FFR$_{CT}$: Present and Future

Bon-Kwon Koo, MD, PhD

Seoul National University Hospital, Seoul, Korea

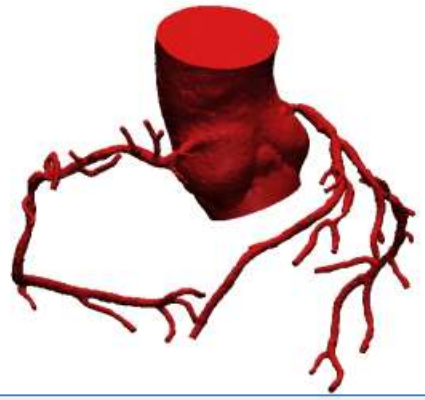
SNUH Seoul National University Hospital
Cardiovascular Center

Patient-specific non-invasive FFR using CT & CFD

Computational Model based on cCTA

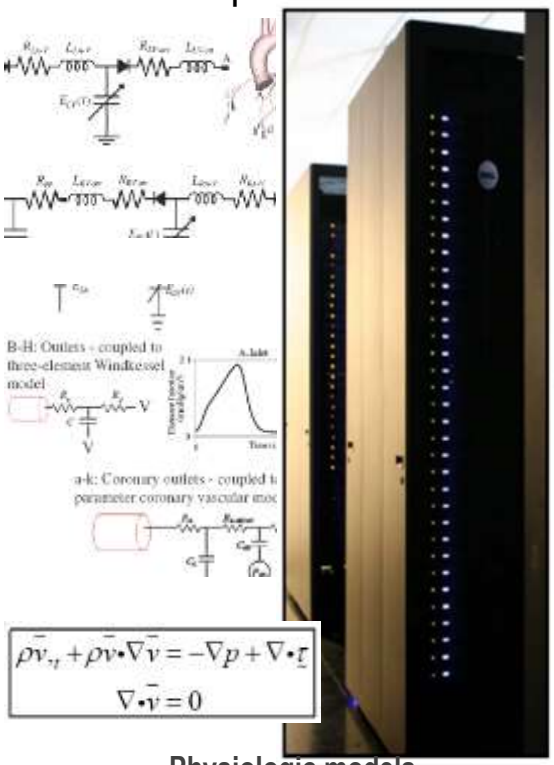
3-D anatomic model from CCTA

No additional imaging
No additional medications



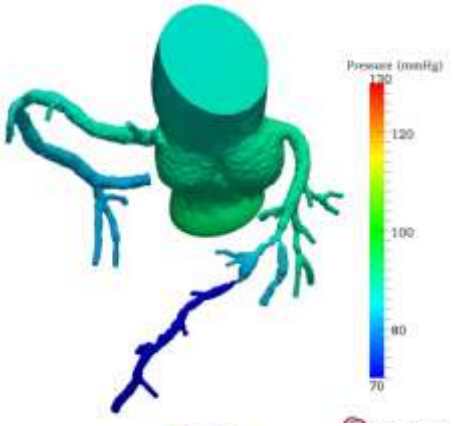
Blood Flow Solution

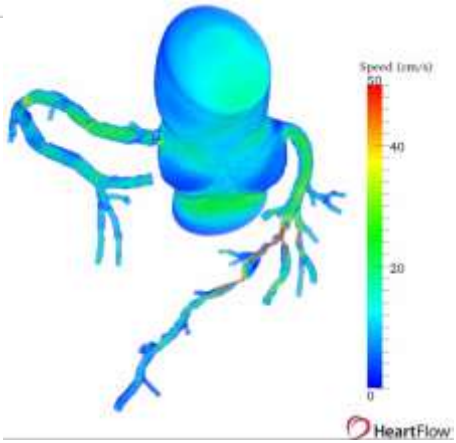
Blood flow equations solved on supercomputer

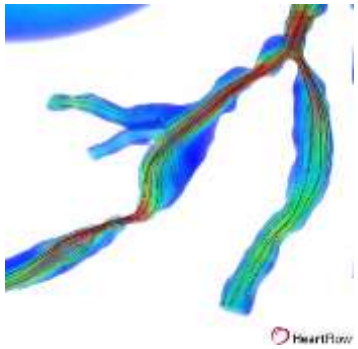


Physiologic models

-Myocardial demand
-Morphometry-based boundary condition
-Effect of adenosine on microcirculation



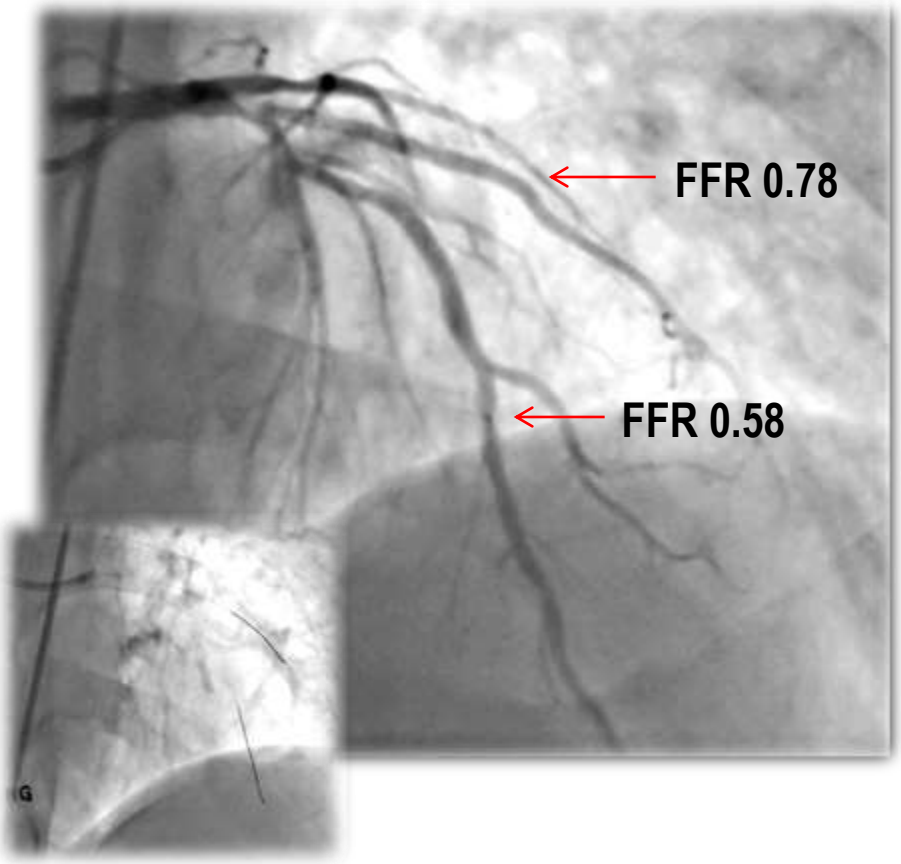


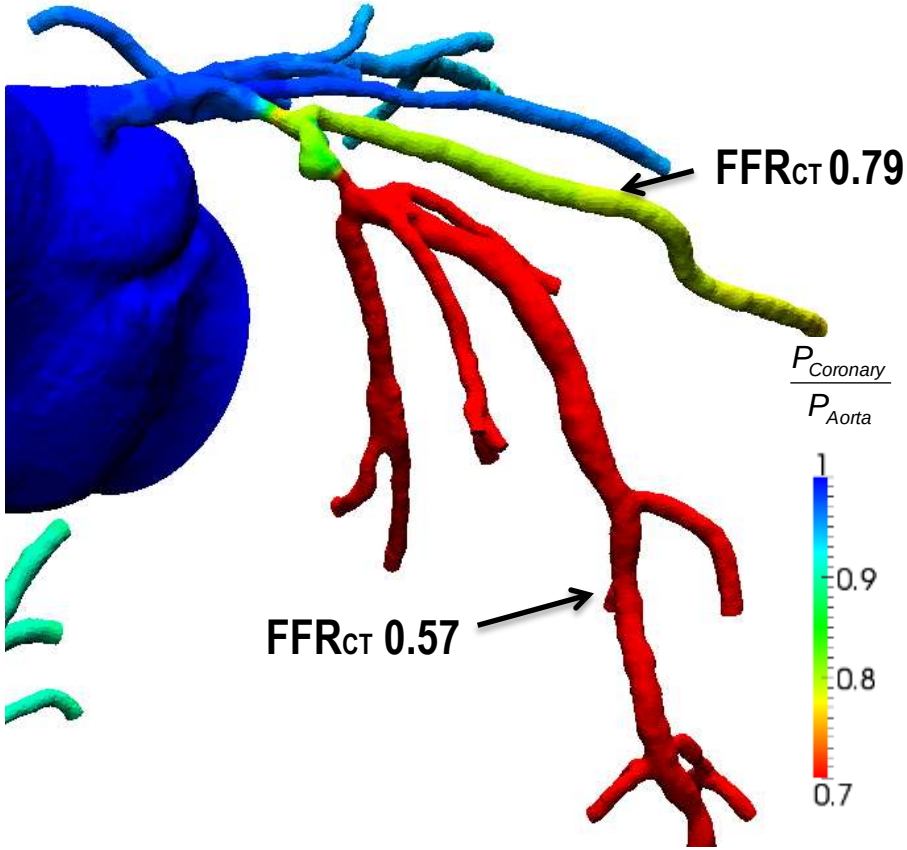


Koo BK, EBC 2011, EuroPCR 2012

LAD-Diagonal bifurcation lesions

(Case #58 from SNUH, Korea)

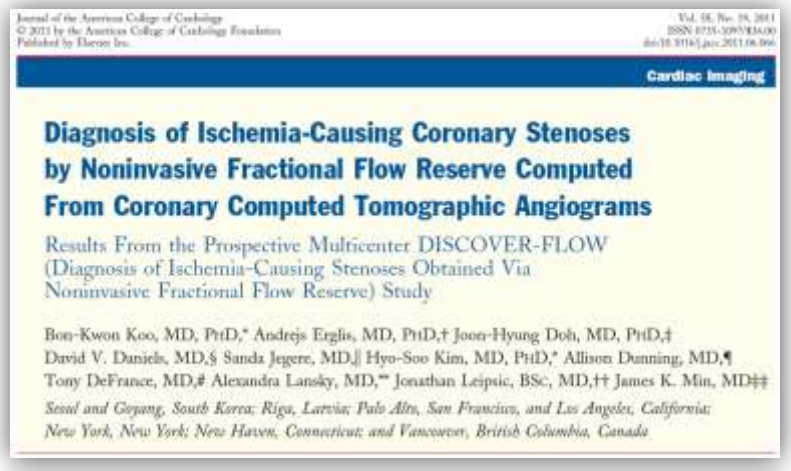




Without invasive procedure
Without pressure wire, without adenosine

Clinical Evidences on Diagnostic Performance

- **DISCOVER-FLOW**
  - 5 center FIH clinical trial
  - Completed 2011
  - N=103 patients
  - Published in JACC
- **DeFACTO**
  - 17 center clinical trial
  - Completed 2012
  - N=252 patients
  - Published in JAMA
- **NXT**
  - 10 center clinical trial
  - Completed August, 2013
  - N=251 patients
  - Published in JACC



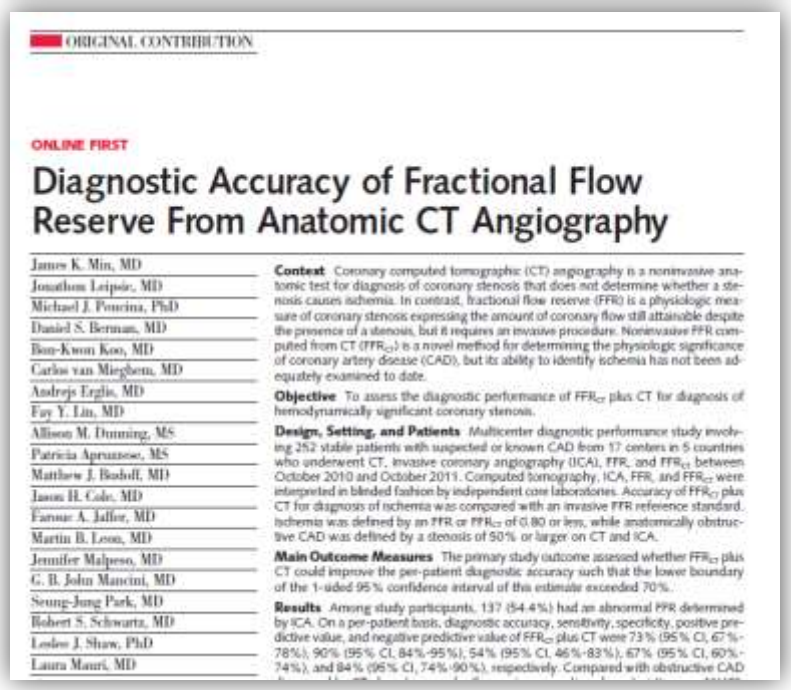
Cardiac Imaging

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



ORIGINAL CONTRIBUTION

ONLINE FIRST

Diagnostic Accuracy of Fractional Flow Reserve From Anatomic CT Angiography

James K. Min, MD
Jonathon Leipsic, MD
Michael J. Pencina, PhD
Daniel S. Berman, MD
Bon-Kwon Koo, MD
Carlos van Mieghem, MD
Andrejs Erglis, MD
Fay Y. Lin, MD
Allison M. Dunning, MS
Patricia Apruzzese, MS
Matthew J. Budoff, MD
Jason H. Cole, MD
Farouc A. Jaffer, MD
Martin B. Leon, MD
Jennifer Malpeso, MD
G. B. John Mancini, MD
Seung-Jung Park, MD
Robert S. Schwartz, MD
Leslee J. Shaw, PhD
Laura Mauri, MD

Context Coronary computed tomographic (CT) angiography is a noninvasive anatomic test for diagnosis of coronary stenosis that does not determine whether a stenosis causes ischemia. In contrast, fractional flow reserve (FFR) is a physiologic measure of coronary stenosis expressing the amount of coronary flow still attainable despite the presence of a stenosis, but it requires an invasive procedure. Noninvasive FFR computed from CT (FFR_{CT}) is a novel method for determining the physiologic significance of coronary artery disease (CAD), but its ability to identify ischemia has not been adequately examined to date.

Objective To assess the diagnostic performance of FFR_{CT} plus CT for diagnosis of hemodynamically significant coronary stenosis.

Design, Setting, and Patients Multicenter diagnostic performance study involving 252 stable patients with suspected or known CAD from 17 centers in 5 countries who underwent CT, invasive coronary angiography (ICA), FFR, and FFR_{CT} between October 2010 and October 2011. Computed tomography, ICA, FFR, and FFR_{CT} were interpreted in blinded fashion by independent core laboratories. Accuracy of FFR_{CT} plus CT for diagnosis of ischemia was compared with an invasive FFR reference standard. Ischemia was defined by an FFR or FFR_{CT} of 0.80 or less, while anatomically obstructive CAD was defined by a stenosis of 50% or larger on CT and ICA.

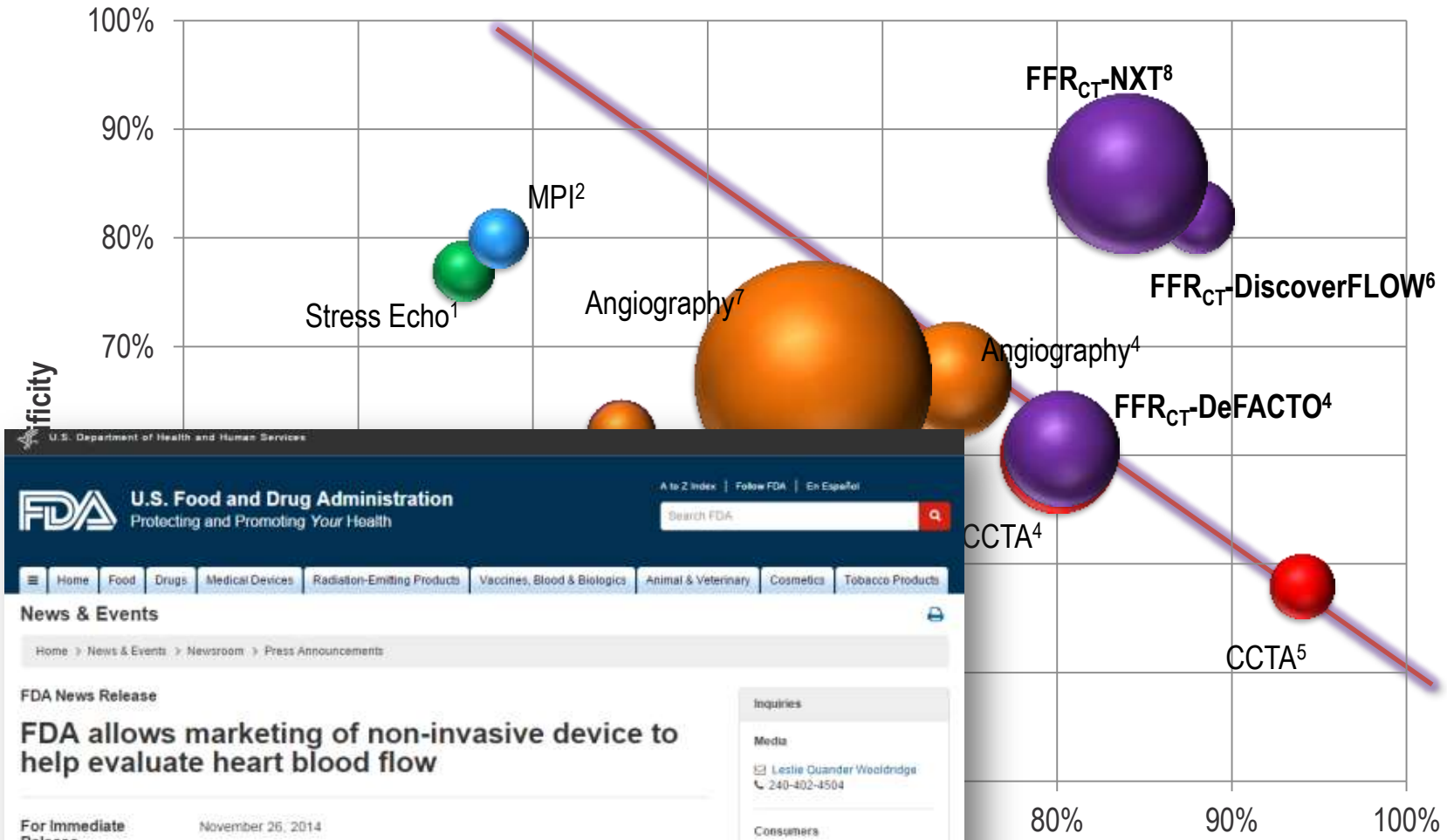
Main Outcome Measures The primary study outcome assessed whether FFR_{CT} plus CT could improve the per-patient diagnostic accuracy such that the lower boundary of the 1-sided 95% confidence interval of this estimate exceeded 70%.

Results Among study participants, 137 (54.4%) had an abnormal FFR determined by ICA. On a per-patient basis, diagnostic accuracy, sensitivity, specificity, positive predictive value, and negative predictive value of FFR_{CT} plus CT were 73% (95% CI, 67%-78%), 90% (95% CI, 84%-95%), 54% (95% CI, 46%-83%), 67% (95% CI, 60%-74%), and 84% (95% CI, 74%-90%), respectively. Compared with obstructive CAD

Diagnostic performance of FFR_{CT}

	Patient No	Sensitivity	Specificity	PPV	NPV	Accuracy
DISCOVER-FLOW	103	93%	82%	85%	91%	87%
DeFACTO	252	90%	54%	67%	84%	73%
NXT	251	86%	79%	65%	92%	81%
	Total: 606	**90%**	**72%**	**72%**	**89%**	**80%**

Non-invasive tests/FFR_{CT}/Angiography vs. FFR



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FDA News Release

FDA allows marketing of non-invasive device to help evaluate heart blood flow

For Immediate Release: November 26, 2014

Release: The U.S. Food and Drug Administration today allowed marketing of the HeartFlow FFR-CT software, which permits health care professionals to non-invasively evaluate blood flow in the coronary arteries of patients showing signs and symptoms of coronary artery disease.

Inquiries

Media

Leslie Quander Wooldridge
240-402-4504

Consumers

888-INFO-FDA

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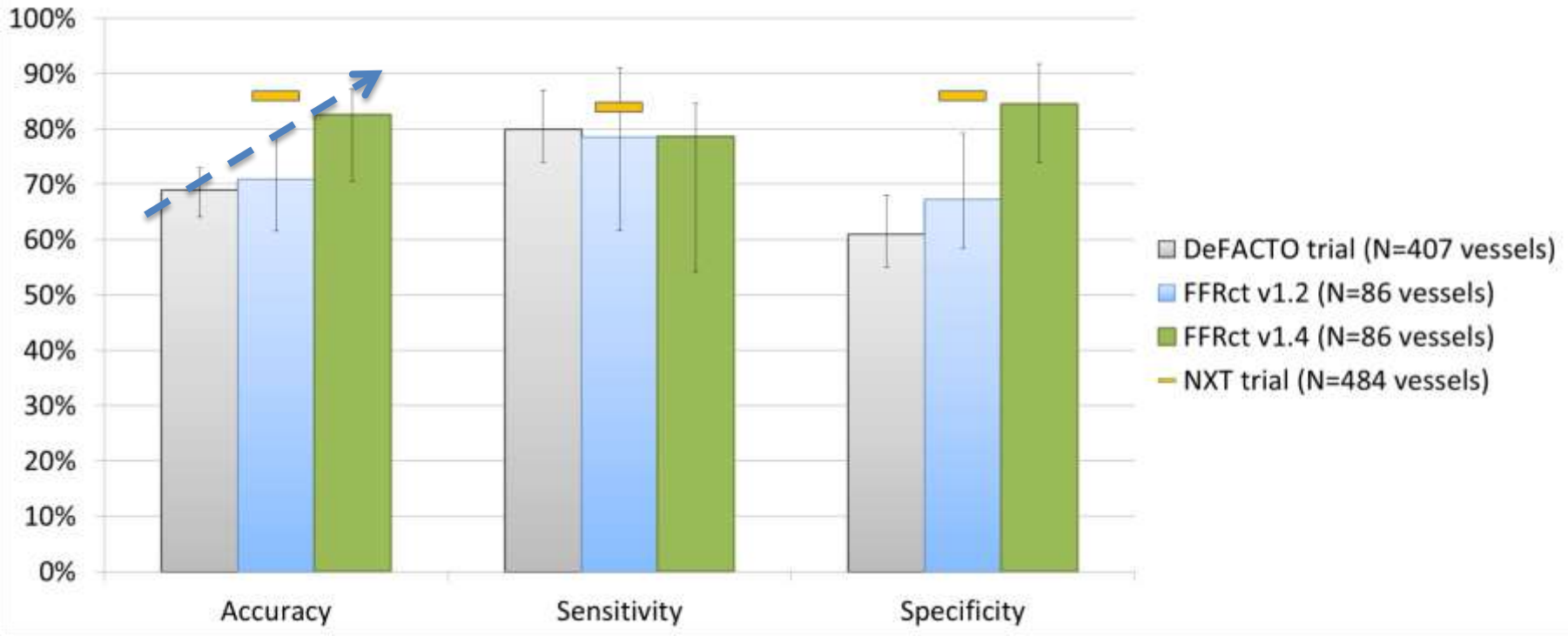
om et al. JACC 2008;52:636–43
al. JACC 2011;58:1989-97
al. JACC 2012

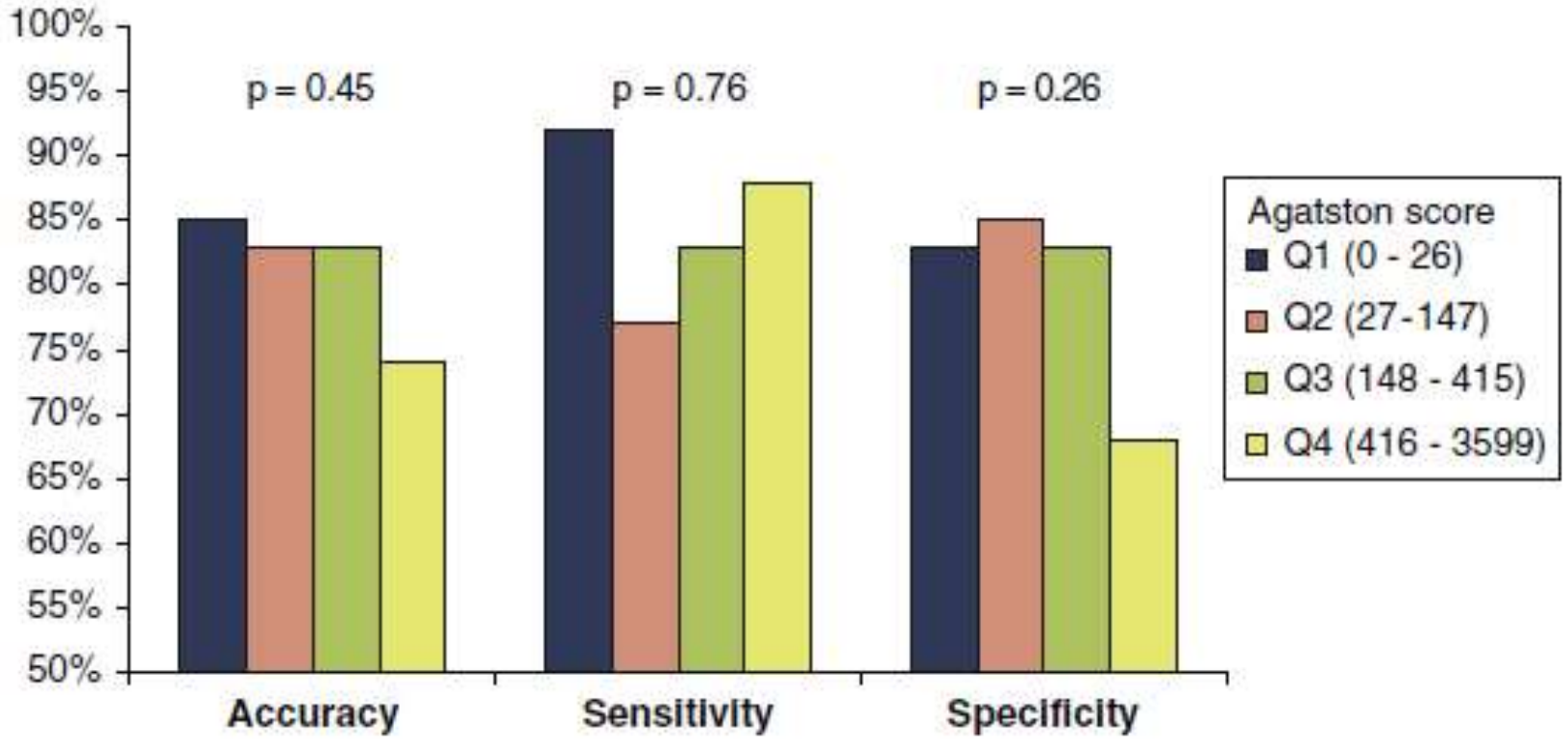
4. Min et al. JAMA 2012;308:1237-1245
8. Norgaard et a. JACC 2014

Impact of CT image quality and updated FFR_{CT} algorithms on FFR_{CT} performance



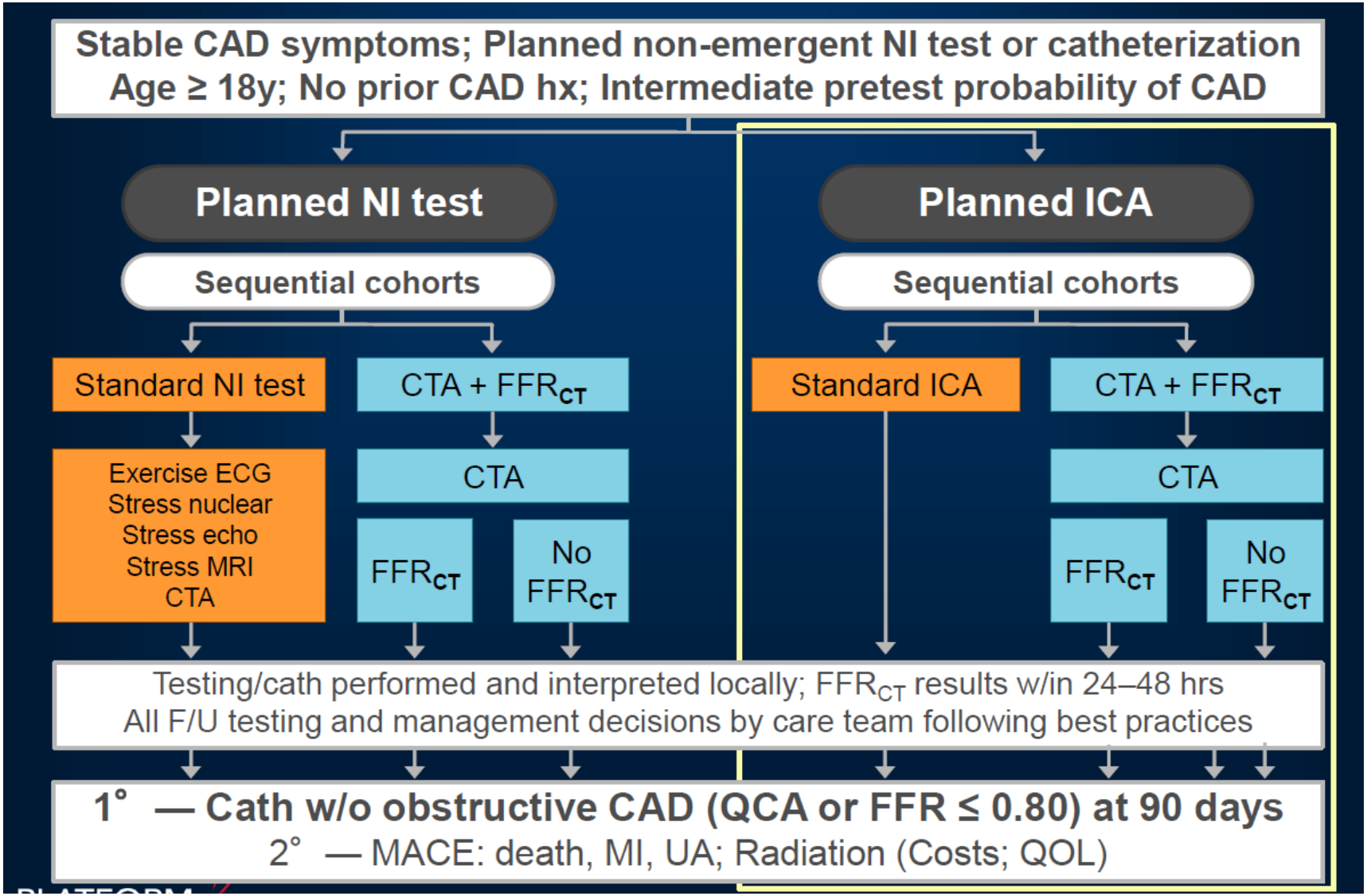
Norgaard et al, SCCT 2014

Impact of CT image quality and updated FFR_{CT} algorithms on FFR_{CT} performance



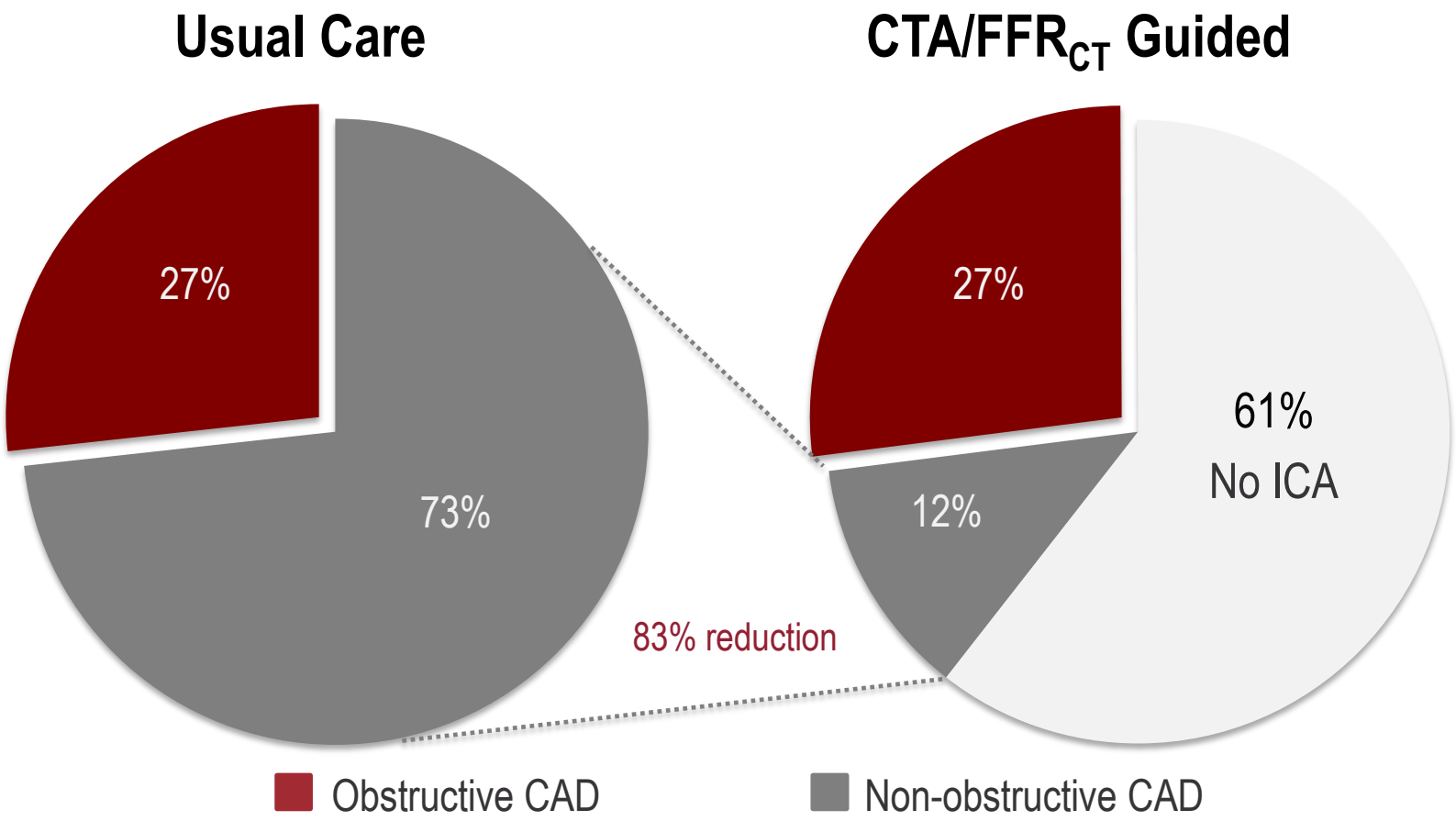
Norgaard et al, JACC imaging 2015

Clinical outcomes of FFR_{CT}-guided decision



Douglas PS, et al. EHJ 2015

Invasive Catheterization (ICA) with No Obstructive Disease



No adverse clinical events in patients in whom ICA was cancelled.

Douglas PS, et al. EHJ 2015

Usual Care Cohort

Patients with suspected CAD

Usual care path

Invasive coronary angiography (ICA)

Revascularization
Obstructive Disease

No obstructive disease found

CTA/FFR_{CT}-Guided Cohort

Patients with suspected CAD

CTA / FFR_{CT}

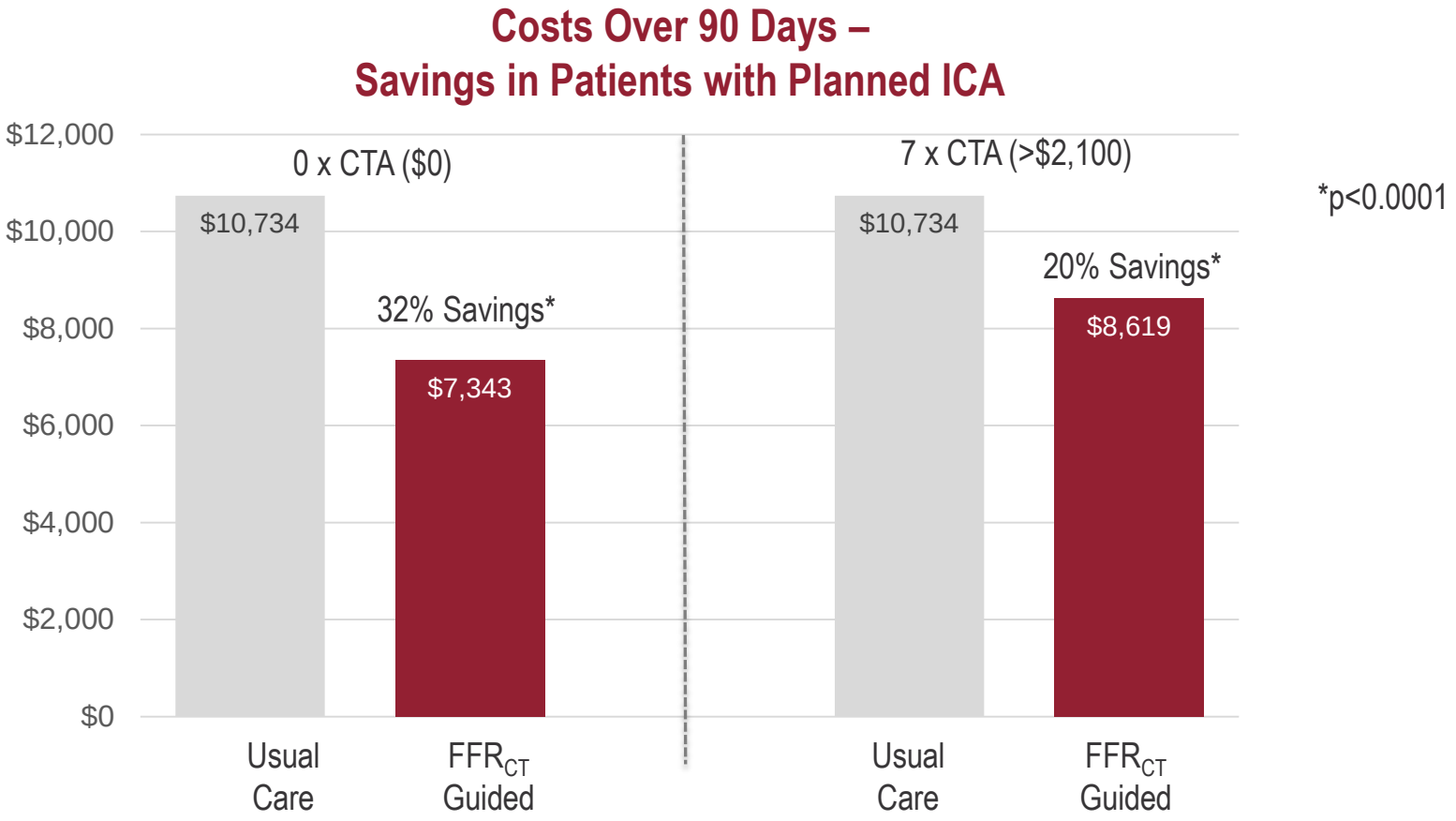
Invasive coronary angiography (ICA)

Revascularization
Obstructive Disease

No obstructive disease found

No need for ICA

Significant Savings for the Health System



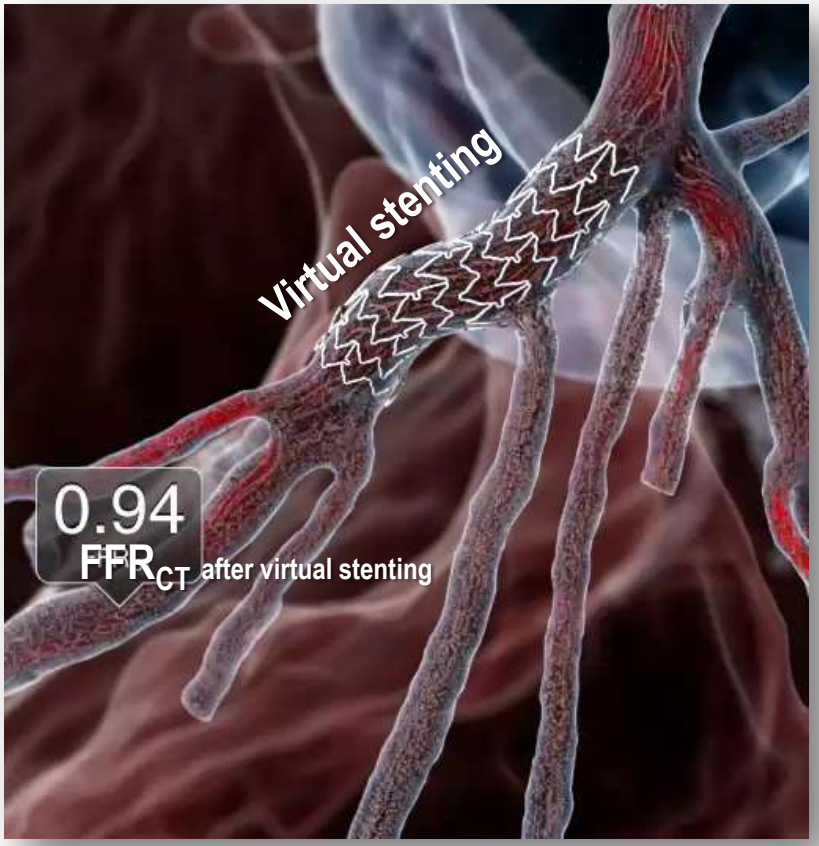
No Medicare reimbursement yet for FFR_{CT}

- Primary analysis used $0 to estimate cost offsets
- Multiples of CTA 2015 Medicare reimbursement ($301) in sensitivity analysis
- Costs equalize when FFR_{CT} reimbursement is 20x CTA

Courtesy of Charles Taylor, PhD

Image-based computerised modelling of coronary circulation: **Future direction**

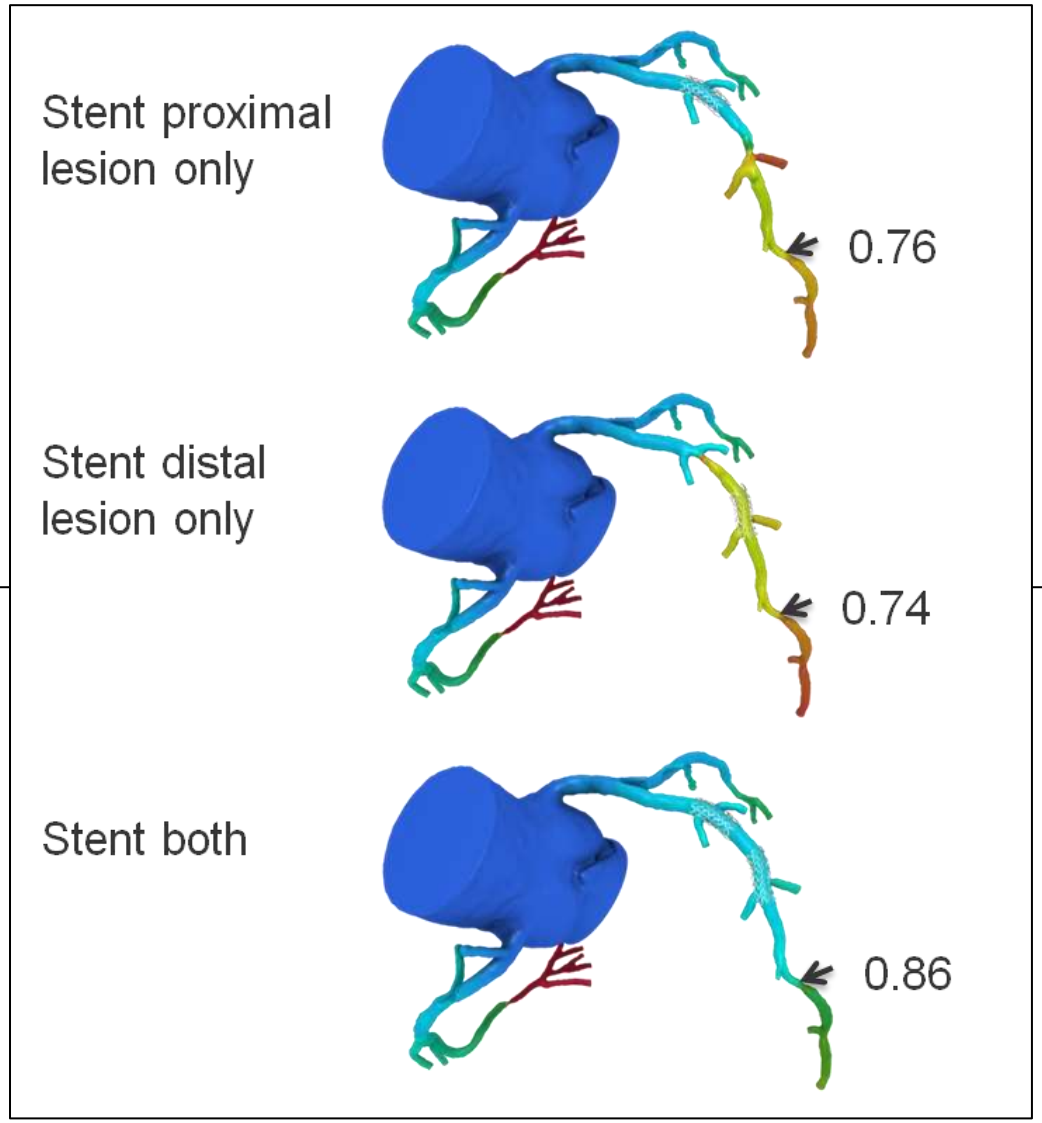
Planning the treatment strategy using **Virtual revascularization & CT-derived computed FFR**



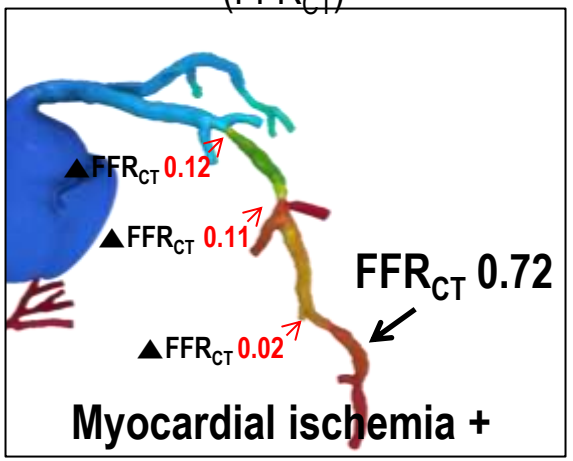
Planning the treatment strategy using
Virtual revascularization & CT-derived computed FFR

Before Stenting

After Stenting

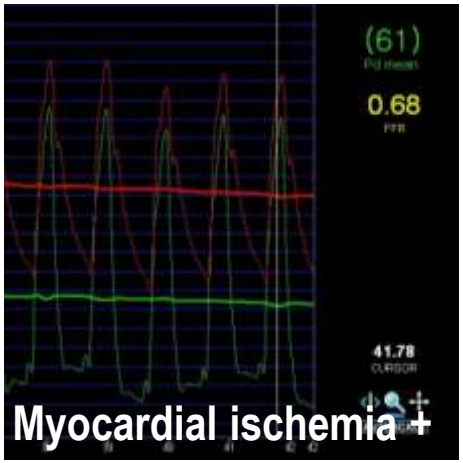
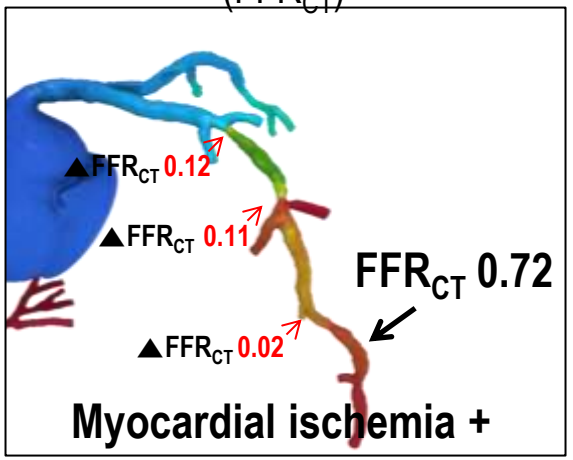
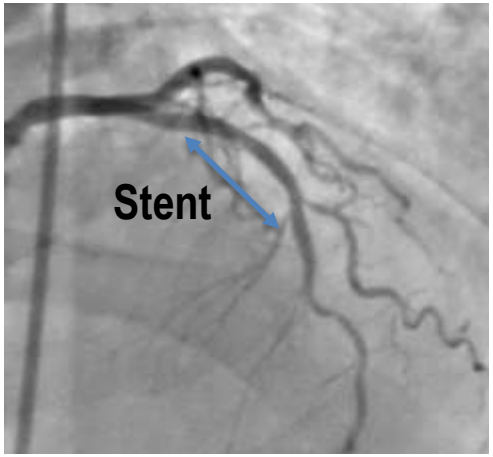
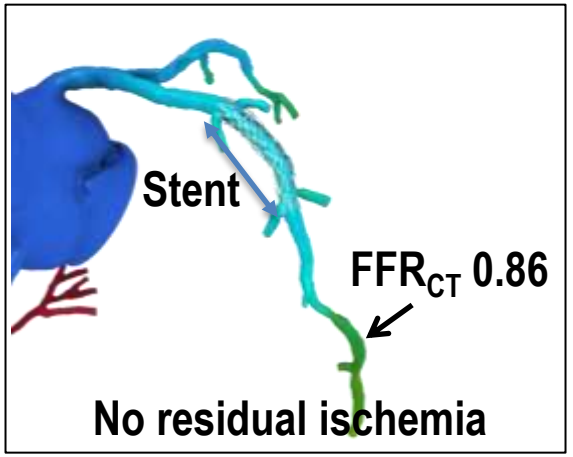


CT-derived computed FFR (FFR_{CT})



Kim KH, Koo BK, et al. JACC interv 2014

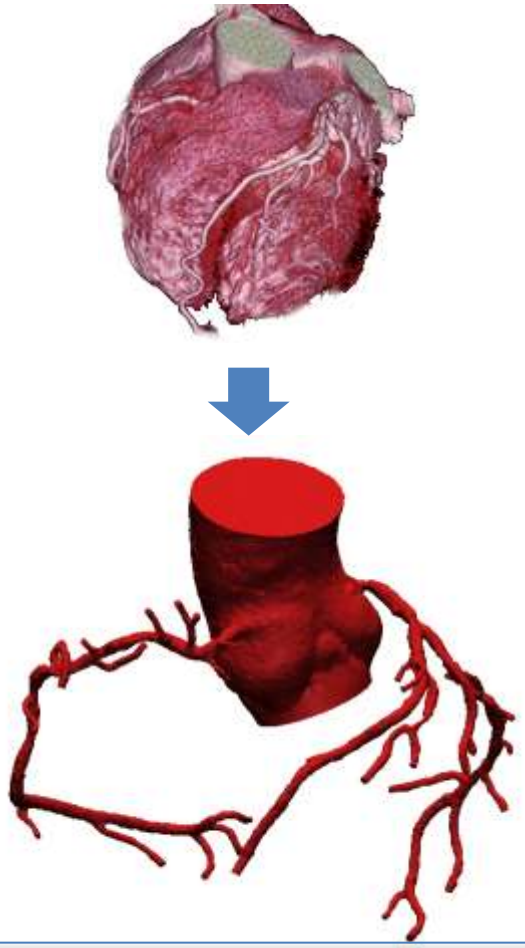
Planning the treatment strategy using
Virtual revascularization & CT-derived computed FFR

	Angiography	Invasive FFR	CT-derived computed FFR (FFR_{CT})
Before Stenting			
After Stenting			

Kim KH, Koo BK, et al. JACC interv 2014

Patient-specific non-invasive coronary hemodynamic assessment

Non-invasive, Pt-specific



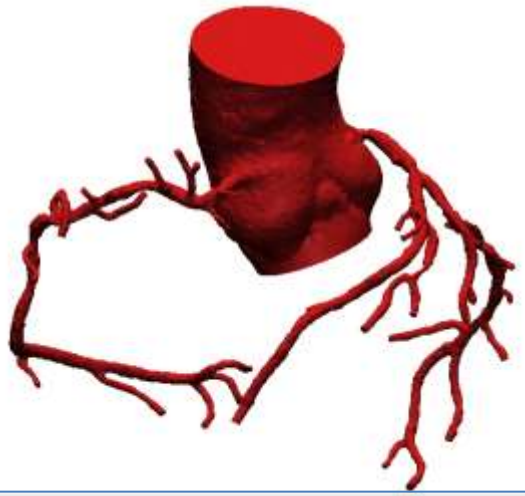
Hemodynamics

- **Pressure**
  - Pressure difference
  - Pressure gradient
  - Pressure recovery
  - **FFR**
- Flow velocity
- Flow rate
- Shear rate
- Shear stress – average, peak, gradient
- Traction
- Oscillatory shear index
- Particle residence time
- Turbulent kinetic energy
- ……..

- **Static**
- Pulsatile
- Resting
- Hyperemic
- Exercise – mild, moderate, peak

Patient-specific non-invasive coronary hemodynamic assessment

Non-invasive, Pt-specific



Hemodynamics

- Pressure
  - Pressure difference
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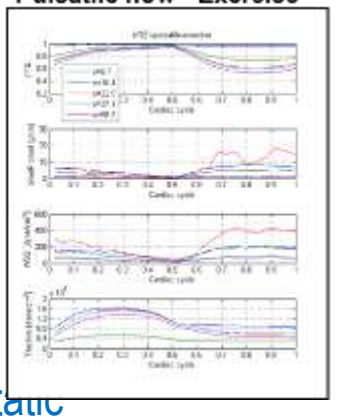
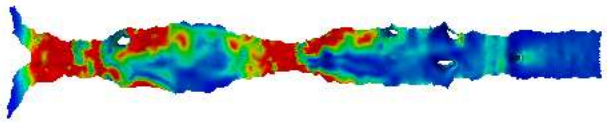
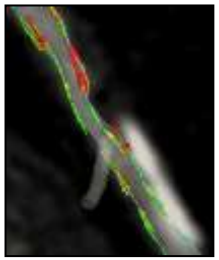
  - FFR
- Flow velocity
- Flow rate
- Shear rate
- Shear stress – average, pe
- Traction
- Oscillatory shear index
- Particle residence time
- Turbulent kinetic energy
- ……

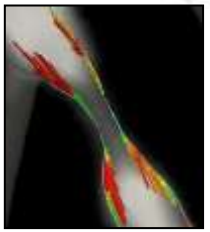
Pulsatile flow - Exercise



- Static
- Pulsatile
- Resting
- Hyperemic
- Exercise – mild, moderate, peak







FFR_{CT}: Present and Future

- Clinical data proved that non-invasive FFR_{CT} can be used to predict the functional significance of coronary stenosis and its application will change the paradigm of current clinical practice.
- FFR_{CT} technology is evolving and its diagnostic performance will also become better.
- Further development of comprehensive hemodynamic assessment and virtual stenting will expand its applicability.