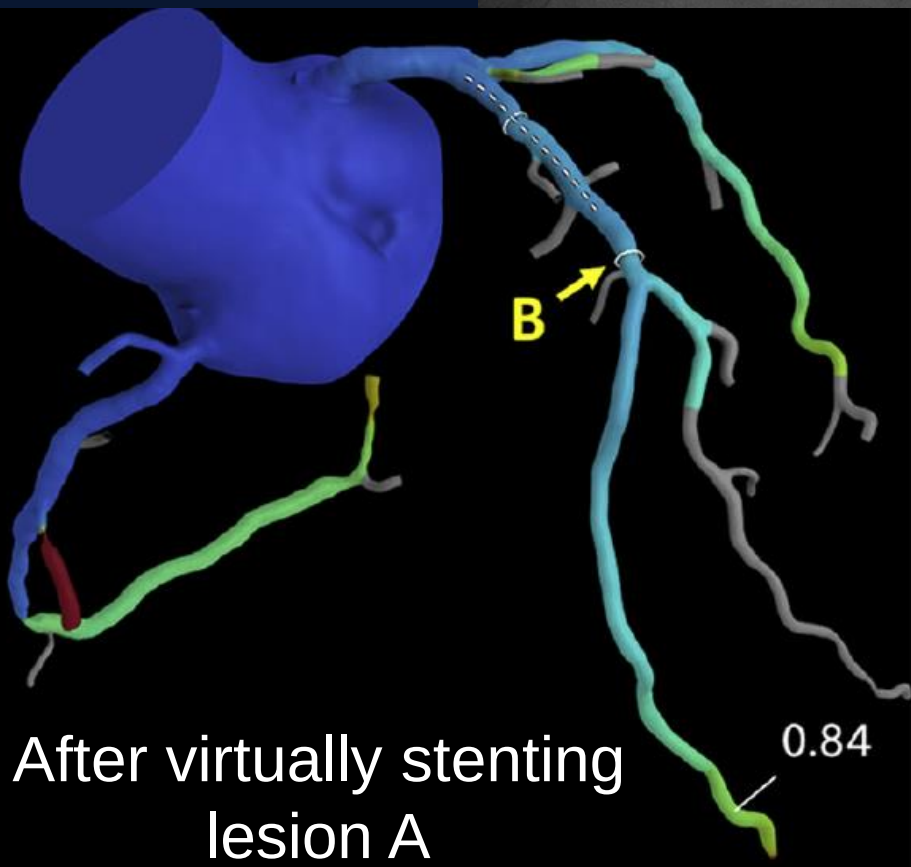


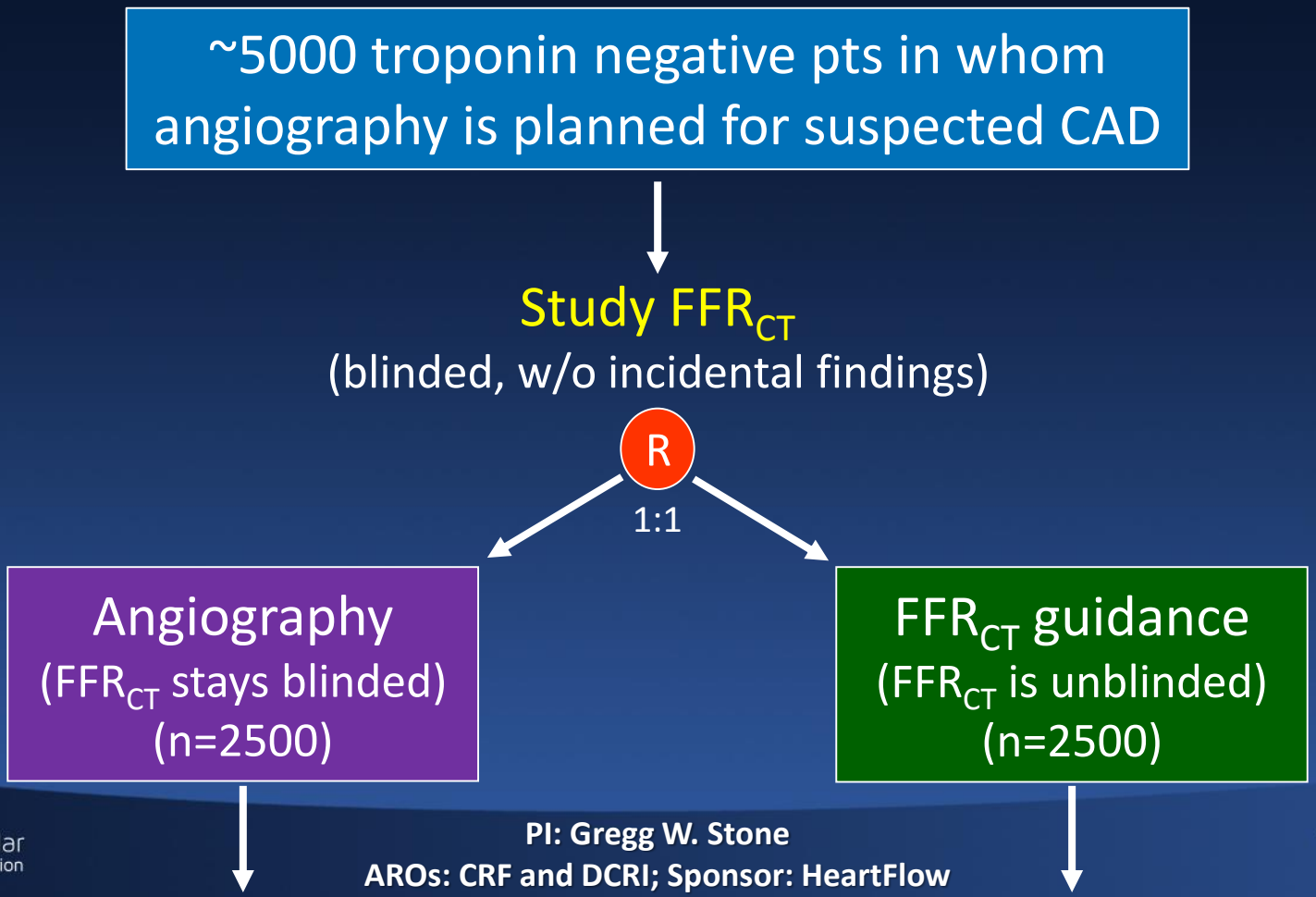
Baseline



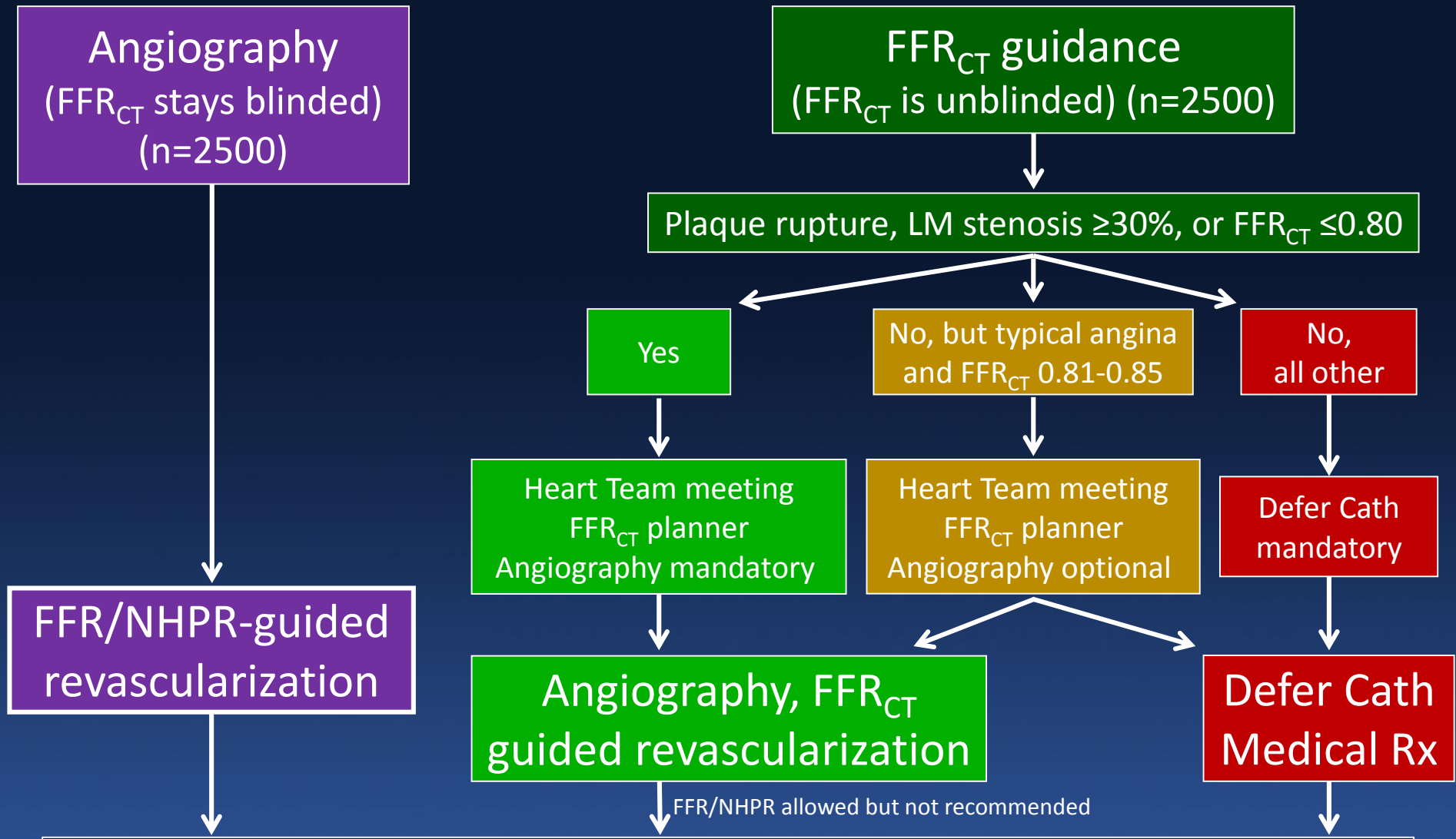
After virtually stenting lesion A

DECISION Trial

A multicenter randomized trial of FFR_{CT}-guided selective angiography and FFR_{CT}-guided revascularization compared with routine angiography and FFR/iFR-guided revascularization in pts with suspected CAD in whom angiography is intended



DECISION Trial



NHPR = Non-Hyperemic Pressure Ratio: iFR, RFR, dPR, dFR

DECISION Trial

Primary endpoints (sequentially tested):

1) 2-year $MACE_1$: all-cause death, MI, or ischemia-driven revascularization (time-to-first event, powered for noninferiority)

2) 2-year $MACE_2$: all-cause death, MI, all revascularization, cardiac catheterization without actionable cardiac pathology (requiring transcatheter or surgical cardiac intervention within 30 days) (Finkelstein-Schoenfeld hierarchical testing, powered for superiority)

Secondary powered endpoints (sequentially tested):

1) 2-year rate of cardiac catheterization without actionable cardiac pathology (time-to-first event, powered for superiority)

2) 2-year total costs (powered for superiority)

Conclusions

- CTA w/FFR_{CT} provides data on coronary anatomy and physiology which more strongly correlates with invasive FFR than any other non-invasive diagnostic test
- Non-randomized studies suggest deferral of ICA in pts with negative FFR_{CT} may safely obviate unnecessary ICA
- The FFR_{CT} Planner has been developed to allow the local heart team to reach revascularization decisions prior to ICA, and provide interventional guidance for PCI procedures w/o the need for invasive physiology
- The DECISION Trial is a large-scale randomized study which will determine whether FFR_{CT}-guidance with use of the FFR_{CT} Planner in pts in whom ICA is otherwise planned may safely defer unnecessary cardiac catheterization procedures while improving overall clinical outcomes and reducing costs