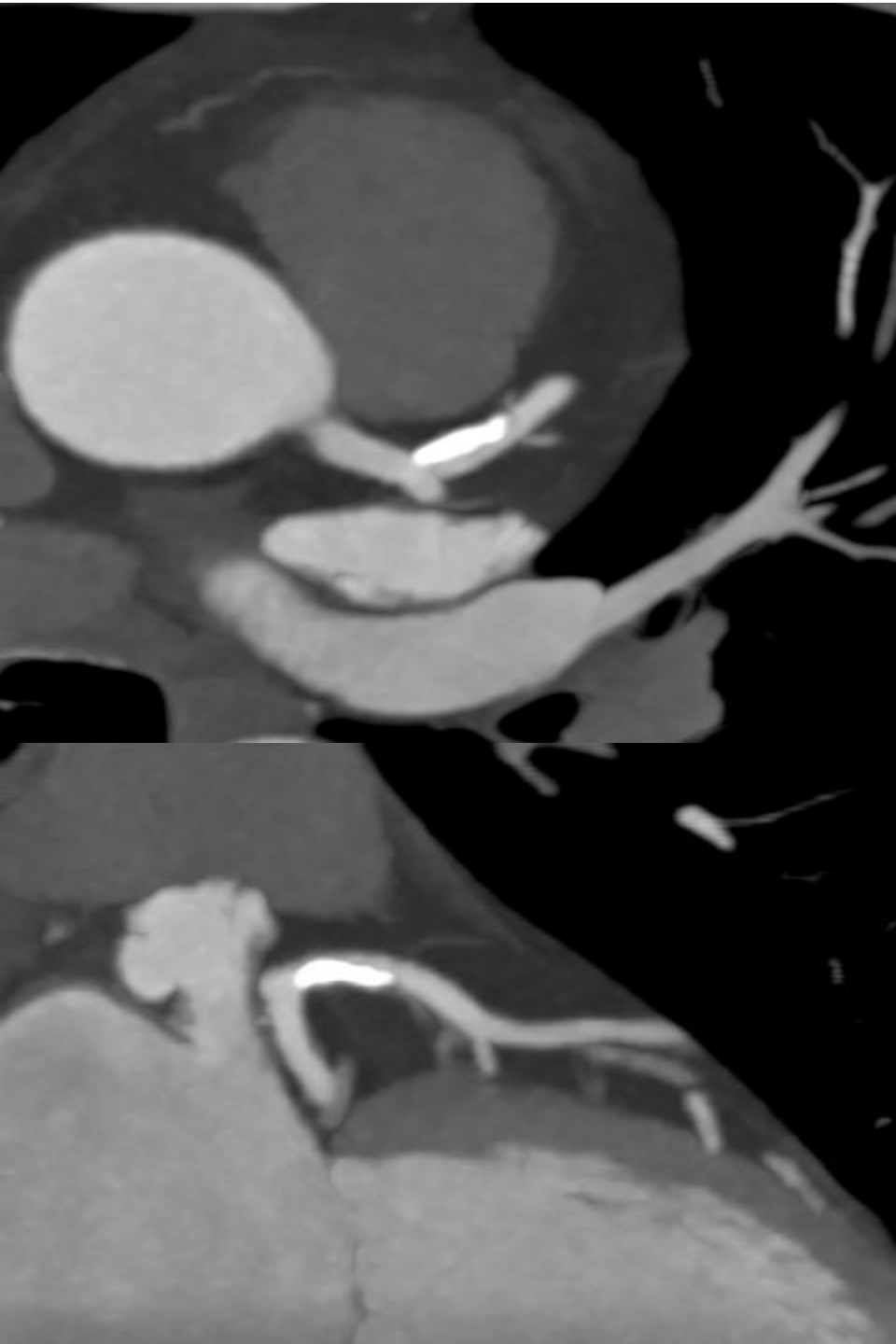


FFR_{CT}: Clinical studies



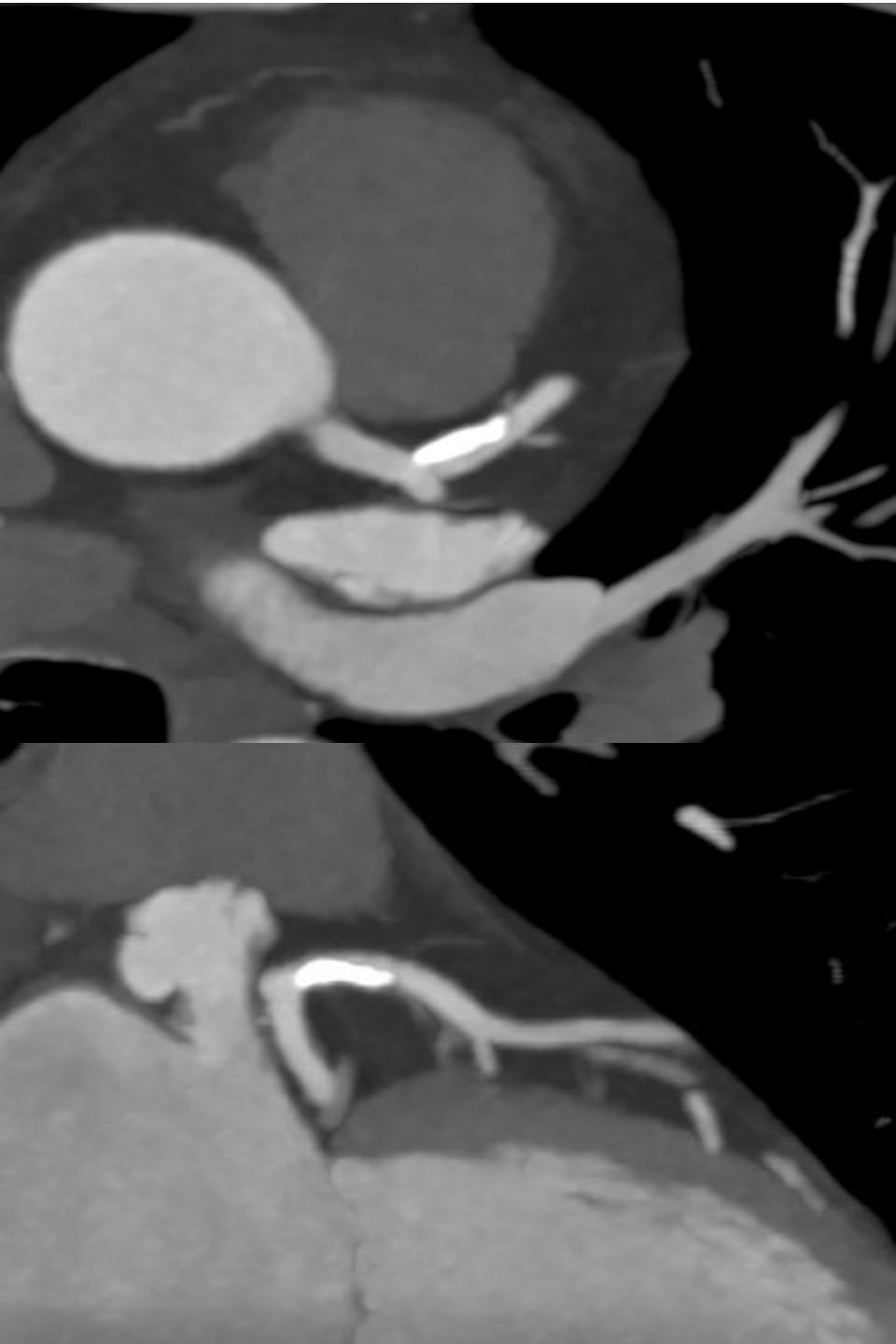
Bjarne Nørgaard
Department Cardiology B
Aarhus University Hospital Skejby,
Denmark

Disclosures: *Research grants:*
Edwards and Siemens



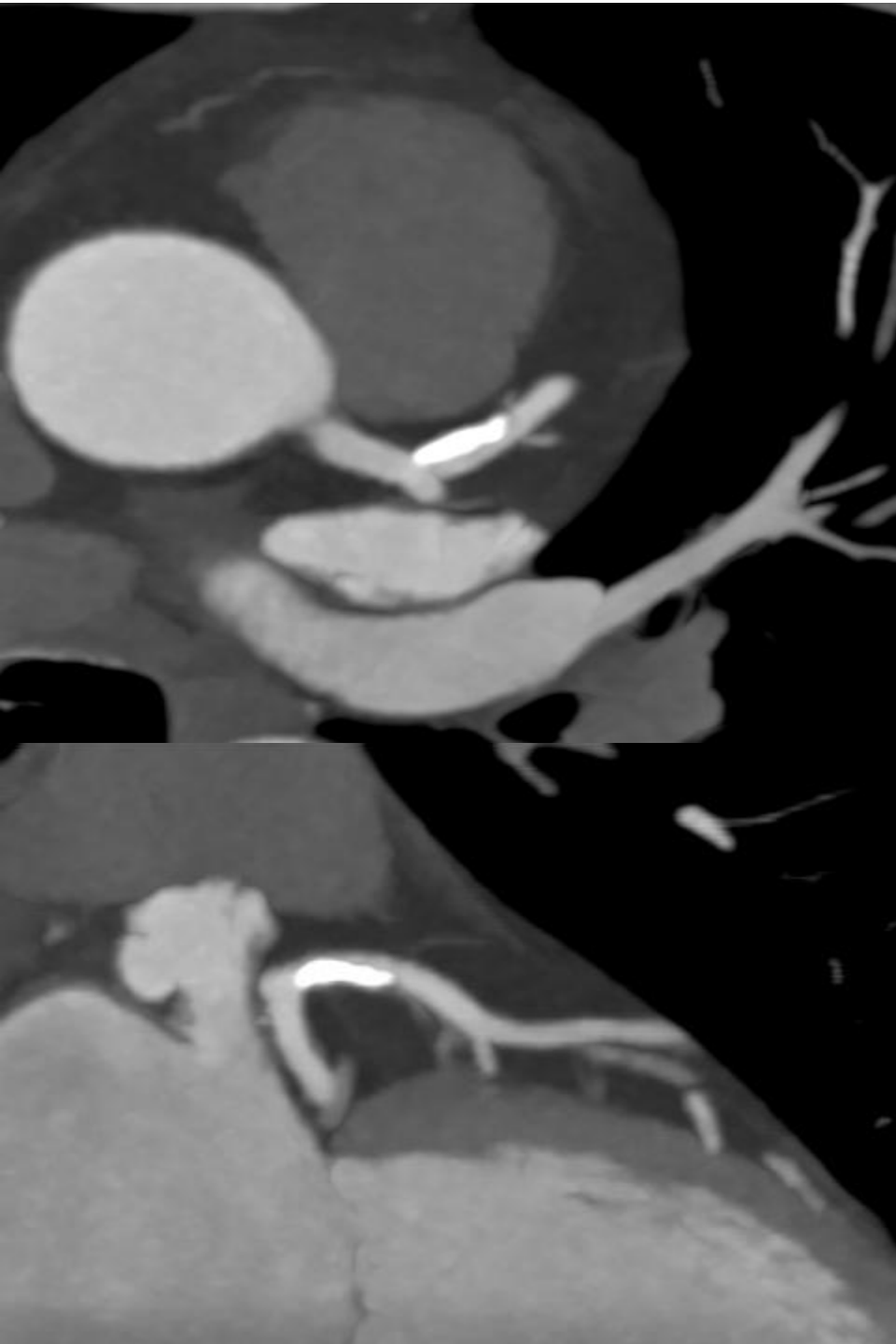
Coronary CTA:

- ***High diagnostic sensitivity for detecting CAD, and the best non-invasive test for ruling-out CAD***
BUT!!



Coronary CTA:

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- ***Poor correlation to stenosis severity as assessed with ICA***



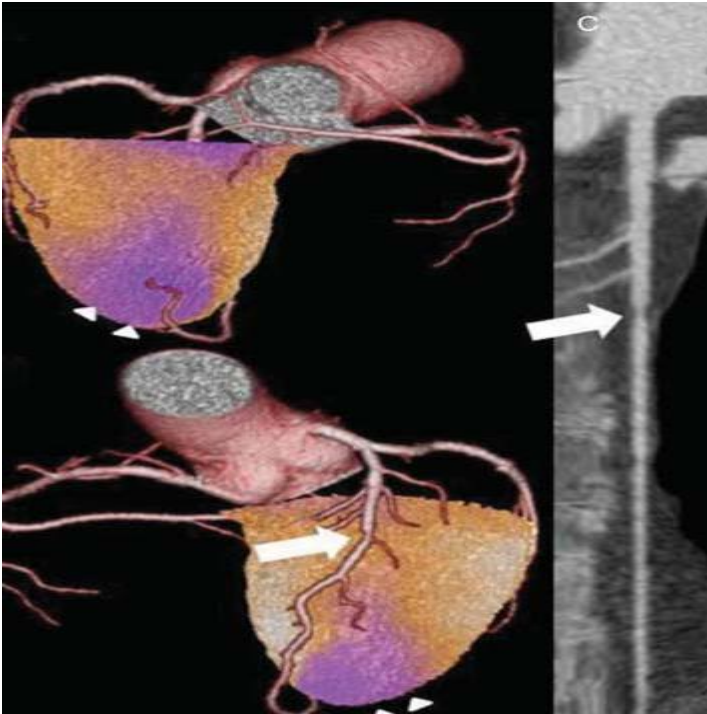
Coronary CTA:

- High diagnostic sensitivity for detecting CAD, and the best non-invasive test for ruling-out CAD BUT!!
- Poor correlation to stenosis severity as assessed with ICA
- ***The hemodynamic significance of a stenosis cannot be assessed***



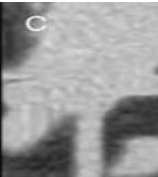
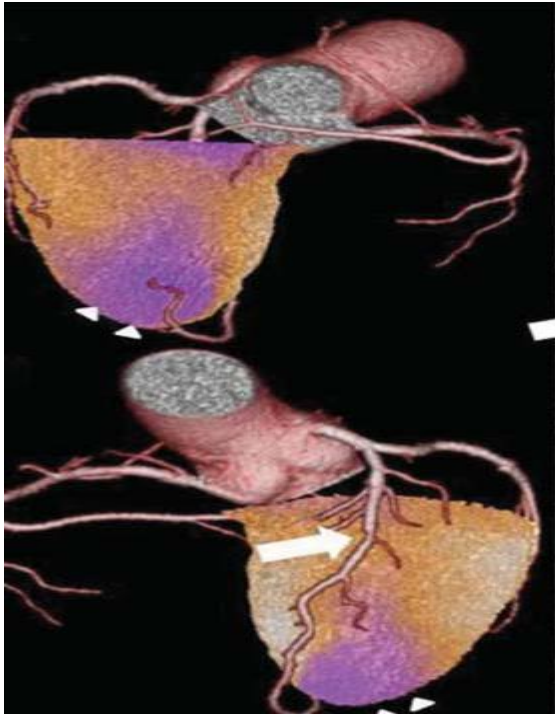
“FFR_{CT}: Clinical studies”

PET-CT

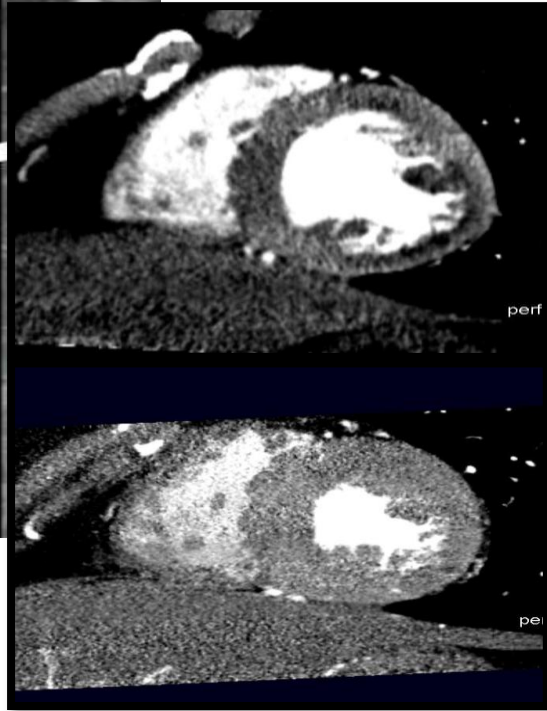


“FFR_{CT}: Clinical studies”

PET-CT

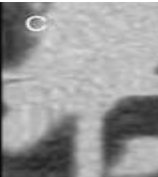


CT-perfusion

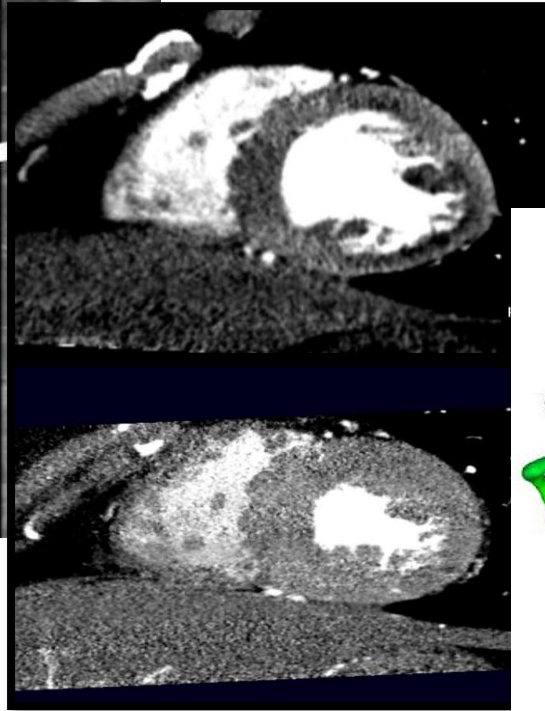


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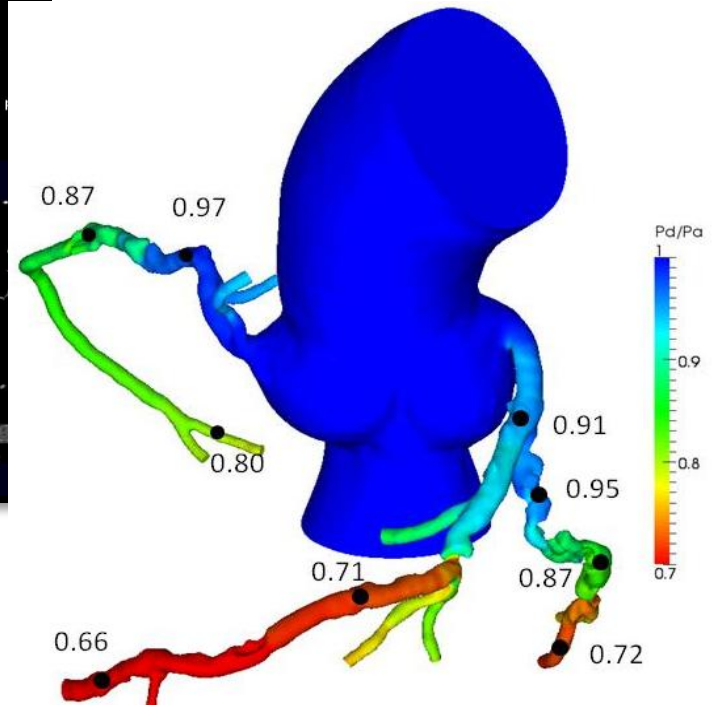
PET-CT



CT-perfusion



FFR_{CT}



“FFR_{CT}: Clinical studies”

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doi:10.1016/j.jacc.2011.06.066

Cardiac Imaging

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

Bon-Kwon Koo, MD, PhD,* Andrejs Erglis, MD, PhD,† Joon-Hyung Doh, MD, PhD,‡
David V. Daniels, MD,§ Sanda Jegere, MD,|| Hyo-Soo Kim, MD, PhD,* Allison Dunning, MD,¶
Tony DeFrance, MD,# Alexandra Lansky, MD,** Jonathan Leipsic, BSc, MD,†† James K. Min, MD‡‡
*Seoul and Goyang, South Korea; Riga, Latvia; Palo Alto, San Francisco, and Los Angeles, California;
New York, New York; New Haven, Connecticut; and Vancouver, British Columbia, Canada*

- **DISCOVER-FLOW**
 - Completed 2011
 - N=104 patients

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

- **NXT**
 - Completed 2013
 - N~254 patients

ONLINE FIRST

Diagnostic Accuracy of Fractional Flow Reserve From Anatomic CT Angiography

JAMA. 2012;308(12):doi:10.1001/2012.jama.11274

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<http://dx.doi.org/10.1016/j.jacc.2013.11.014>

CLINICAL RESEARCH

Clinical Trials

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)

Bjame L. Norgaard, MD, PhD,* Jonathon Leipsic, MD, PhD,† Sara Gaur, MD,*
Sujith Seneviratne, MBBS,‡ Brian S. Ko, MBBS, PhD,‡ Hiroshi Ito, MD, PhD,§
Jesper M. Jensen, MD, PhD,* Laura Mauri, MD, PhD,|| Bernard De Bruyne, MD, PhD,¶
Hiram Bezerra, MD, PhD,# Kazuhiro Osawa, MD,§ Mohamed Marwan, MD, PhD,**
Christoph Naber, MD, PhD,†† Andrejs Erglis, MD, PhD,‡‡ Seung-Jung Park, MD, PhD,§§
Ewald H. Christiansen, MD, PhD,* Anne Kaltoft, MD, PhD,* Jens F. Lassen, MD, PhD,*
Hans Erik Botker, MD, DMSci,* Stephan Achenbach, MD, PhD,**
on behalf of the NXT Trial Study Group

*Aarhus, Denmark; Vancouver, British Columbia, Canada; Victoria, Australia; Okayama, Japan;
Boston, Massachusetts; Aalst, Belgium; Cleveland, Ohio; Erlangen and Essen, Germany; Riga, Latvia;
and Seoul, South Korea*



- **4 centers**
- **Patients with suspected or known CAD who underwent cCTA, ICA and FFR**

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- **Significant CAD by cCTA: stenosis >50% (>2 mm vessel)**
- **Ischemia def: FFR_{CT} / FFR ≤0.80**
- **FFR_{CT} and cCTA core lab reads, FFR local reads**

- 4 centers
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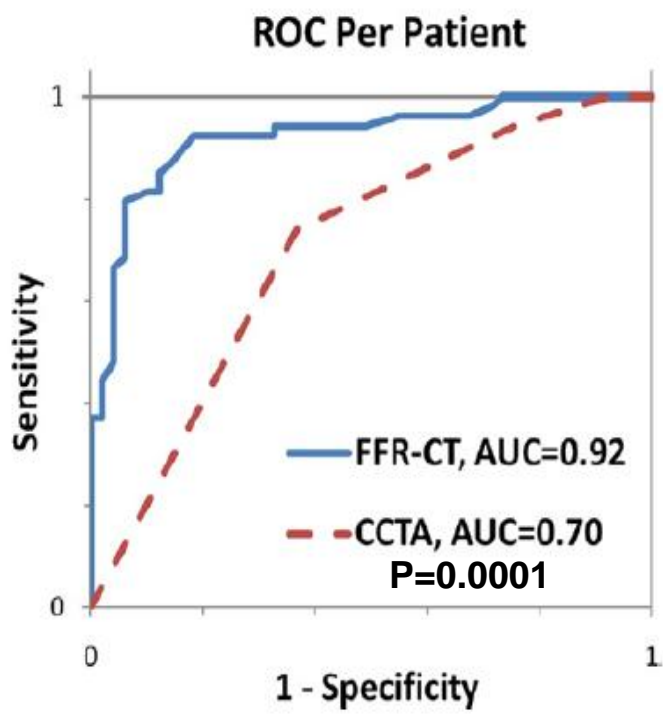
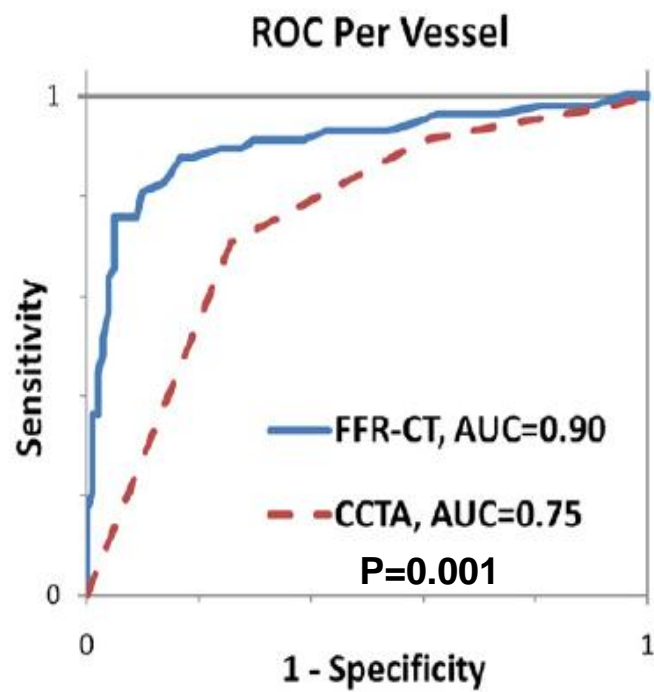
- Significant CAD by cCTA: stenosis >50% (>2 mm vessel)
- Ischemia def: FFR_{CT} / FFR ≤0.80
- FFR_{CT} and cCTA core lab reads, FFR local reads

- **104 patients, 159 vessels**
- **Mean age, 63 y, 20% with known disease (AMI / PCI), 56% with FFR ≤0.80**

“FFR_{CT}: Clinical studies”, *DISCOVER-FLOW trial*

Measure	Per-Vessel		Per-Patient	
	FFR _{CT} ≤0.80 (95% CI)	CCTA Stenosis ≥50% (95% CI)	FFR _{CT} ≤0.80 (95% CI)	CCTA Stenosis ≥50% (95% CI)
Accuracy	84.3 (77.7-90.0)	58.5 (50.4-66.2)	87.4 (79.4-93.1)	61.2 (51.1-70.6)
Sensitivity	87.9 (76.7-95.0)	91.4 (81.0-97.1)	92.6 (82.1-97.9)	94.4 (84.6-98.8)
Specificity	82.2 (73.3-89.1)	39.6 (30.0-49.8)	81.6 (68.0-91.2)	24.5 (13.3-38.9)
PPV	73.9 (61.9-83.7)	46.5 (37.1-56.1)	84.7 (73.0-92.8)	58.0 (47.0-68.4)
NPV	92.2 (84.6-96.8)	88.9 (75.9-96.3)	90.9 (78.3-97.5)	80.0 (51.9-95.7)

“FFR_{CT}: Clinical studies”, *DISCOVER-FLOW trial*



- **17 centers**
- **Clinically non-emergent indicated ICA after cCTA <60 days**
- **ICA stenosis 30%-90% (>2 mm vessel)**

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- **FFR_{CT} and cCTA core lab reads, FFR local reads**

- 17 centers
- Clinically non-emergent indicated ICA after cCTA <60 days
- ICA stenosis 30%-90% (>2 mm vessel)

- Significant CAD by cCTA: stenosis >50% (>2 mm vessel)
- Ischemia def: cCTA stenosis >50%, FFR_{CT} / FFR ≤0.80

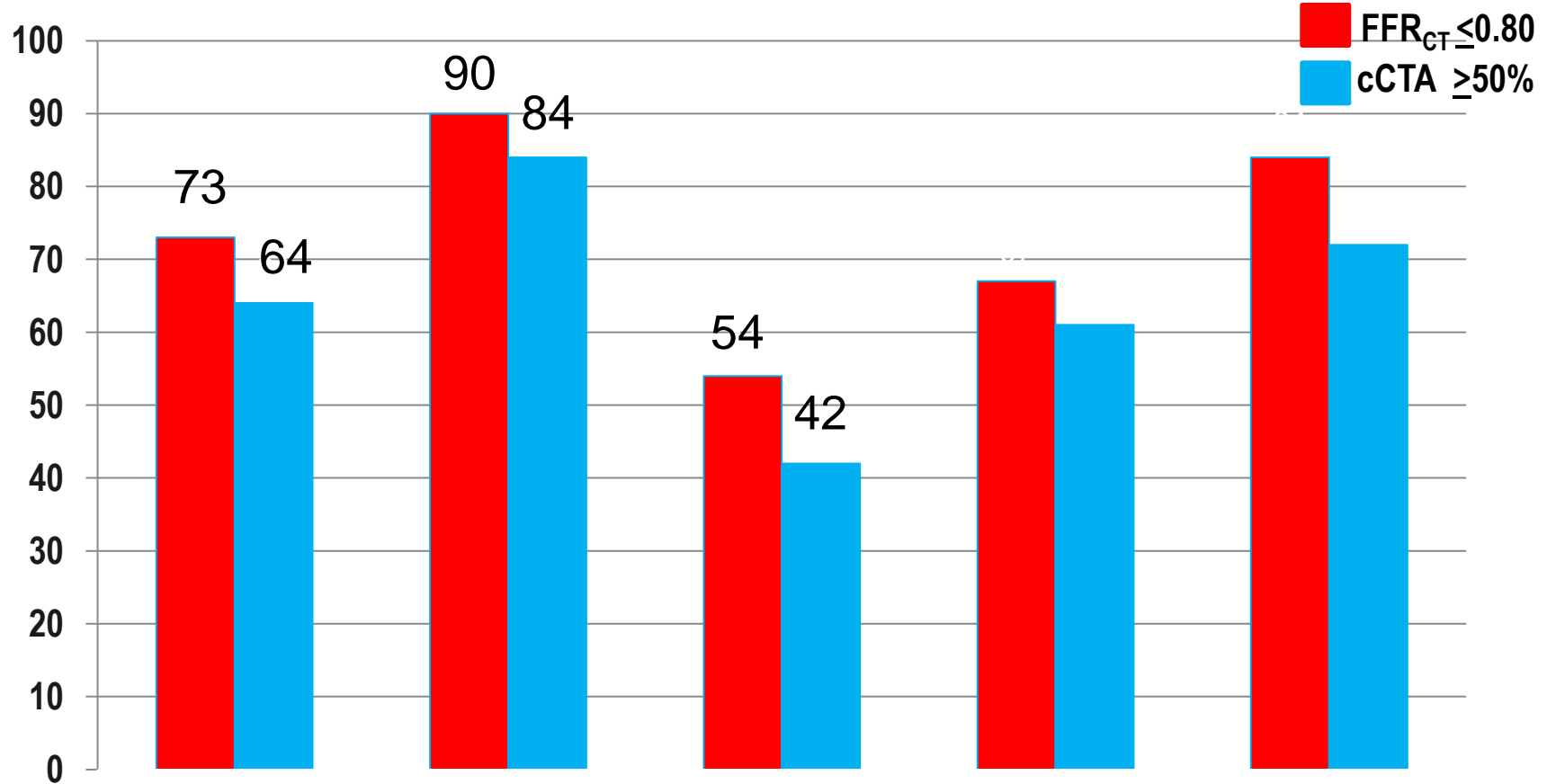
- FFR_{CT} and cCTA core lab reads, FFR local reads

- **Primary study end-point: Per-patient diagnostic accuracy of FFR_{CT} for the diagnosis of ischemia with a lower limit of 95% CI >70%**

- **252 patients, 406 vessels**

Patient Characteristics	
Age (years) [mean \pm SD]	63 \pm 9
Male gender	71%
Prior MI	6%
Prior PCI	6%
Hypertension	71%
Diabetes mellitus	22%
Agatston score [mean \pm SD]	382 \pm 401
FFR \leq 0.80	37%

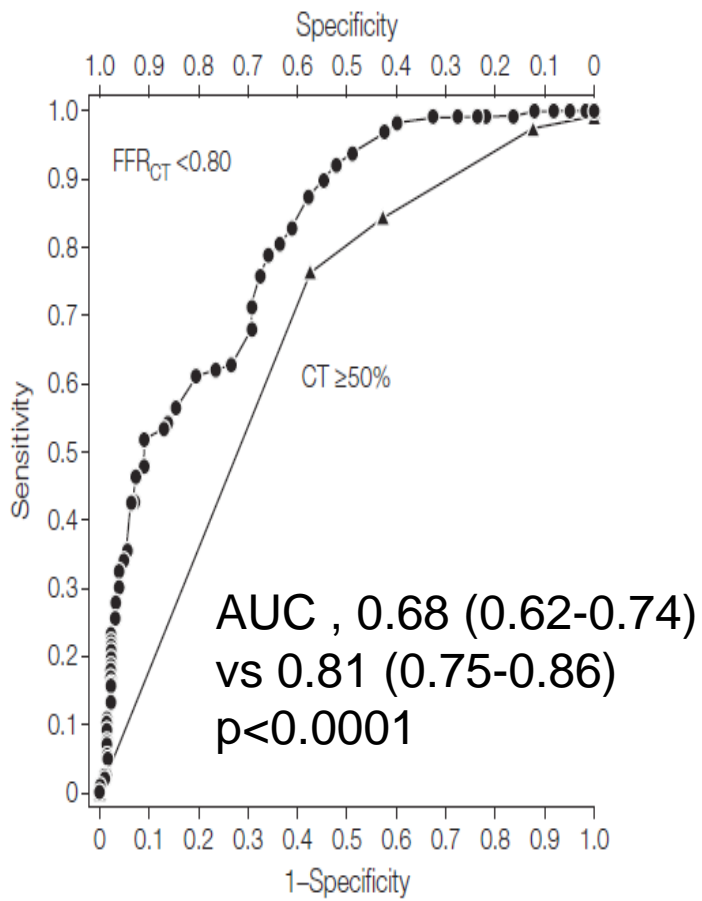
Primary end point



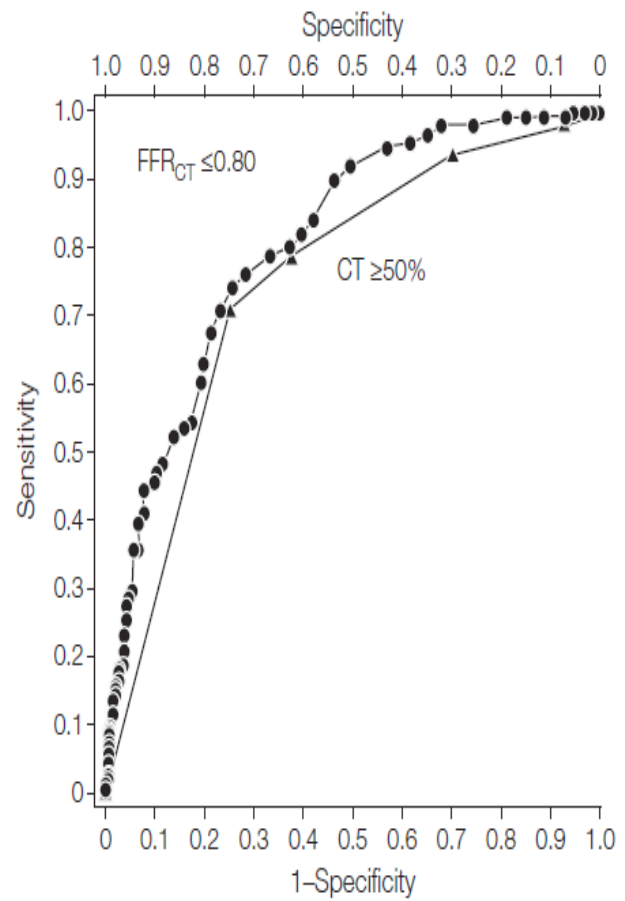
	Accuracy	Sensitivity	Specificity	PPV	NPV
95% CI					
FFR _{CT}	67-78	84-95	46-83	60-74	74-90
cCTA	58-70	77-90	34-51	53-67	61-81

“FFR_{CT}: Clinical studies”, *DeFACTO* trial

A Per-patient performance



B Per-vessel performance



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)

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and Seoul, South Korea*



“FFR_{CT}: Clinical studies”, *DeFACTO vs NXT trial design*

Factors	DeFACTO	HeartFlowNXT
Case analyst training	Based on experience from the DISCOVER-FLOW trial	Modified case analyst training to reduce variability
Software version	V1.2	V1.4
Primary CT readings	Per Core Lab	Per site (Core Lab readings used in secondary analysis)
Site selection	CT expertise <u>or</u> FFR expertise	CT expertise <u>and</u> FFR expertise
Coronary CTA training	Unofficial CT discussions, Core Lab communication	Peer to peer training
Coronary CTA Pre-Qualification	None	15 coronary CTA scans submitted for quality pre-screening
Coronary CTA Quality Check	None	Coronary CTAs preapproved by HeartFlow, Inc. prior to FFR
FFR training	Presentation by sponsor	Peer to peer training
FFR Core Lab Review	No consistent documentation process	Full electronic FFR tracing captured, Core Lab reviews
Site Management	Limited case support	Dedicated site managers; FFR case support

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- To determine the diagnostic performance of non-invasive FFR_{CT} using FFR as the reference standard
- To compare the diagnostic performance of FFR_{CT} vs. anatomic testing (coronary CTA or invasive coronary angiography)

Inclusion Criteria:

- Underwent ≥ 64 -row CT and ICA scheduled
- < 60 days between CT and ICA

Exclusion Criteria:

- Prior CABG or PCI
- Suspected ACS
- Recent MI within 30 days of CT
- Contraindication to nitrates, beta blockade or adenosine

Primary Endpoint:

- Per-patient diagnostic performance as assessed by the area under the receiver operating characteristic curve (AUC) of FFR_{CT} vs. coronary CTA for the diagnosis of ischemia in patients with stenosis severity 30%-90% (vessel diameter >2 mm)

Secondary Endpoint:

- Diagnostic performance (accuracy, sensitivity, specificity, PPV and NPV) of FFR_{CT}, coronary CTA, and invasive coronary angiography

- **Blinded core laboratories for FFR, FFR_{CT}, and ICA**
- **CT:** -Acquisition protocols according to societal guidelines¹
 - Image quality independently evaluated using a predefined scoring system²
 - Site-read stenosis severity >50%³
- **ICA:** -Core-lab read stenosis severity >50%
- **FFR:** At maximum hyperemia during ICA
 - Adenosine 140 – 180 micg/kg/min IV
 - Positive: ≤0.80⁴

¹Abbara S et al. JCCT 2009

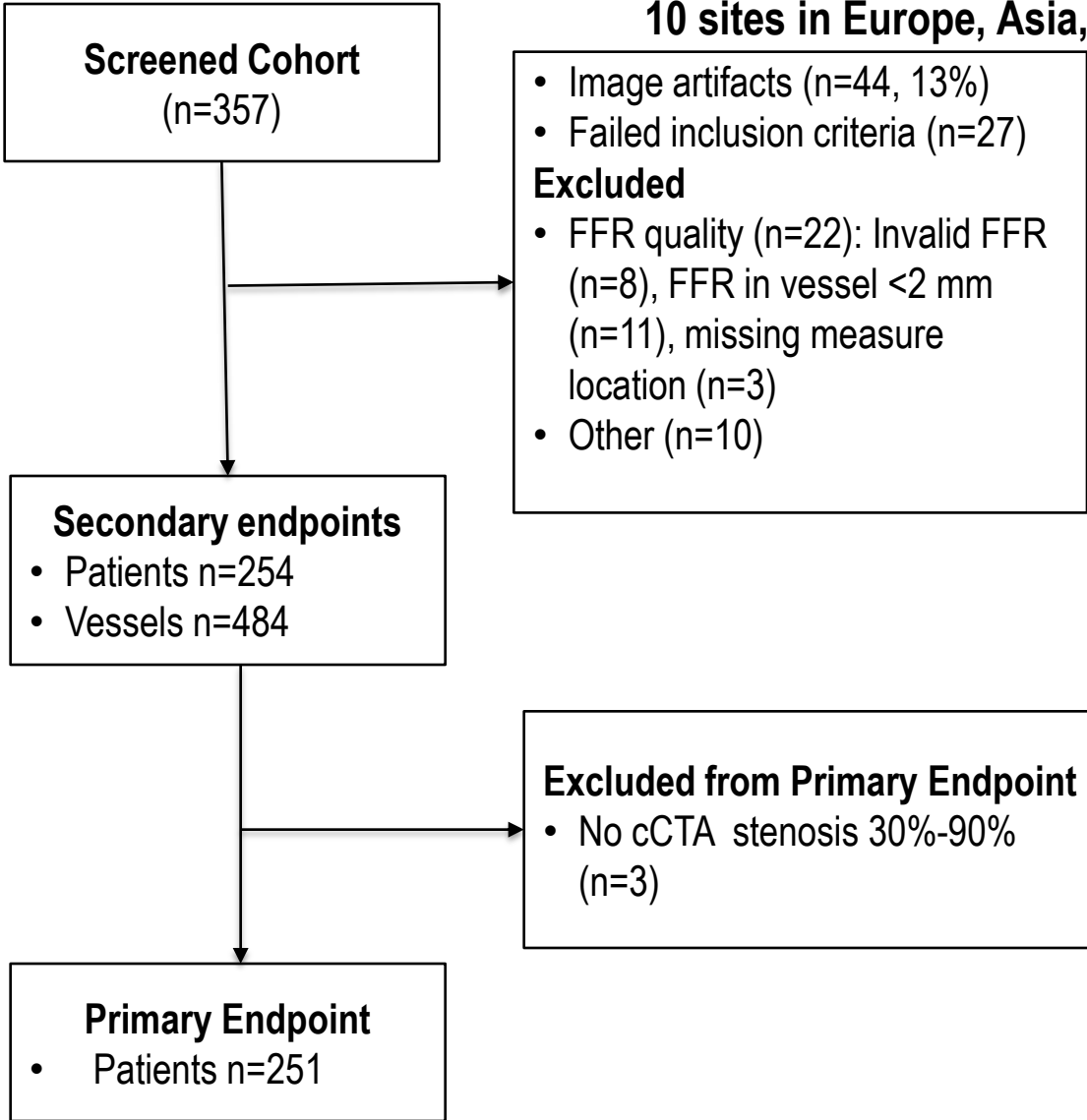
²Nørgaard B et al. JCCT 2013

³Raff GL et al. JCCT 2009

⁴Tonino PA et al. NEJM 2009

“FFR_{CT}: Clinical studies”, *NXT trial*, Patient enrollment

Study enrollment 9/2012 – 8/2013
10 sites in Europe, Asia, and Australia



“FFR_{CT}: Clinical studies”, *NXT trial*, Patients and CT characteristics

Patient Characteristics	
Age (years) [mean \pm SD]	64 \pm 10
Male gender	64%
Prior MI	2%
Diabetes mellitus	23%
Hypertension	69%
Pre-test Likelihood of CAD	58%
FFR \leq 0.80	32%
FFR assigned a value of 0.50 in 16 occluded vessels	3%

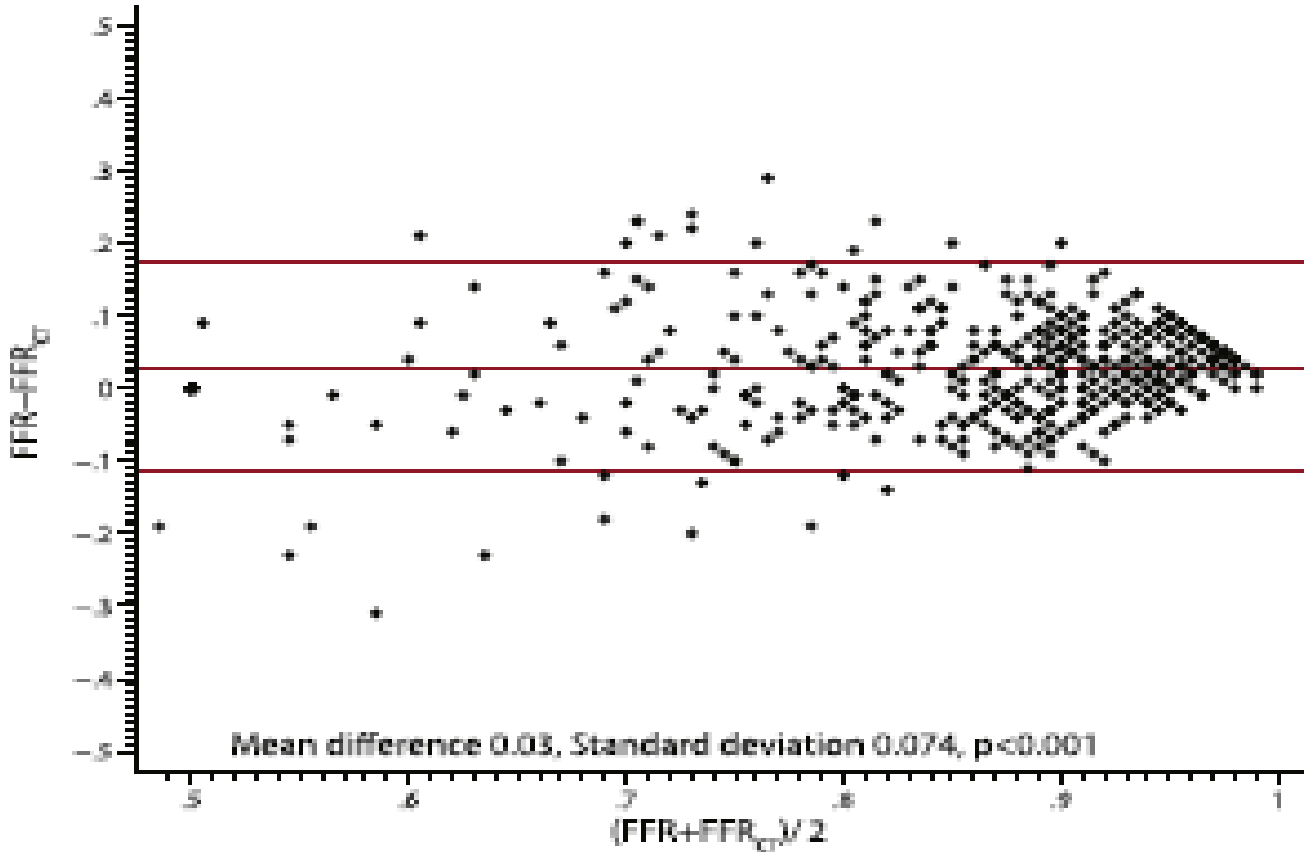
CT Characteristics

Nitrates	99.6%
Beta Blockers	78%
Heart Rate (bpm)	63
Range	37-110
Prospective	54%
mean dose (mSv)	3
Retrospective	46%
mean dose (mSv)	14
Calcium score*	
Mean	302
Range	0 – 3599
>300	33%

*Available for 214 patients

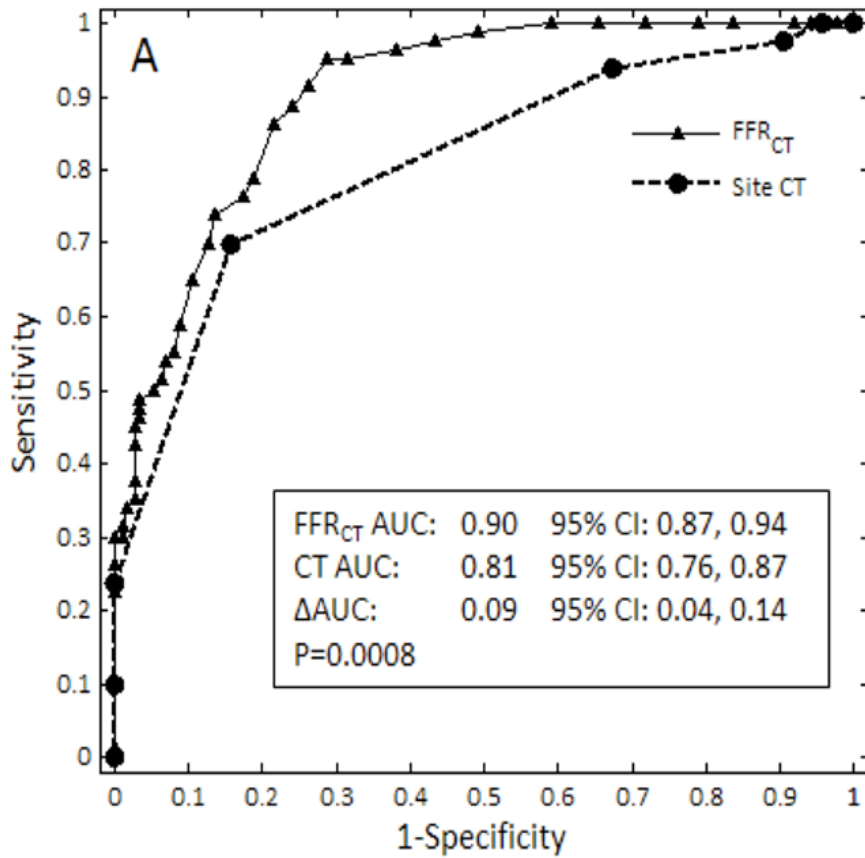
“FFR_{CT}: Clinical studies”, *NXT trial*, Per-vessel FFR - FFR_{CT} correlation

Pearson's CC
= 0.82,
P<0.0001

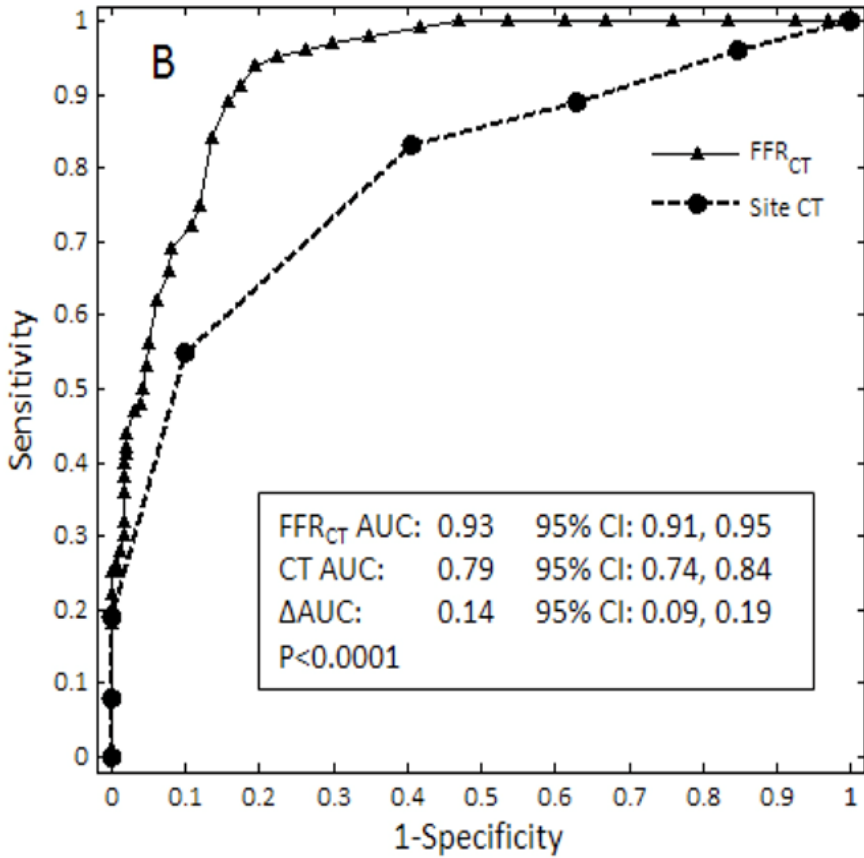


“FFR_{CT}: Clinical studies”, *NXT trial*, Discrimination of ischemia

Per-patient



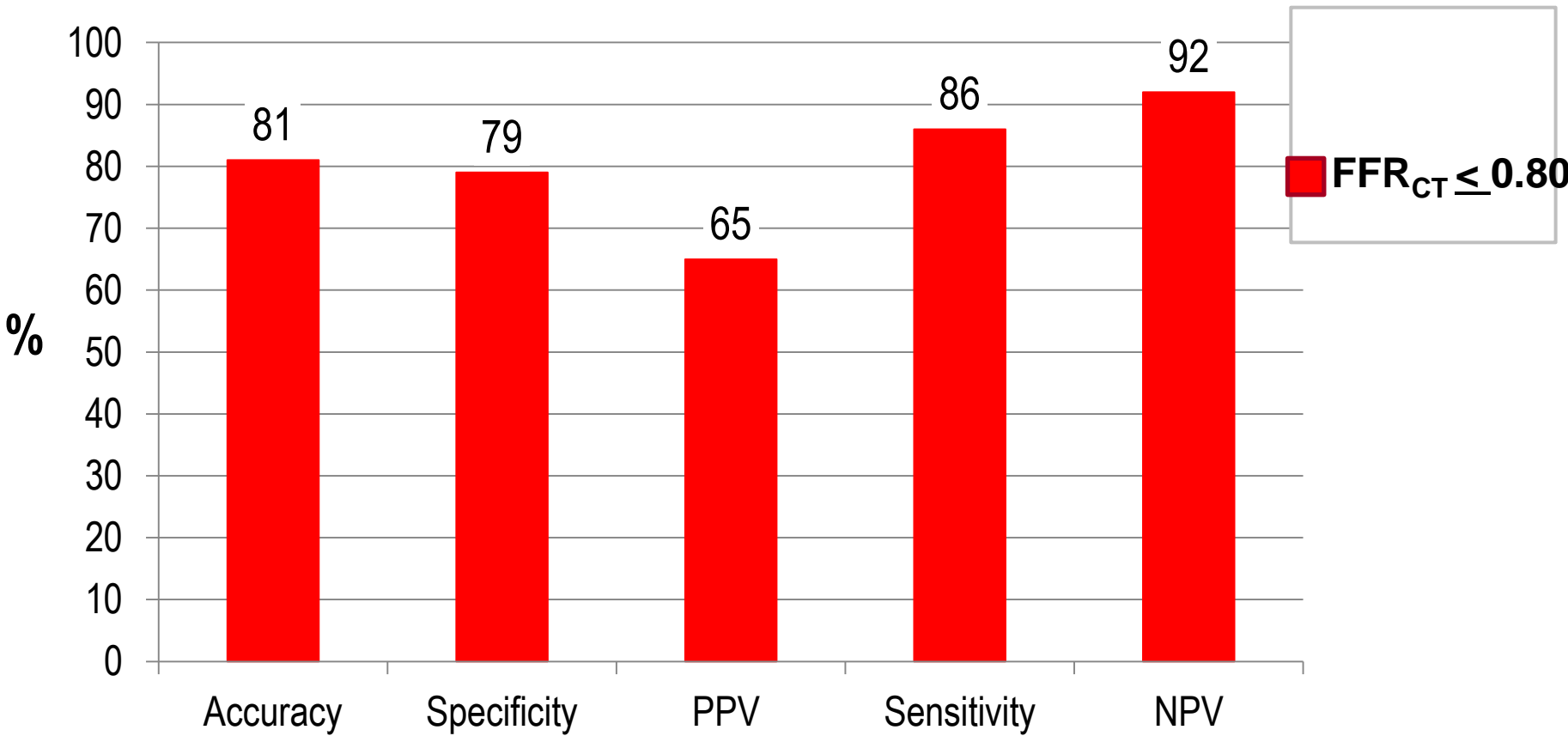
Per-vessel



N=252

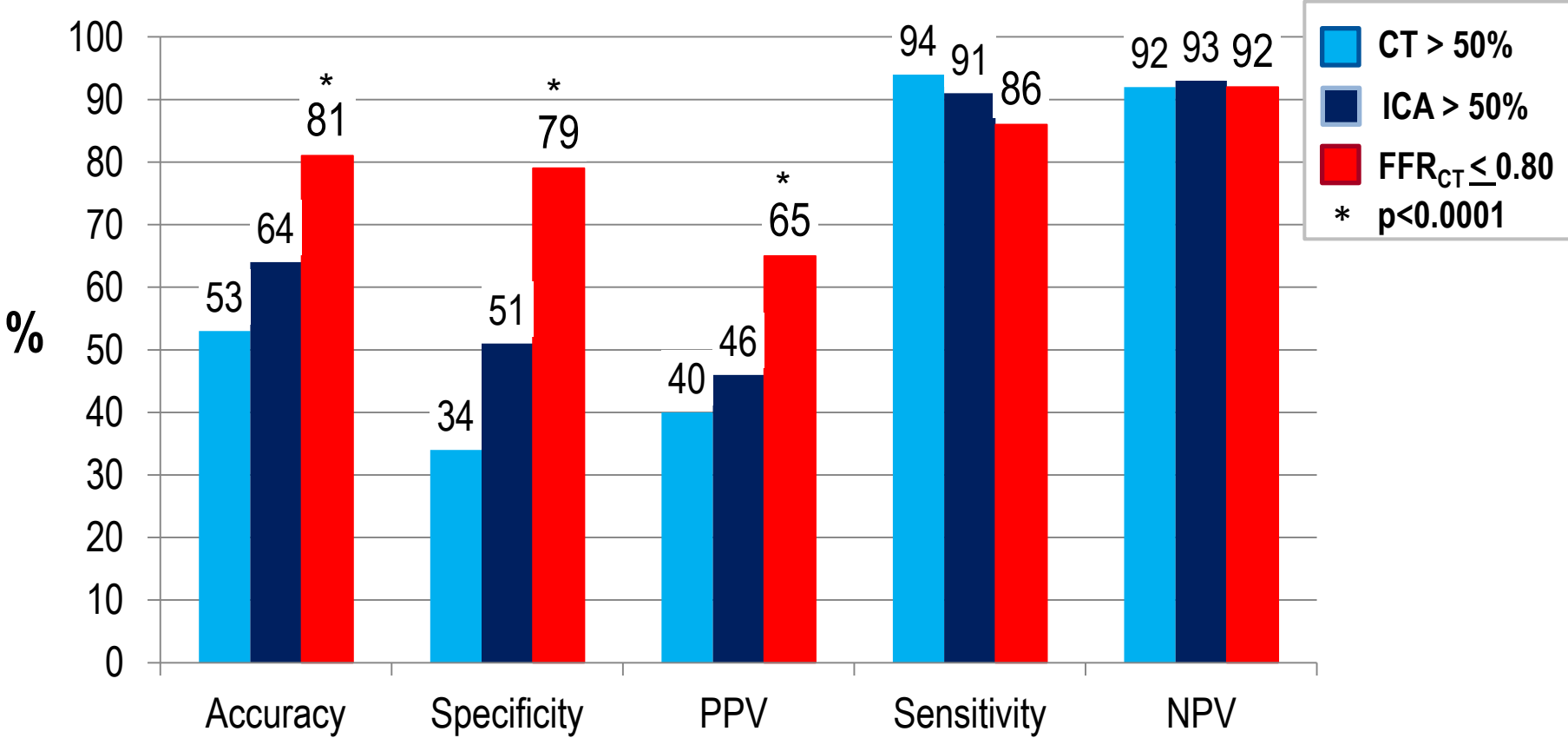
*Area under the receiver operating characteristics curve

“FFR_{CT}: Clinical studies”, *NXT trial*, Per-patient diagnostic performance



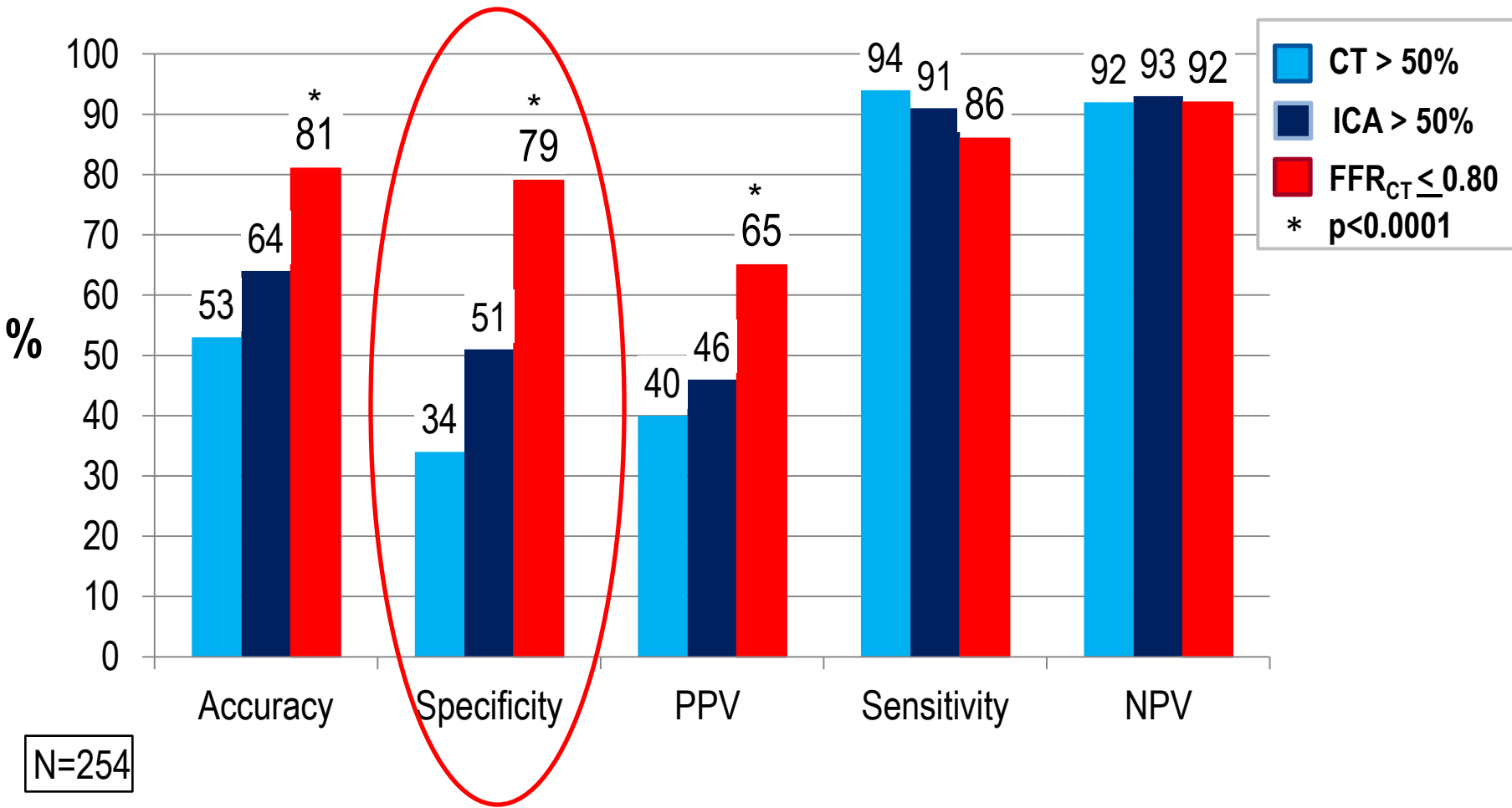
N=254

“FFR_{CT}: Clinical studies”, *NXT trial*, Per-patient diagnostic performance

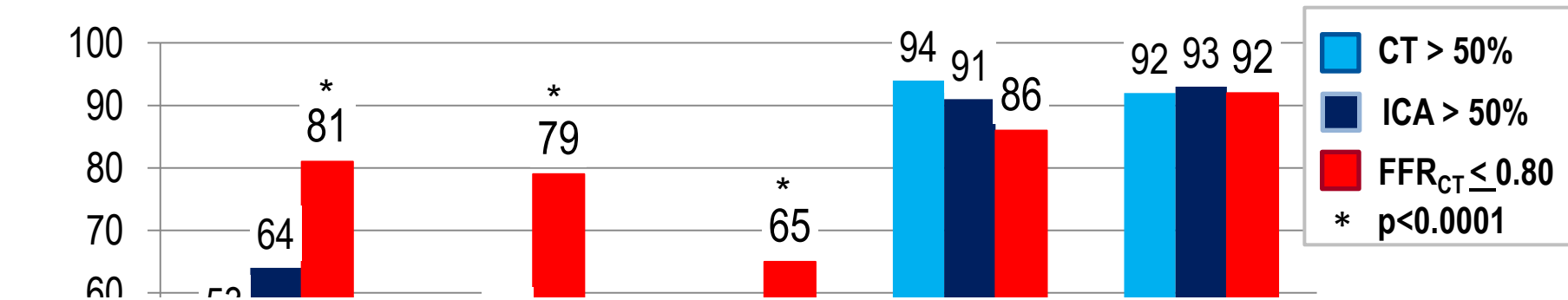


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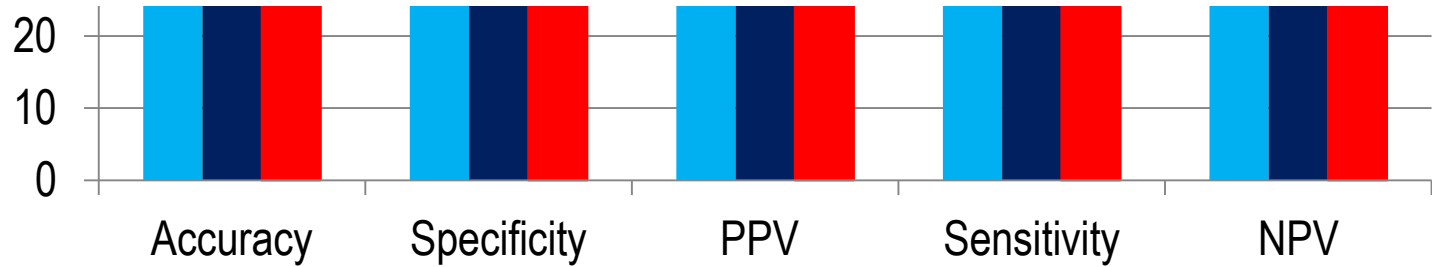
“FFR_{CT}: Clinical studies”, *NXT trial*, Per-patient diagnostic performance



“FFR_{CT}: Clinical studies”, *NXT trial*, Per-patient diagnostic performance



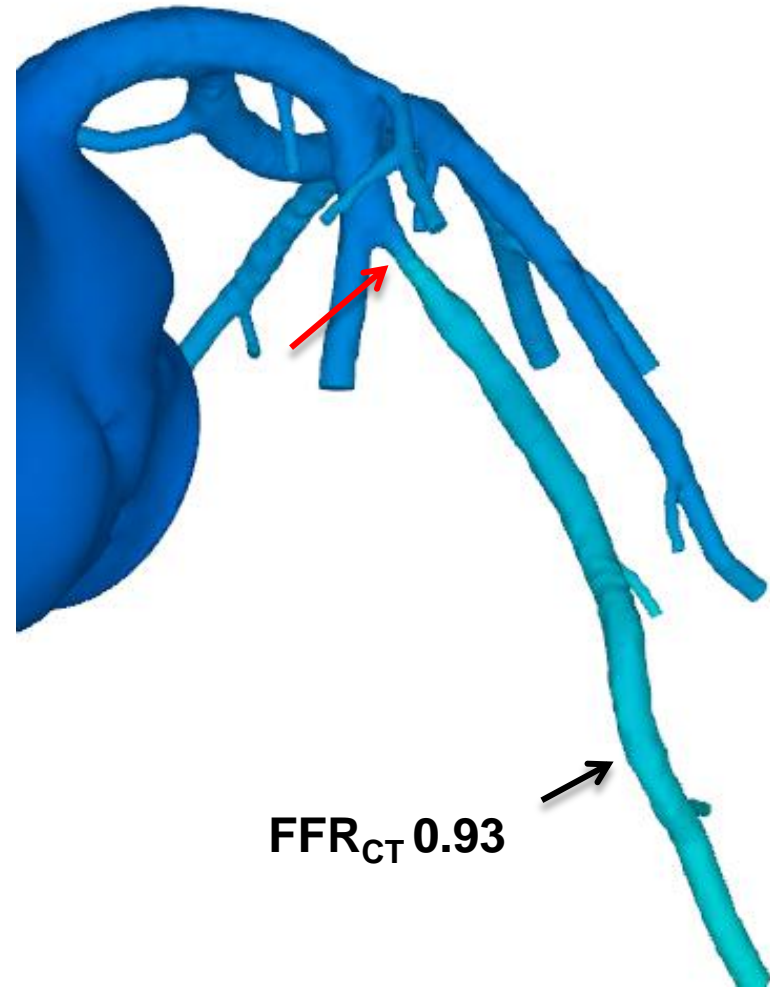
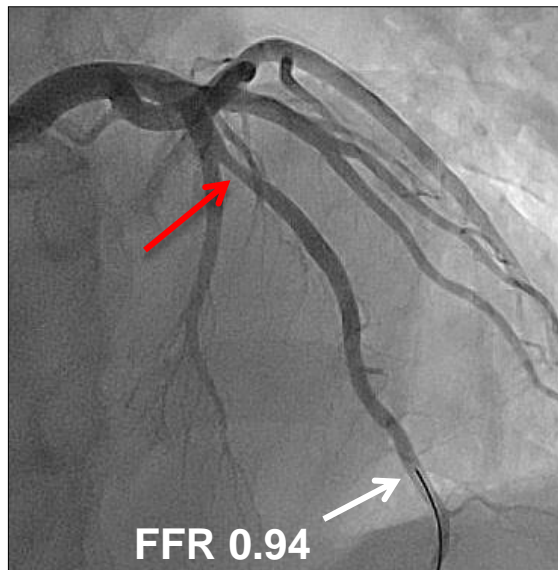
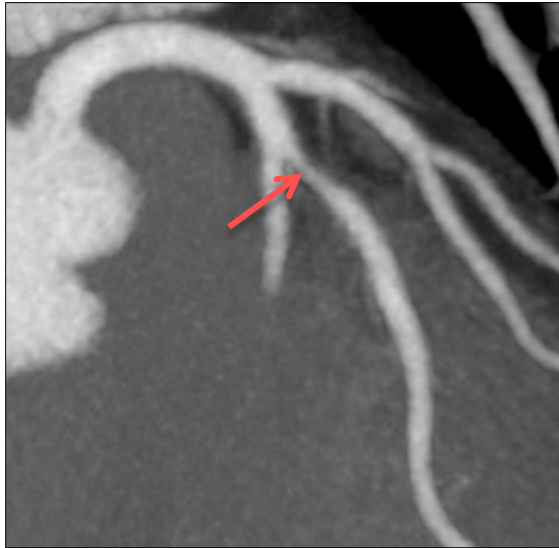
FFR_{CT} correctly reclassified 68% of CT false positive to true negatives



N=254

FFR_{CT}: Clinical studies”, *NXT trial*, Per-patient diagnostic performance

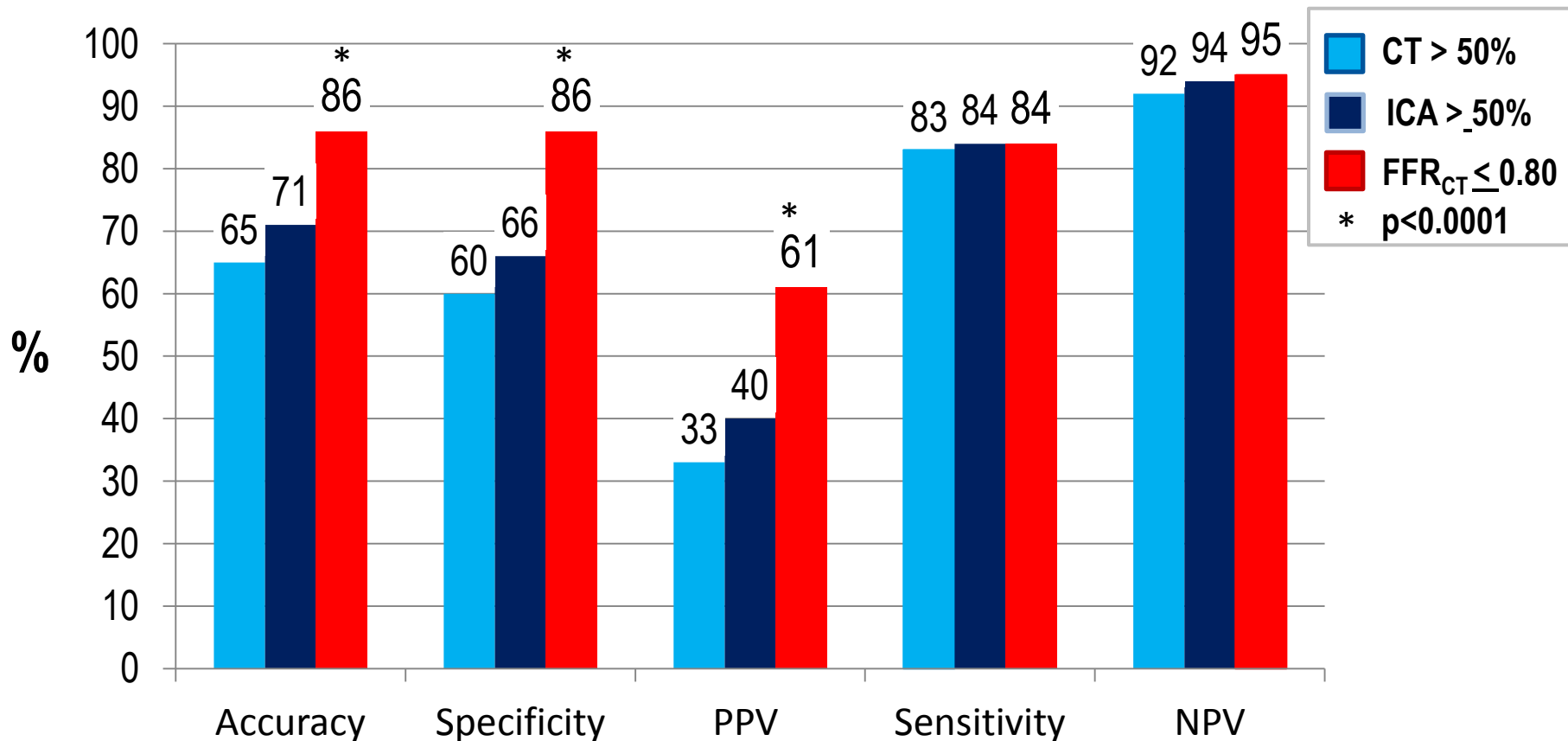
LAD stenosis 70-90%



FFR_{CT} 0.93

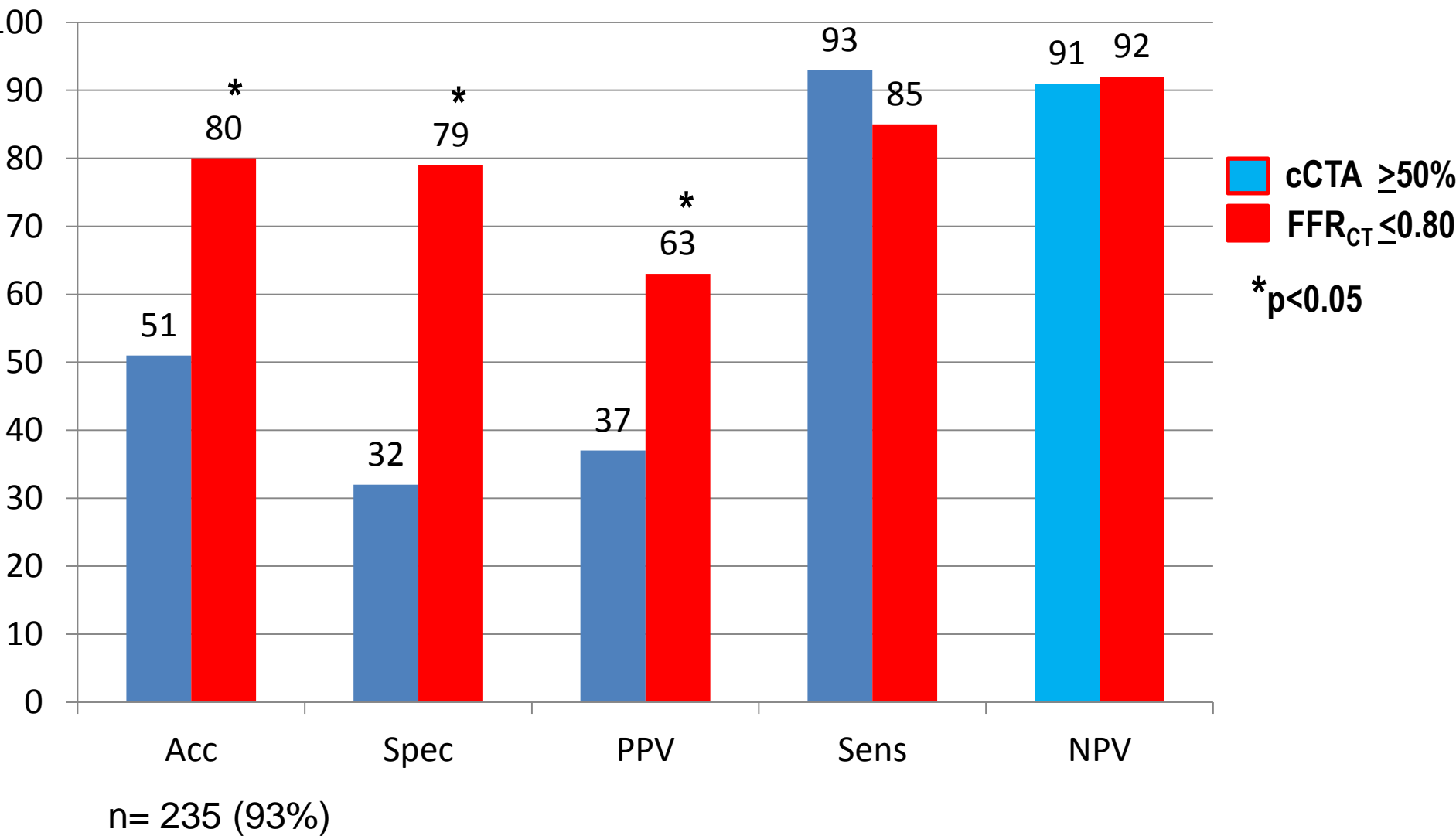
FFR_{CT} Model

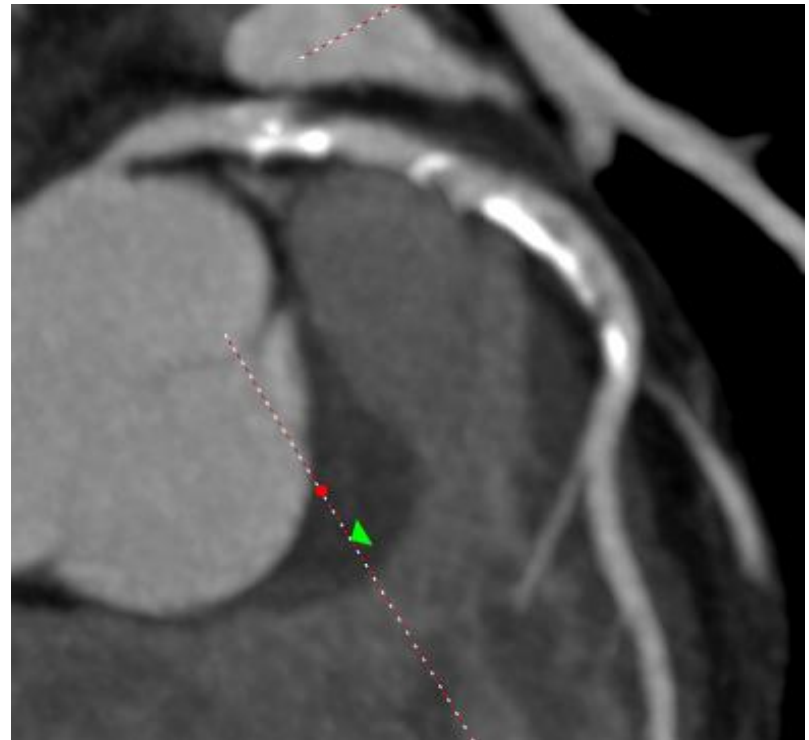
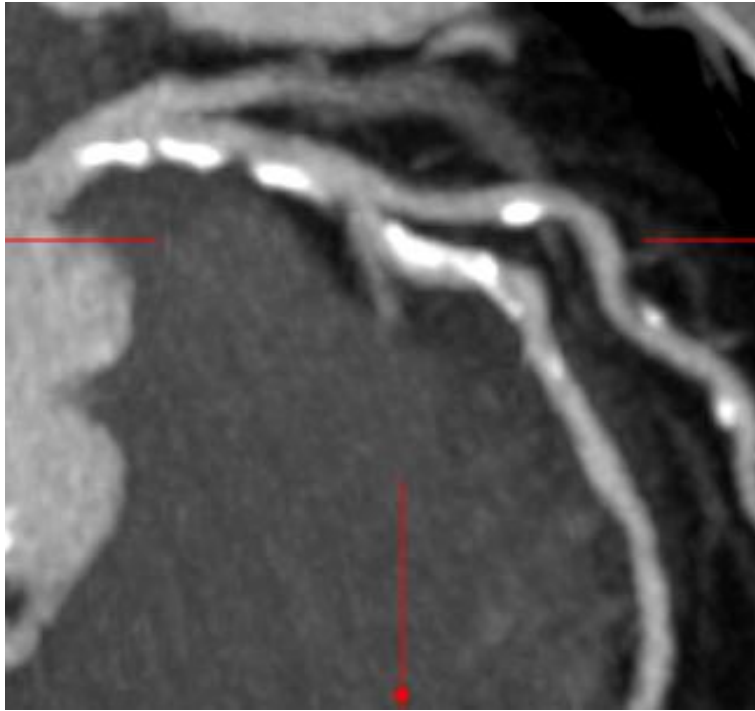
“FFR_{CT}: Clinical studies”, *NXT trial*, Per-vessel diagnostic performance



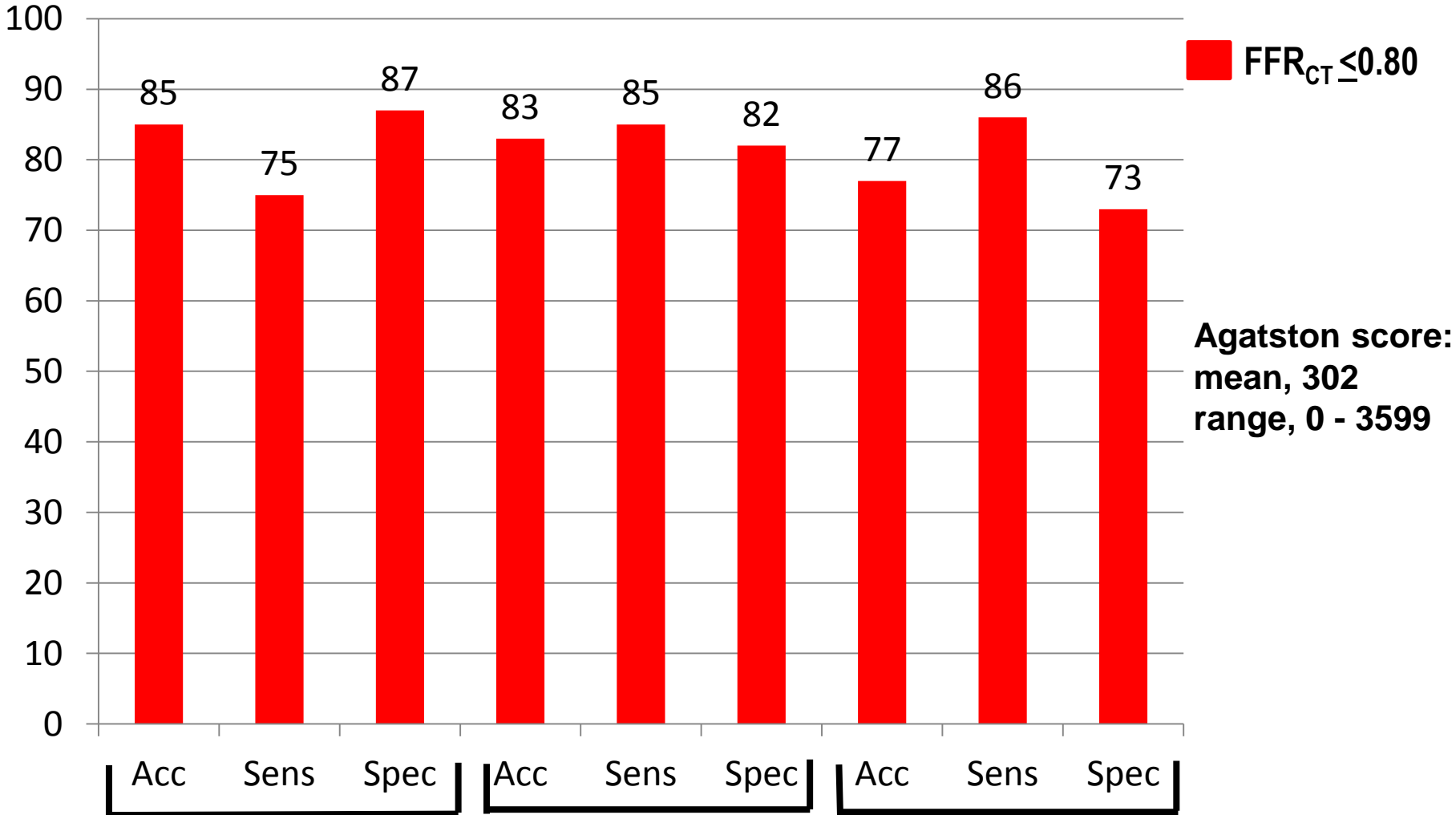
N=484

“FFR_{CT}: Clinical studies”, *NXT trial*, Intermediate lesions (30%-70%)



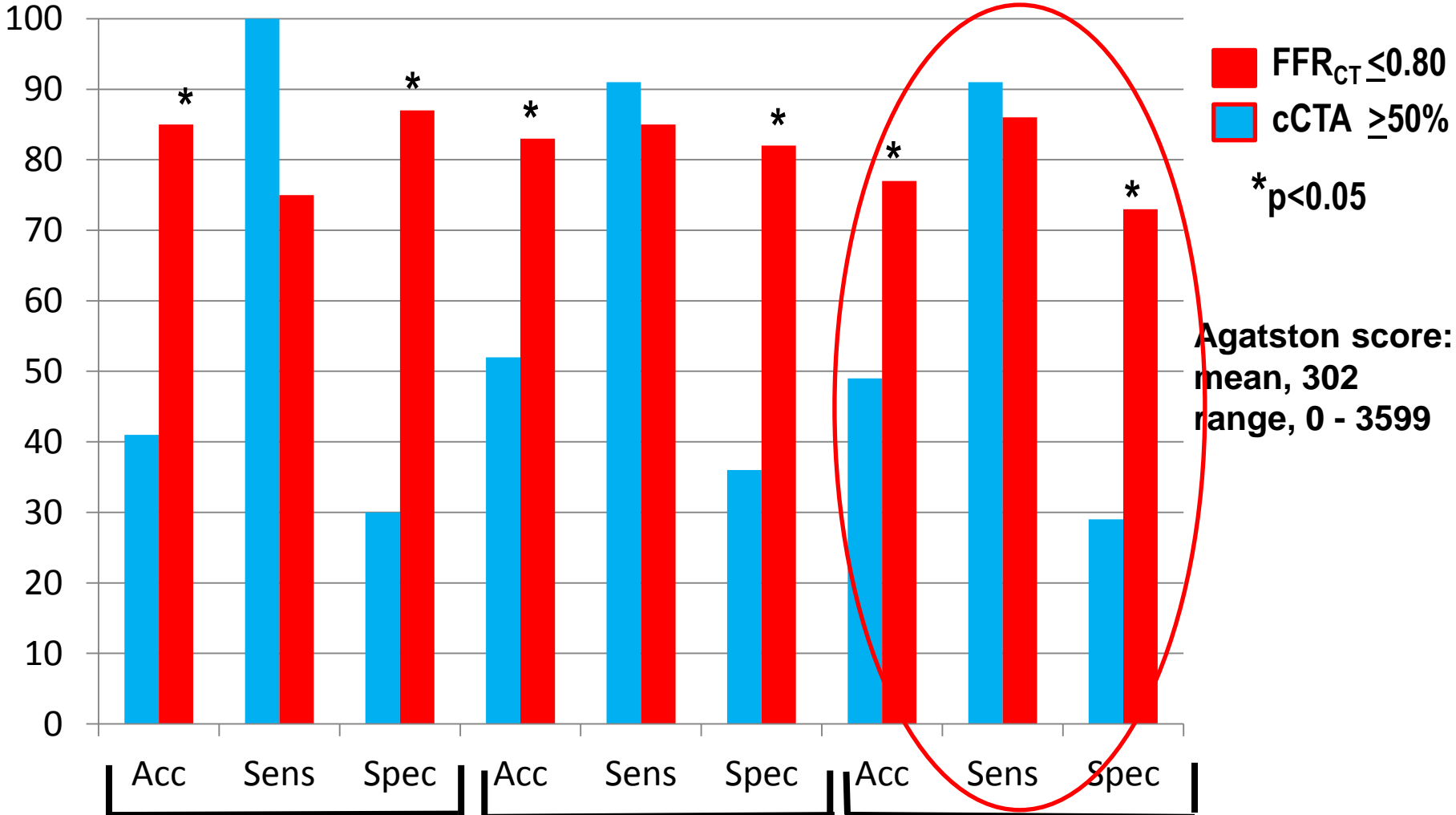


“FFR_{CT}: Clinical studies”, *NXT trial*, Coronary calcification



Ag: **"0"** **"1-300"** **">300"**
N (214): **27** **117** **70**

“FFR_{CT}: Clinical studies”, *NXT trial*, Coronary calcification



Ag: "0" "1-300" ">300"
N (214): 27 117 70

- **FFR_{CT} has high diagnostic accuracy and discrimination for the diagnosis of ischemia**

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- **When compared to anatomic interpretation by coronary CTA or invasive angiography, FFR_{CT} leads to a marked increase in diagnostic accuracy, specificity, and PPV**

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- When compared to anatomic interpretation by coronary CTA or invasive angiography, FFR_{CT} leads to a marked increase in diagnostic accuracy, specificity, and PPV
- **FFR_{CT} is performed from standard acquired CT datasets without the need for additional imaging, radiation or medication**

Diagnostic Performance of Cardiac Stress Perfusion MRI in the Detection of Coronary Artery Disease Using Fractional Flow Reserve as the Reference Standard: A Meta-Analysis

Ravi R. Desai¹
Saurabh Jha²

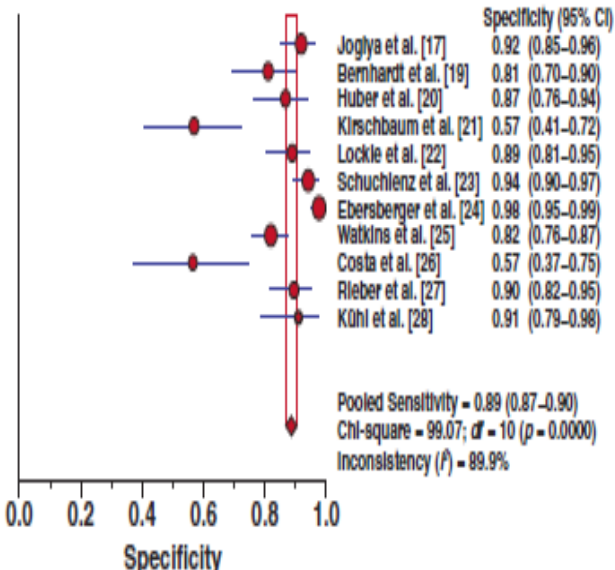
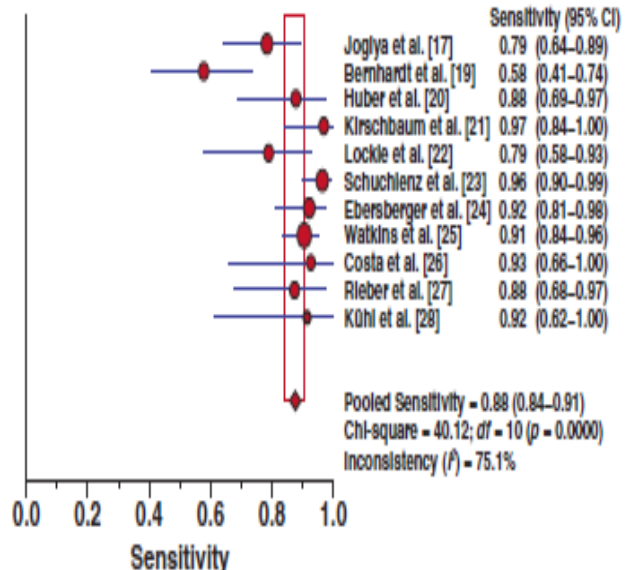
OBJECTIVE. This is an analysis of pooled studies for the determination of the test characteristics of stress perfusion cardiac MRI in the diagnosis of flow-limiting obstructive coronary artery disease (CAD) using fractional flow reserve (FFR) at catheter coronary angiography as the reference standard.

MATERIALS AND METHODS. Traditionally, planimetric measurement of coronary stenosis at catheter coronary angiography has been considered the reference standard and has been used to verify the diagnostic characteristics of gatekeeper tests. FFR is a physiologic measure of flow limitation and is considered a more authentic reference standard in the diagnosis of CAD. The emergence of a new reference standard questions the true diagnostic accuracy of gatekeeper tests. A systematic literature review was performed for qualifying studies. The DerSimonian-Laird random effects model and a random-effects symmetric summary receiver operating characteristic curve analysis were performed.

RESULTS. Twelve studies (761 patients) met the inclusion criteria. Four hundred six stenotic coronary arteries had FFR less than 0.75. Perfusion stress MRI has a sensitivity of 89.1% (95% CI, 84–93%) and specificity of 84.9% (95% CI, 76.6–91.1%) on a patient basis and a sensitivity of 87.7% (95% CI, 84.4–90.6%) and specificity of 88.6% (95% CI, 86.7–90.4%) on a coronary territory basis.

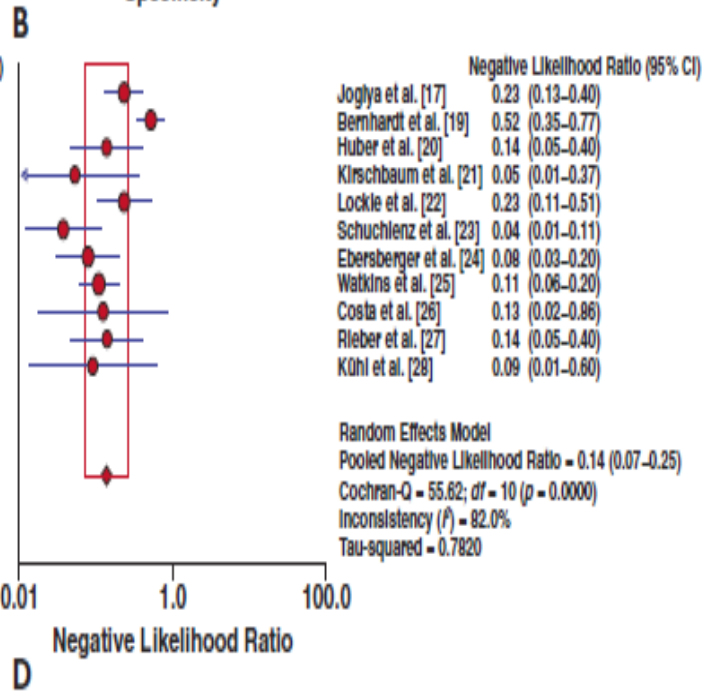
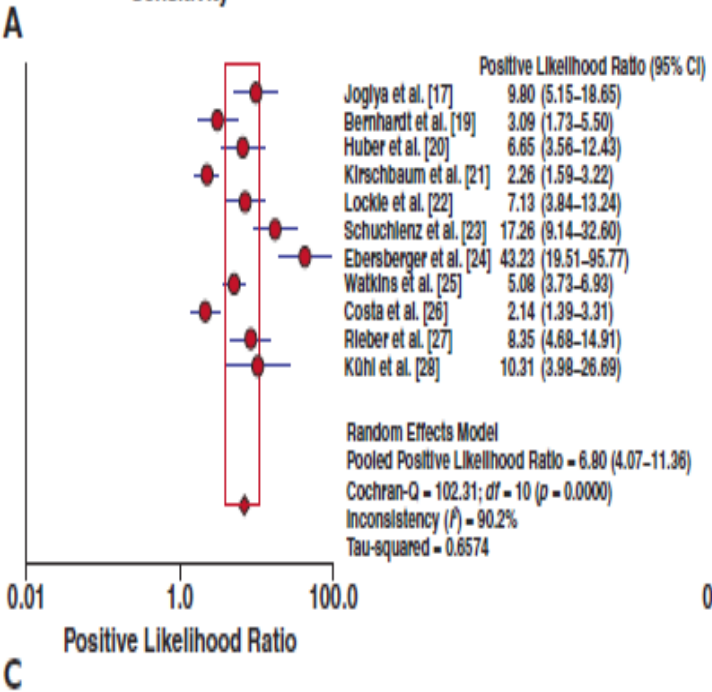
CONCLUSION. Stress perfusion MRI remains an accurate test for the detection of flow-limiting stenosis when adjudicated by a physiologic reference standard.

“FFR_{CT}: Clinical studies”, FFR_{CT} vs other non-invasive testing modalities



Per patient
 pooled sens / spec:
89% (95% CI, 84-93) /
85% (77-91)

Per-territory
 pooled sens / spec:
88% (84-91) /
89% (87-90)



	Sensitivity (95% CI)	
Joglyya et al. [17]	0.79	(0.64–0.89)
Bernhardt et al. [19]	0.58	(0.41–0.74)
Huber et al. [20]	0.88	(0.69–0.97)
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	Specificity (95% CI)	
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- **Single-center studies**

“FFR_{CT}: Clinical studies”, FFR_{CT} vs other non-invasive testing modalities

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- Single-center studies
- # patients: 28 - 120

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- # patients: 28 - 120
- **Local FFR reads**

“FFR_{CT}: Clinical studies”, FFRct vs other non-invasive testing modalities

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- Single-center studies
- # patients: 28 - 120
- Local FFR reads
- **The rate of actual FFR measurements was <70% in 10 of 12 studies (ICA stenosis >90% => FFR, 0.50, and in normal vessels => FFR, 0.95)**

“FFR_{CT}: Clinical studies”, FFRct vs other non-invasive testing modalities

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- Local FFR reads
- The rate of actual FFR measurements was <70% in 10 of 12 studies (ICA stenosis >90% => FFR, 0.50, and in normal vessels => FFR, 0.95)

Abnormal Epicardial Coronary Resistance in Patients With Diffuse Atherosclerosis but “Normal” Coronary Angiography

Bernard De Bruyne, MD, PhD; Ferry Hersbach, MD; Nico H.J. Pijls, MD, PhD; Jozef Bartunek, MD, PhD; Jan-Willem Bech, MD; Guy R. Heyndrickx, MD, PhD; K. Lance Gould, MD; William Wijns, MD, PhD

Background—Coronary arteries without focal stenosis at angiography are generally considered non-flow-limiting. However, atherosclerosis is a diffuse process that often remains invisible at angiography. Accordingly, we hypothesized that in patients with coronary artery disease, nonstenotic coronary arteries induce a decrease in pressure along their length due to diffuse coronary atherosclerosis.

Methods and Results—Coronary pressure and fractional flow reserve (FFR), as indices of coronary conductance, were obtained from 37 arteries in 10 individuals without atherosclerosis (group I) and from 106 nonstenotic arteries in 62 patients with arteriographic stenoses in another coronary artery (group II). In group I, the pressure gradient between aorta and distal coronary artery was minimal at rest (1±1 mm Hg) and during maximal hyperemia (3±3 mm Hg). Corresponding values were significantly larger in group II (5±4 mm Hg and 10±8 mm Hg, respectively; both P<0.001). The FFR was near unity (0.97±0.02; range, 0.92 to 1) in group I, indicating no resistance to flow in truly normal coronary arteries, but it was significantly lower (0.89±0.08; range, 0.69 to 1) in group II, indicating a higher resistance to flow. In 57% of arteries in group II, FFR was lower than the lowest value in group I. In 8% of arteries in group II, FFR was <0.75, the threshold for inducible ischemia.

Conclusion—Diffuse coronary atherosclerosis without focal stenosis at angiography causes a graded, continuous pressure resistance to flow. In 57% of arteries in group II, FFR was lower than the lowest value in group I. In 8% of arteries in group II, FFR was <0.75, the threshold for inducible ischemia and has consequences for myocardial ischemia and has consequences for prognosis. (Circulation. 2001;104:2401-2406.)

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Angiographic Versus Functional Severity of Coronary Artery Stenoses in the FAME Study

Functional Flow Reserve Versus Angiography in Multivessel Evaluation

n A. L. Tonino, MD,* William F. Fearon, MD,† Bernard De Bruyne, MD, PhD,‡
Joh G. Oldroyd, MD,§ Massoud A. Leesar, MD,|| Peter N. Ver Lee, MD,‡
Philip A. MacCarthy, MD, PhD,¶ Marcel van't Veer, MSc, PhD,‡ Nico H. J. Pijls, MD, PhD,‡
Cindysoven, the Netherlands; Stanford, California; Aalst, Belgium; Glasgow and London, United Kingdom; Cincinnati, Ohio; and Bangor, Maine

Objectives
The purpose of this study was to investigate the relationship between angiographic and functional severity of coronary stenoses in the FAME (Fractional Flow Reserve Versus Angiography in Multivessel Evaluation) of coronary stenoses that induce ischemia improves a patient's functional status and outcome. Revascularization does not induce ischemia, however, the benefit of revascularization is less clear.

Background
It can be difficult to determine on the coronary angiogram which lesions cause ischemia. Revascularization of coronary stenoses that induce ischemia improves a patient's functional status and outcome. Revascularization does not induce ischemia, however, the benefit of revascularization is less clear.

Methods
In the FAME study, routine measurement of the fractional flow reserve (FFR) was compared with percutaneous coronary intervention in patients with multivessel coronary artery disease. The 2,424 lesions (509 patients) in the FFR-guided arm of the FAME study, 1,229 were in the FFR and are included in this analysis.

Results
Before FFR measurement, these lesions were categorized into 50% to 70% (47% of all lesions), 30% to 49% (33% of all lesions), and 9% to 29% (12% of all lesions) diameter stenosis by visual estimation. After FFR measurement, 35% were functionally significant (FFR <0.80) and 65% were not functionally significant (FFR ≥0.80). In the 50% to 70% stenosis category, 90% were functionally significant and 10% were not functionally significant. In the 30% to 49% stenosis category, 94% were functionally significant and 6% were not functionally significant. In the 9% to 29% stenosis category, 94% were functionally significant and 6% were not functionally significant. In the 50% to 70% stenosis category, 90% were functionally significant and 10% were not functionally significant. In the 30% to 49% stenosis category, 94% were functionally significant and 6% were not functionally significant. In the 9% to 29% stenosis category, 94% were functionally significant and 6% were not functionally significant.

Conclusions
Angiography is inaccurate in assessing the functional significance of a coronary stenosis when the FFR, not only in the 50% to 70% category but also in the 70% to 90% angiographic severity category. (J Am Coll Cardiol. 2010;55:2516-2521) © 2010 by the American College of Cardiology Foundation

Comprehensive Assessment of Coronary Artery Stenoses

Computed Tomography Coronary Angiography Versus Conventional Coronary Angiography and Correlation With Fractional Flow Reserve in Patients With Stable Angina

W. Bob Meijboom, MD,† Carlos A. G. Van Mieghem, MD,† Niels van Pelt, MD,† Annick Weustink, MD,† Francesca Pugliese, MD,† Nico R. Mollet, MD, PhD,† Eric Boersma, PhD,† Eveline Regar, MD, PhD,† Robert J. van Geuns, MD, PhD,† Peter J. de Jaegere, MD, PhD,† Patrick W. Serruys, MD, PhD, FACC,† Gabriel P. Krestin, MD, PhD,† Pim J. de Feyter, MD, PhD, FACC,† Rotterdam, the Netherlands

— 22%-69% of FFR values were directly measured

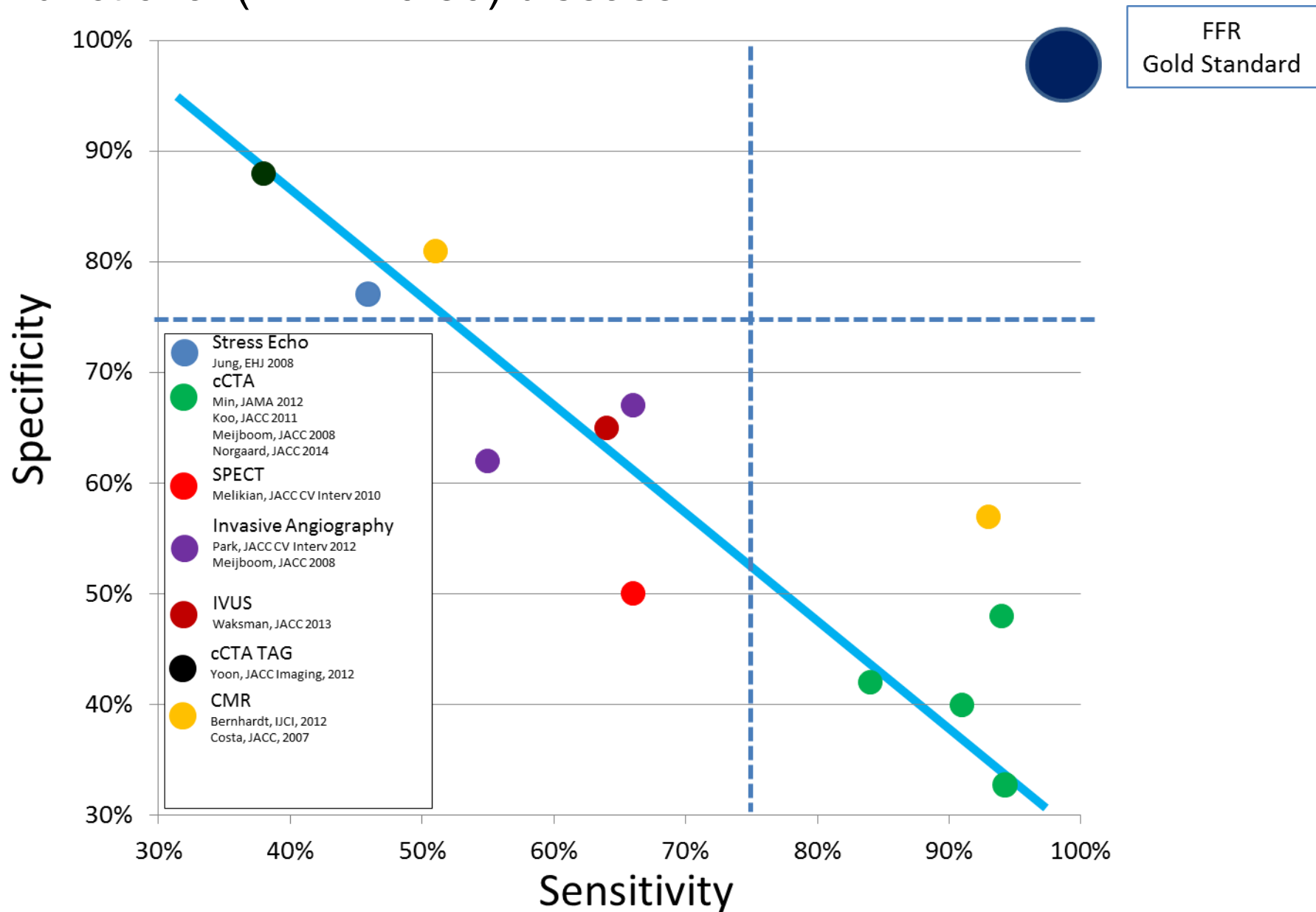
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“FFR_{CT}: Clinical studies”, FFR_{ct} vs other non-invasive testing modalities

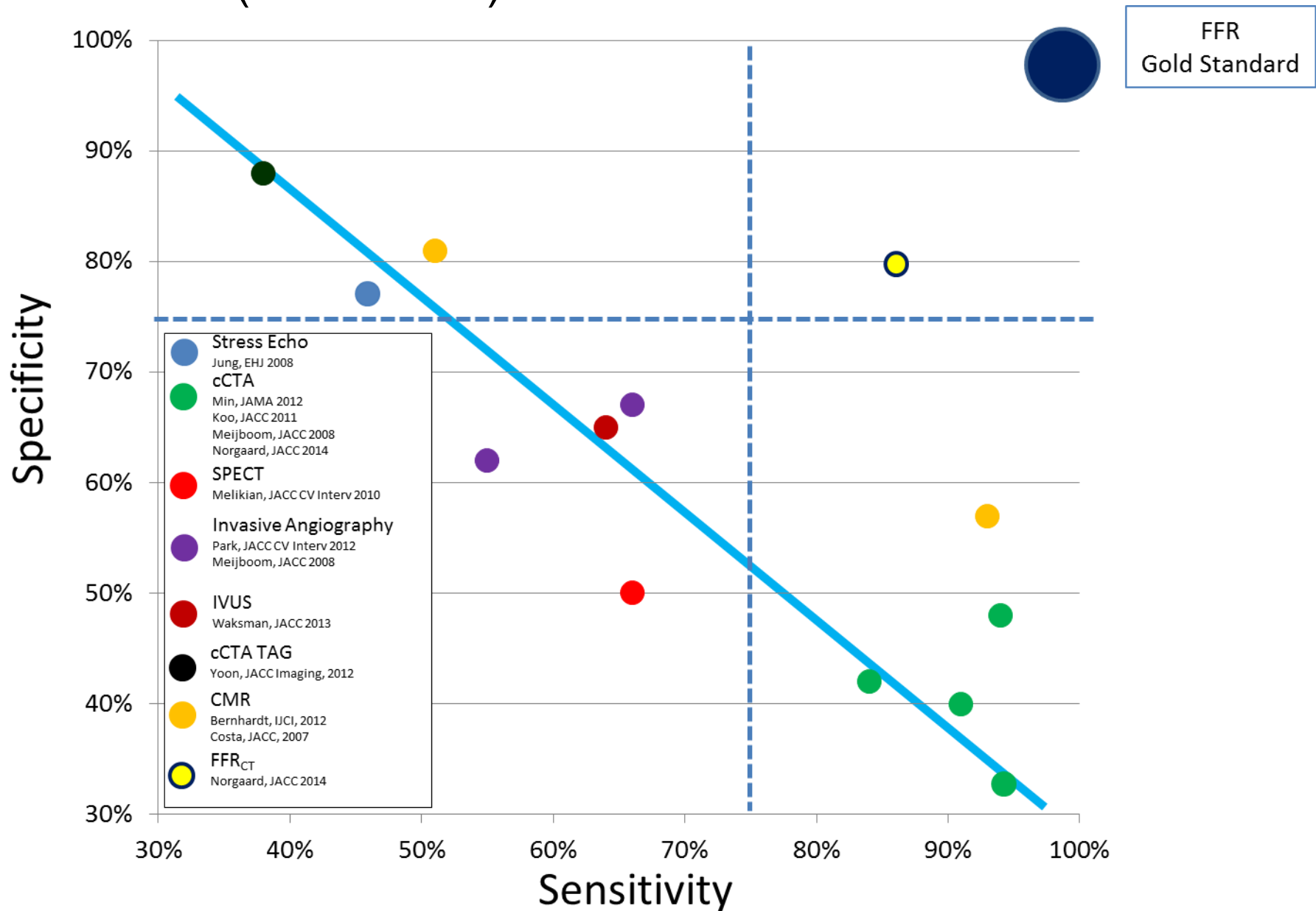
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Diagnostic performance of Coronary diagnostic tests for Functional (FFR ≤ 0.80) disease



Diagnostic performance of Coronary diagnostic tests for Functional ($FFR \leq 0.80$) disease



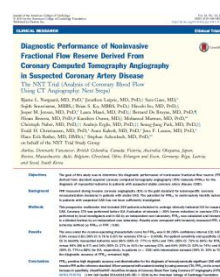
“FFR_{CT}: Clinical studies”, *Building the Body of Evidence*

- 609 patients
- 1051 vessels,
- FFR directly measured in 1035 vessels (98%)

DISCOVER-FLOW

NXT

DeFACTO



**Cath lab
Population
Dx Accuracy**

**30-90%
Stenosis
Dx Accuracy**

2012

2013

2014

2015

...



- **Use of FFR_{CT} to select patients for ICA and PCI may result in 30% lower costs and 12% fewer events at one year compared to the most common strategy of ICA**

	Diagnostic Strategy				
	ICA/Visual	ICA/FFR _{ICA}	cCTA/ICA/Visual	cCTA/ICA/FFR _{ICA}	cCTA/FFR _{CT} /ICA
No. of ICAs (per 100 patients)	100	100	84	84	51
No. of patients undergoing PCI (per 100 patients)	81	48	72	47	49
No. of vessels treated by PCI (per 100 patients)	98	51	88	50	59
No. of vessels treated per patient undergoing PCI	1.21	1.07	1.22	1.07	1.21
Death/MI rate at 1 year	2.63%	1.96%	2.56%	2.06%	2.31%
Initial treatment costs per patient	\$10702	\$8499	\$9635	\$8035	\$7674

Projected Procedure Use, Costs, and 1-Year Death/Myocardial Infarction Rates

Abbreviations: cCTA, coronary computed tomography angiography; FFR_{CT}, fractional flow reserve derived from coronary computed tomography angiography; FFR_{ICA}, fractional flow reserve measured during invasive coronary angiography; ICA, invasive coronary angiography; MI, myocardial infarction; PCI, percutaneous coronary intervention.

“FFR_{CT}: Clinical studies”, *Building the Body of Evidence*

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PLATFORM

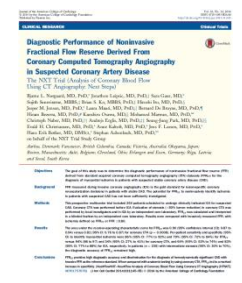
Randomized
Controlled
Trials

Analysis of existing
databases

DISCOVER-FLOW

NXT

DeFACTO



ACS
(- enzyme)
Outcomes and
resources

Stable
Angina
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resources

30-90%
Stenosis
Dx Accuracy

Cath lab
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2012

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...



**Thank you for the
attention**

FFR_{CT} false-negatives and FFR "grey zone"

- 24 vessels had false negative results of FFR_{CT} when compared to FFR.
- FFR 0.75-0.80 ("grey zone"), n=17

FFR_{CT} false-negatives and FFR "grey zone"

- 24 vessels had false negative results of FFR_{CT} when compared to FFR.
- FFR 0.75-0.80 ("grey zone"), n=17
- Assuming, patients with false-negative FFR_{CT} values in the grey zone are in fact true negatives, the NPV for FFR_{CT} increased to 98%.
- Thus, in vessels with FFR_{CT} >0.80 the risk of having an FFR <0.75 is only 2%.

Limitations

- No control over CT image acquisition protocol at clinical sites
- Did not interrogate every vessel with invasive FFR
- Did not solely enroll patients with intermediate stenosis
- Did not test whether FFR_{CT} -based revascularization reduces ischemia

Conclusions

- FFR_{CT} demonstrated **improved accuracy** over CT for diagnosis of patients and vessels with ischemia
 - FFR_{CT} diagnostic accuracy 73% (95% CI 67-78%)
 - Pre-specified primary endpoint >70% lower bound of 95% CI
 - Increased discriminatory power
- FFR_{CT} superior to CT for **intermediate stenoses**
- FFR_{CT} computed **without additional radiation** or imaging
- First large-scale demonstration of **patient-specific computational models to calculate physiologic pressure and velocity fields** from CT images
- **Proof of feasibility of FFR_{CT} for diagnosis of lesion-specific ischemia**