4th Imaging and Physiology Summit
October 29th, 2010
Seoul, Korea

FFR-Guided PCI

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Disclosure Statement of Financial Interest

I, William Fearon, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

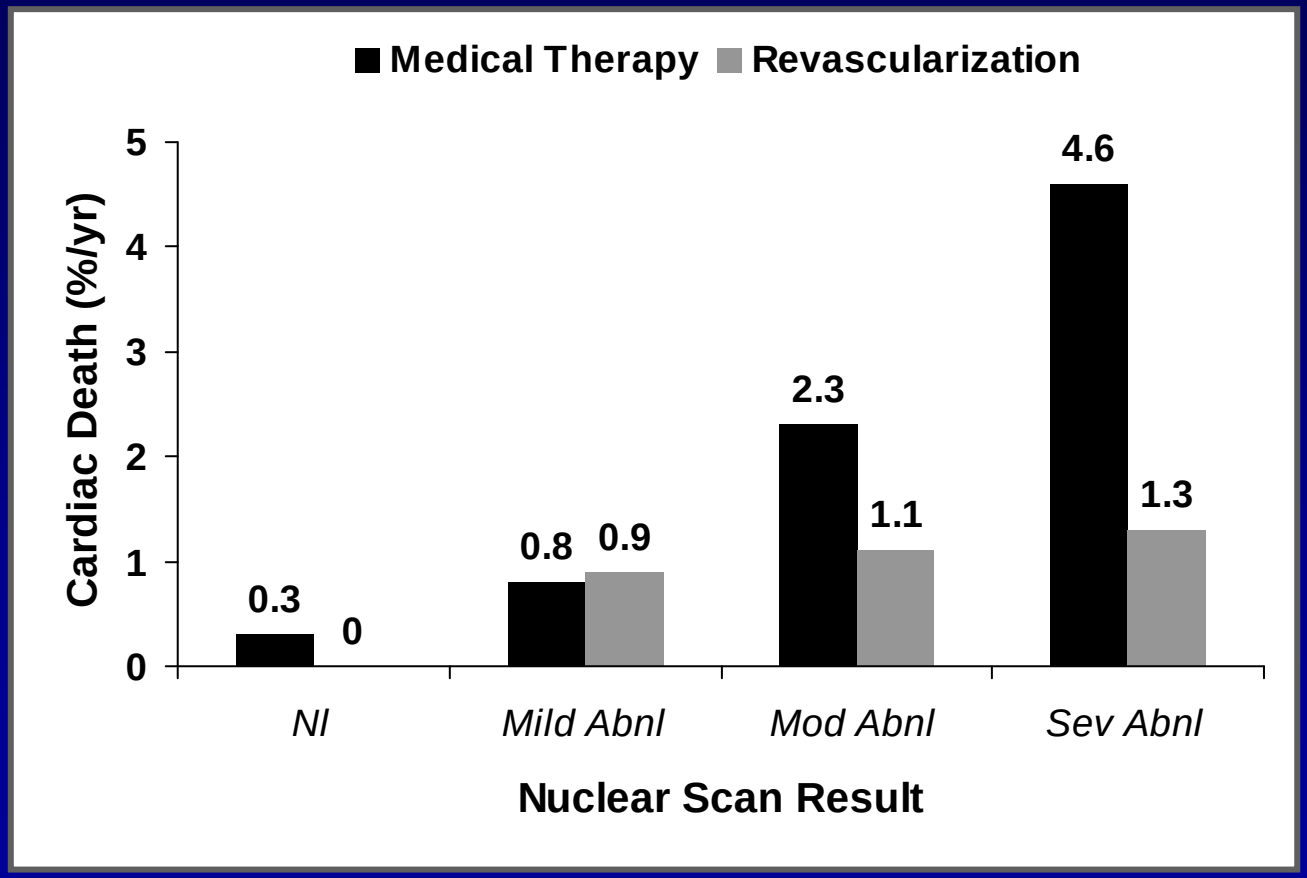
Stanford receives research support from St. Jude Medical.

Why do we need FFR?

- Importance of ischemia
- Limitations of noninvasive testing
- Limitations of angiography
- Limitations of IVUS/OCT

Importance of Ischemia

Nuclear perfusion scans performed in > 5000 patients



Hachamovitch et al. Circulation 1998;97:535-543

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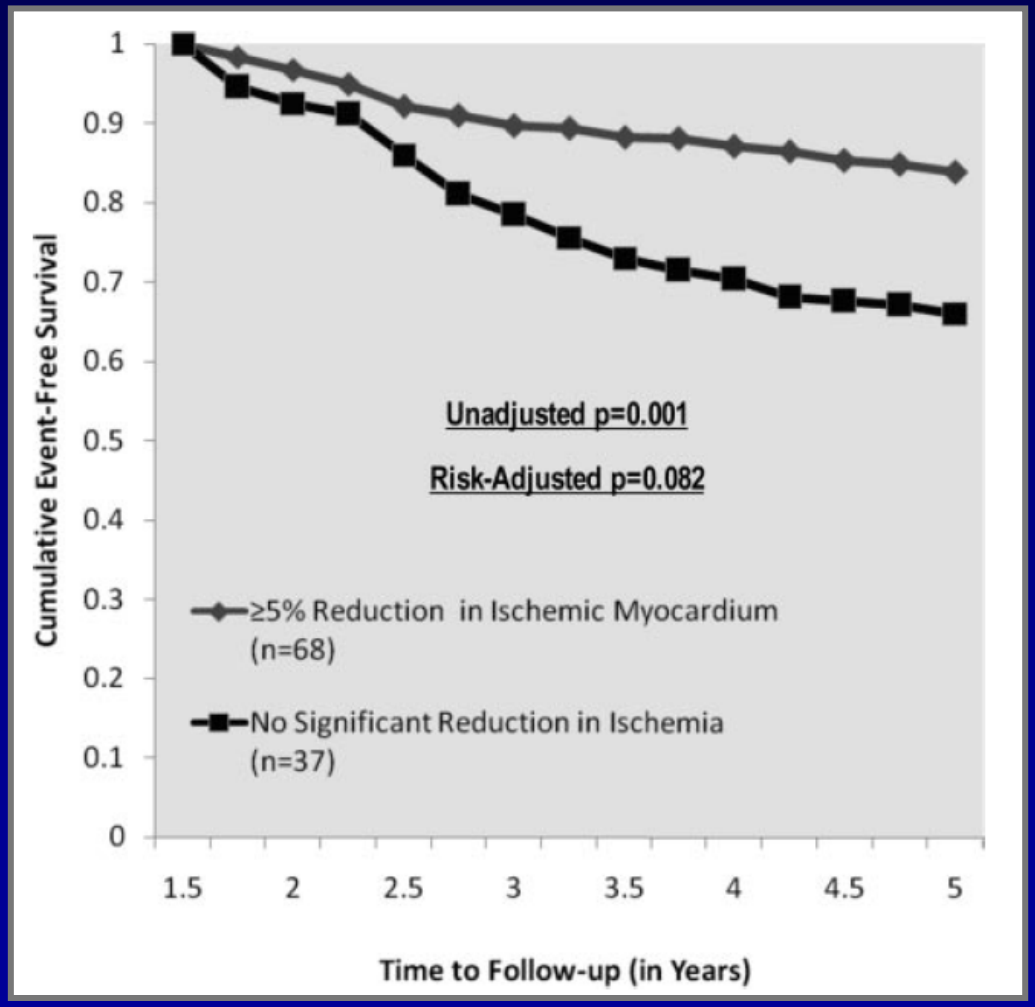
COURAGE Nuclear Substudy

Comparison of death/MI in patients with mod-severe pre-treatment ischemia



Shaw et al. Circulation 2008;117:1283

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Frequency of Stress Testing to Document Ischemia Prior to Elective Percutaneous Coronary Intervention

Grace A. Lin, MD, MAS
R. Adams Dudley, MD, MBA
F. L. Lucas, PhD
David J. Malenka, MD
Eric Vittinghoff, PhD
Rita F. Redberg, MD, MSc

Context Guidelines call for documenting ischemia in patients with stable coronary artery disease prior to elective percutaneous coronary intervention (PCI).

Objective To determine the frequency and predictors of stress testing prior to elective PCI in a Medicare population.

Design, Setting, and Patients Retrospective, observational cohort study using claims data from a 20% random sample of 2004 Medicare fee-for-service beneficiaries aged 65 years or older who had an elective PCI (N=23 887).

Main Outcome Measures Percentage of patients who underwent stress testing within 90 days prior to elective PCI; variation in stress testing prior to PCI across 306 hospital referral regions; patient, physician, and hospital characteristics that predicted the appropriate use of stress testing prior to elective PCI.

Results In the United States, 44.5% (n=10 629) of patients underwent stress testing within the 90 days prior to elective PCI. There was wide regional variation among the hospital referral regions with stress test rates ranging from 22.1% to 70.6% (national mean, 44.5%; interquartile range, 39.0%-50.9%). Female sex (adjusted odds ratio [AOR], 0.91; 95% confidence interval [CI], 0.86-0.97), age of 85 years or older (AOR, 0.83; 95% CI, 0.72-0.95), a history of congestive heart failure (AOR, 0.85; 95% CI, 0.79-0.92), and prior cardiac catheterization (AOR, 0.45; 95% CI, 0.38-0.54) were associated with a decreased likelihood of prior stress testing. A history of chest pain (AOR, 1.28; 95% CI, 1.09-1.54) and black race (AOR, 1.26; 95% CI, 1.09-1.46) increased the likelihood of stress testing prior to PCI. Patients treated by physicians performing 150 or more PCIs per year were less likely to have stress testing prior to PCI (AOR, 0.84; 95% CI, 0.77-0.93). No hospital characteristics were associated with receipt of stress testing.

Conclusion The majority of Medicare patients with stable coronary artery disease do not have documentation of ischemia by noninvasive testing prior to elective PCI.

JAMA. 2008;300(15):1765-1773 www.jama.com

In the United States, percutaneous coronary intervention (PCI) has become a common treatment strategy for patients with stable coronary artery disease (CAD) and such patients now account for the majority of PCIs performed.[1,2] However, multiple studies have established that some important outcomes for patients with stable CAD (death and risk of future myocardial infarction) do not differ between patients treated with PCI plus optimal medical therapy and patients treated with optimal medical therapy alone.[3-10] The addition of PCI does offer quicker relief of angina than medical therapy alone but also carries an increased risk of repeat revascularization, late-stent thrombosis, and a decreased

JAMA 2008;300:1765

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FFR vs. Nuclear Perfusion Scan in MVD

67 patients with angiographic 2 or 3 vessel CAD

B

FFR	MPI positive	MPI negative
< 0.80	38	42
> 0.80	24	97

Melikian et al. J Am Coll Cardiol Int 2010;3:307-14

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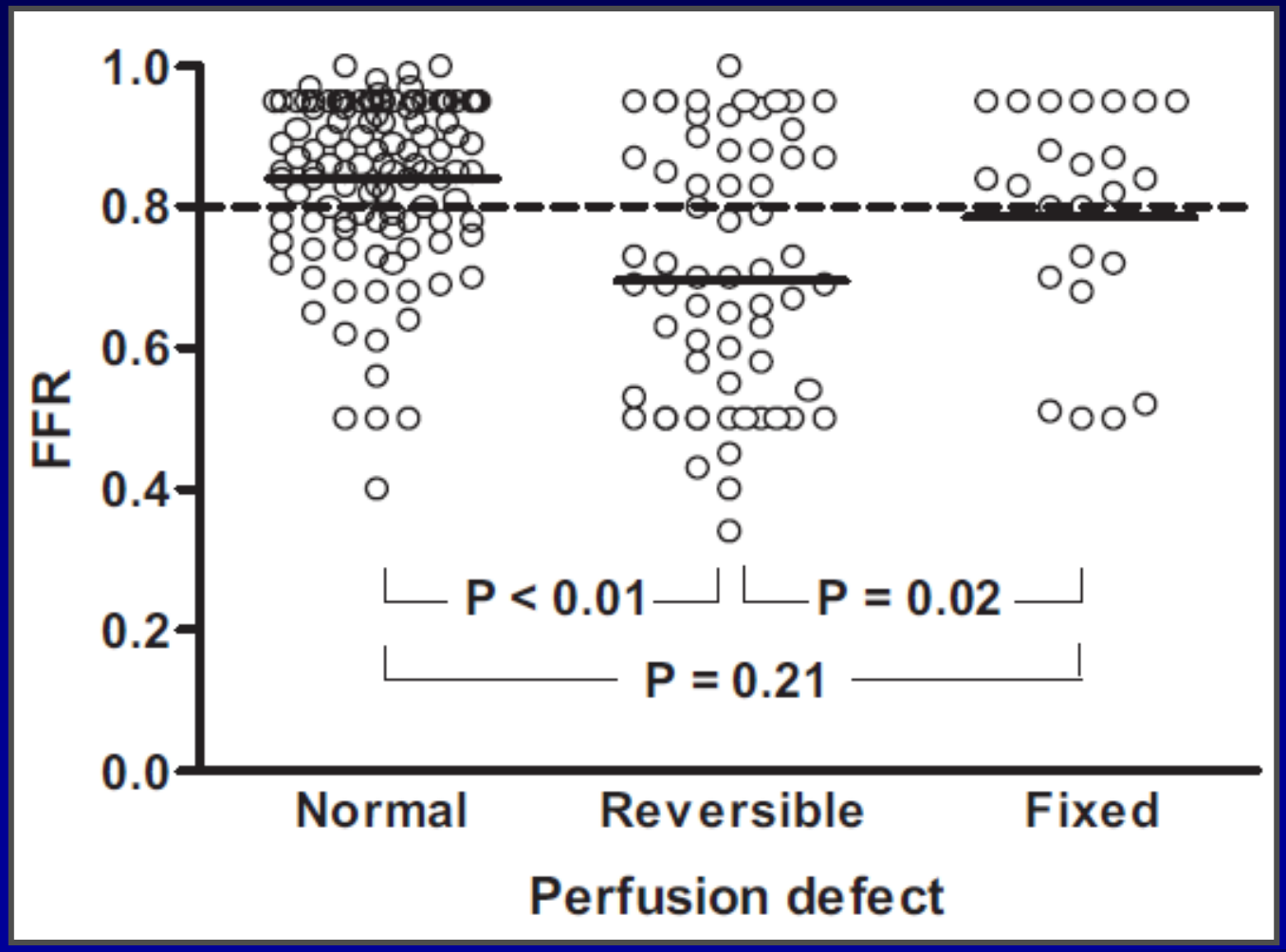
FFR vs. Nuclear Perfusion Scan in MVD

67 patients with angiographic 2 or 3 vessel CAD



Melikian et al. J Am Coll Cardiol Int 2010;3:307-14

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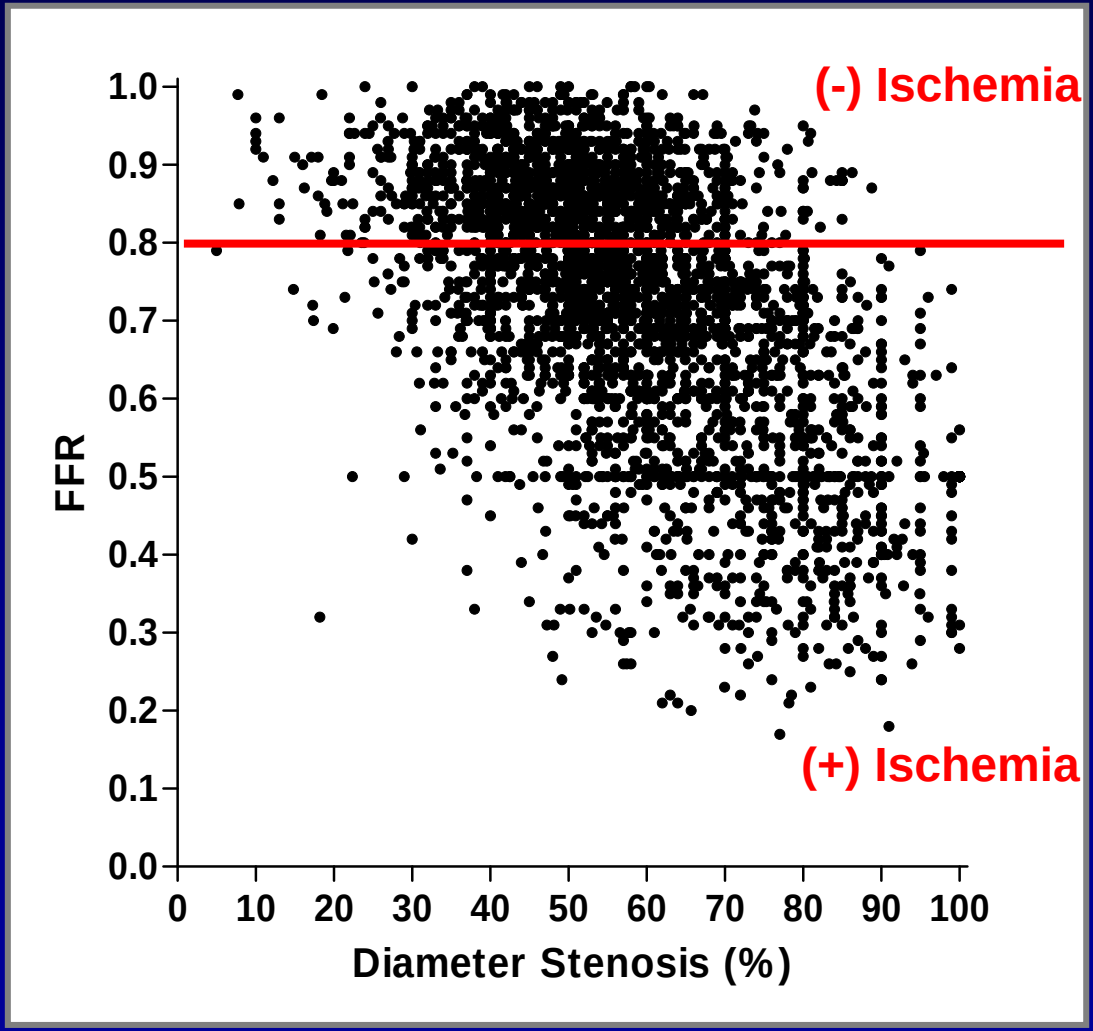
Limitation of Angiography

Comparison of QCA to FFR in over 3,000 lesions



Courtesy of Bernard De Bruyne, MD, PhD

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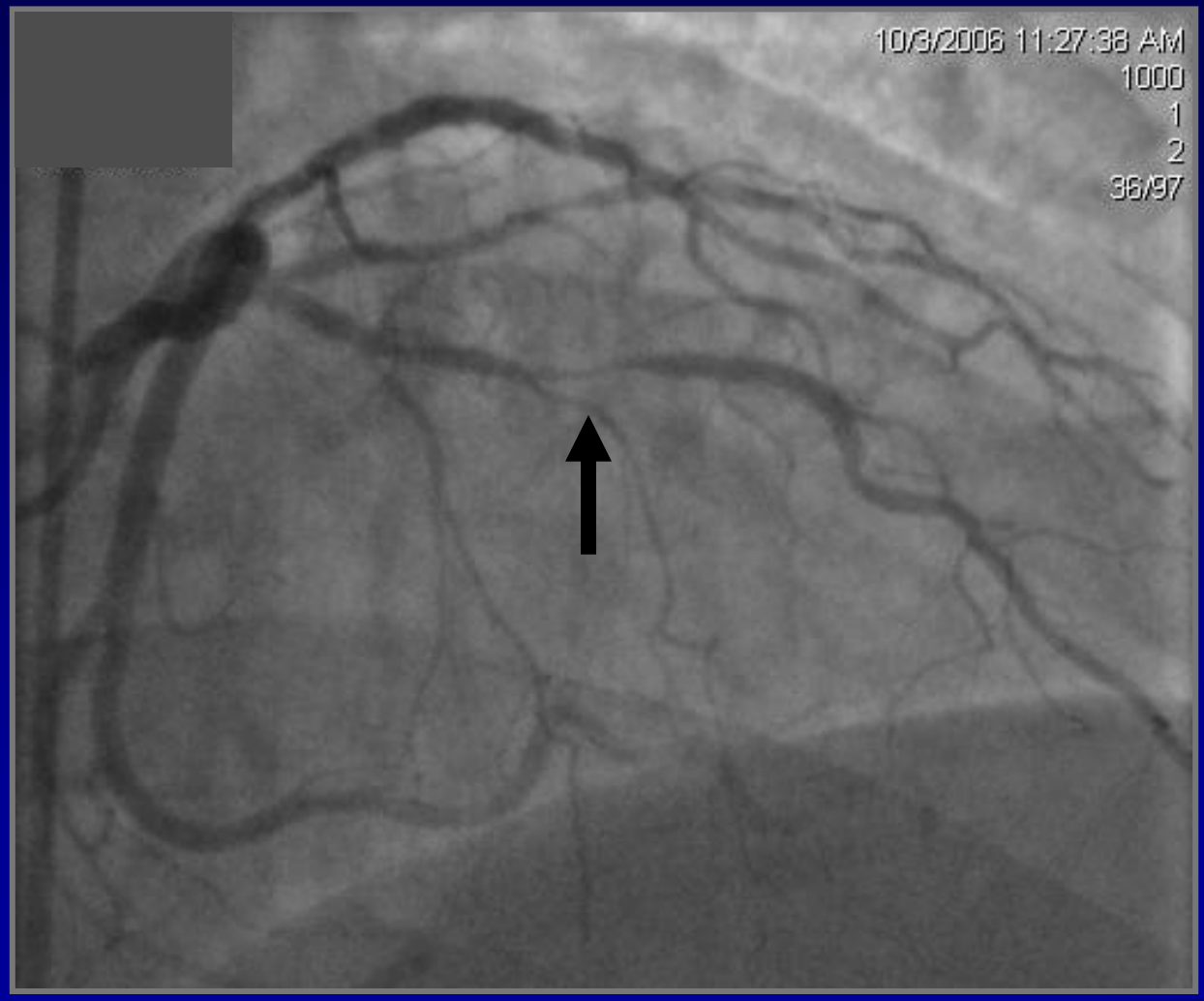
FFR should not guide *ALL* PCI!

70 year old man with angina and anterior ischemia



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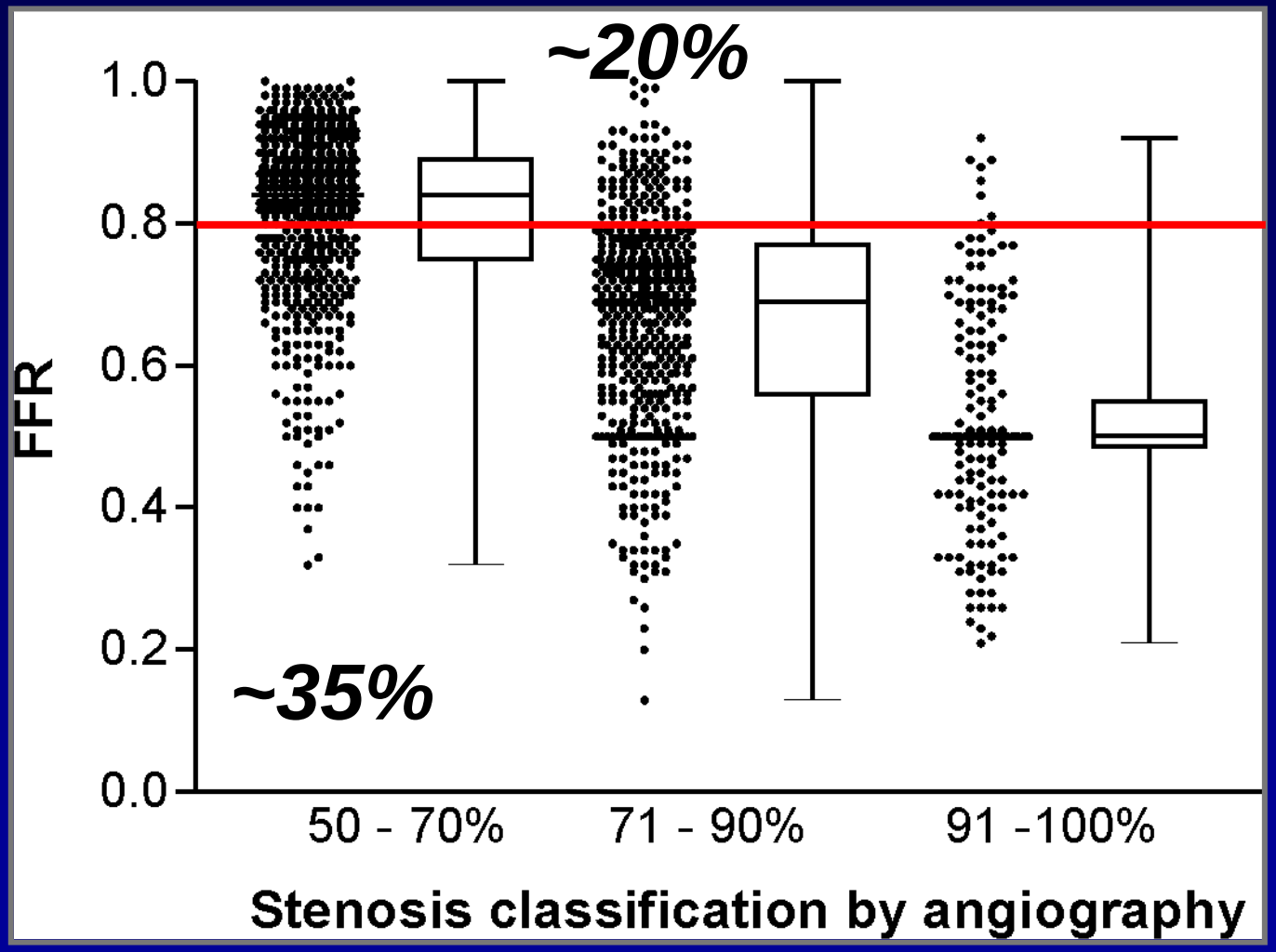
When should we use FFR?

- In patients with coronary narrowings in the 50-90% range and unclear, equivocal or absent noninvasive stress imaging studies.
  - Most commonly in patients with multivessel CAD.

Which Lesions Need FFR?

1329 lesions in the FFR-guided arm of the FAME Study



J Am Coll Cardiol 2010;55:2816-21.

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Why should FFR Guide PCI?

- Improves outcomes
- Saves money
- PCI of intermediate lesions is not benign
- Medical treatment of hemodynamically insignificant lesions is safe
- FFR-guided PCI can simplify a procedure and may increase PCI volume

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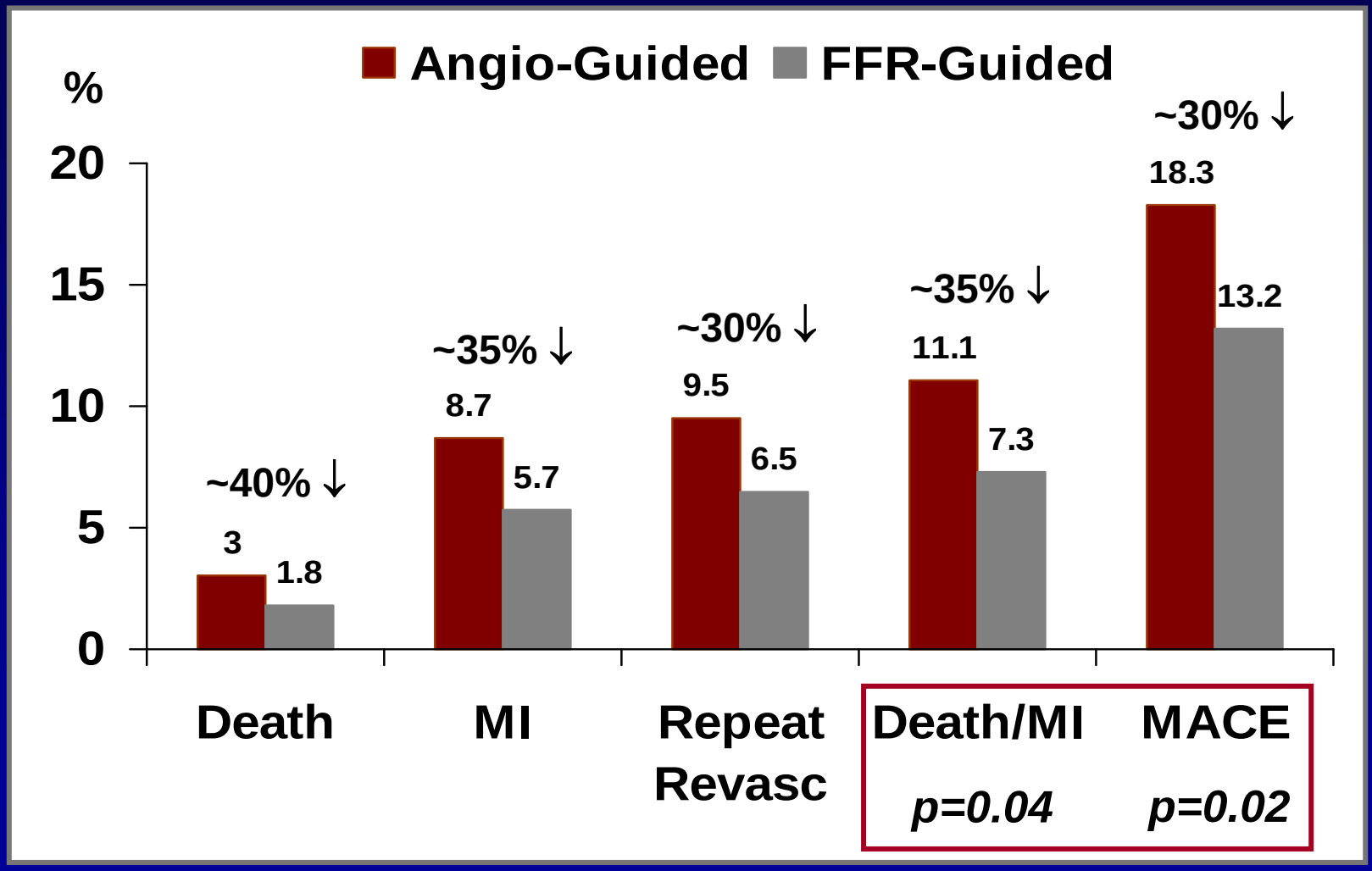
FAME Study: One Year Outcomes

Over 1,000 patients with MVD undergoing PCI and randomized to FFR or angiographic guidance alone



New Engl J Med 2009;360:213-24.

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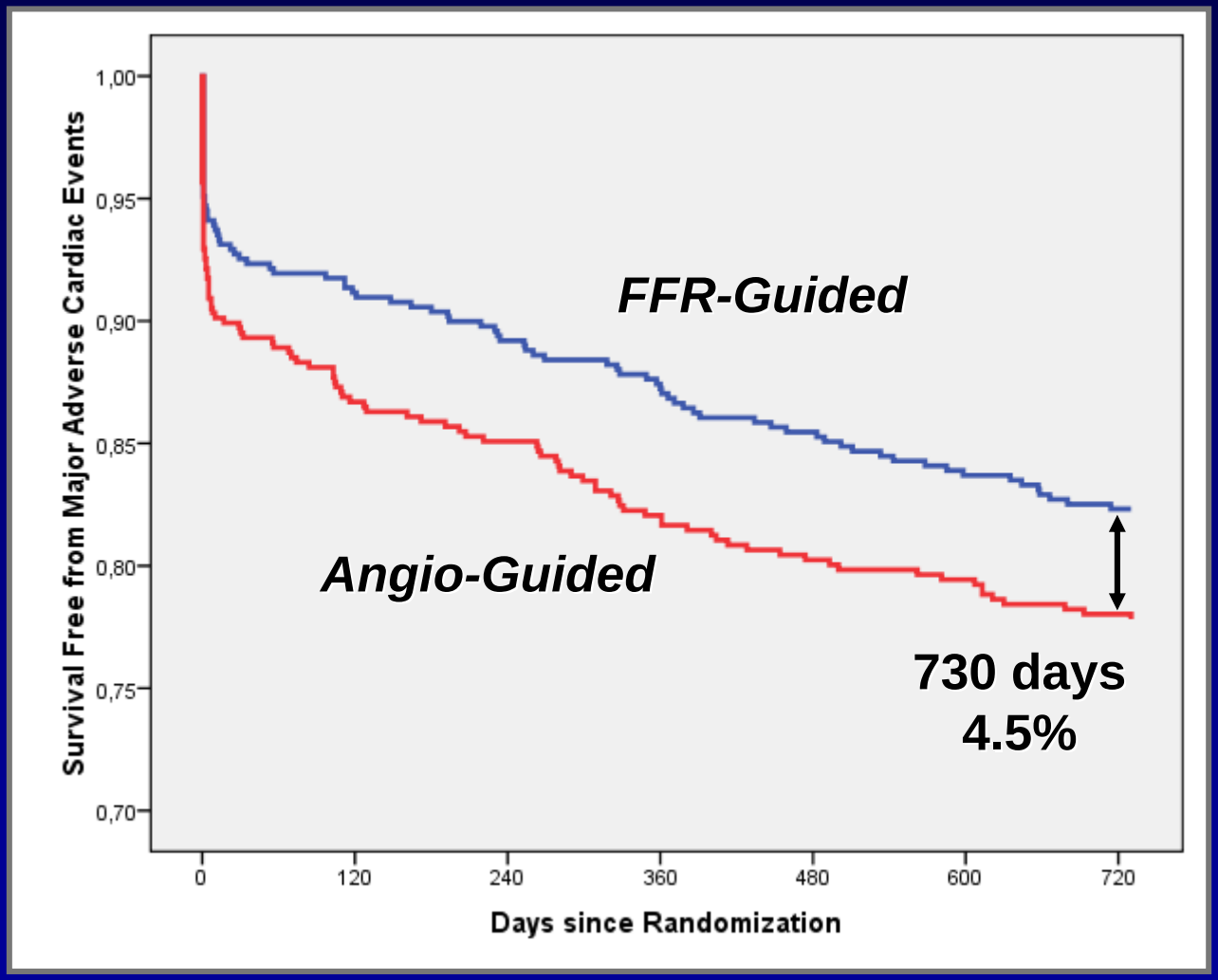
FAME Study: Two Year Outcomes



J Am Coll Cardiol 2010;56:177-184

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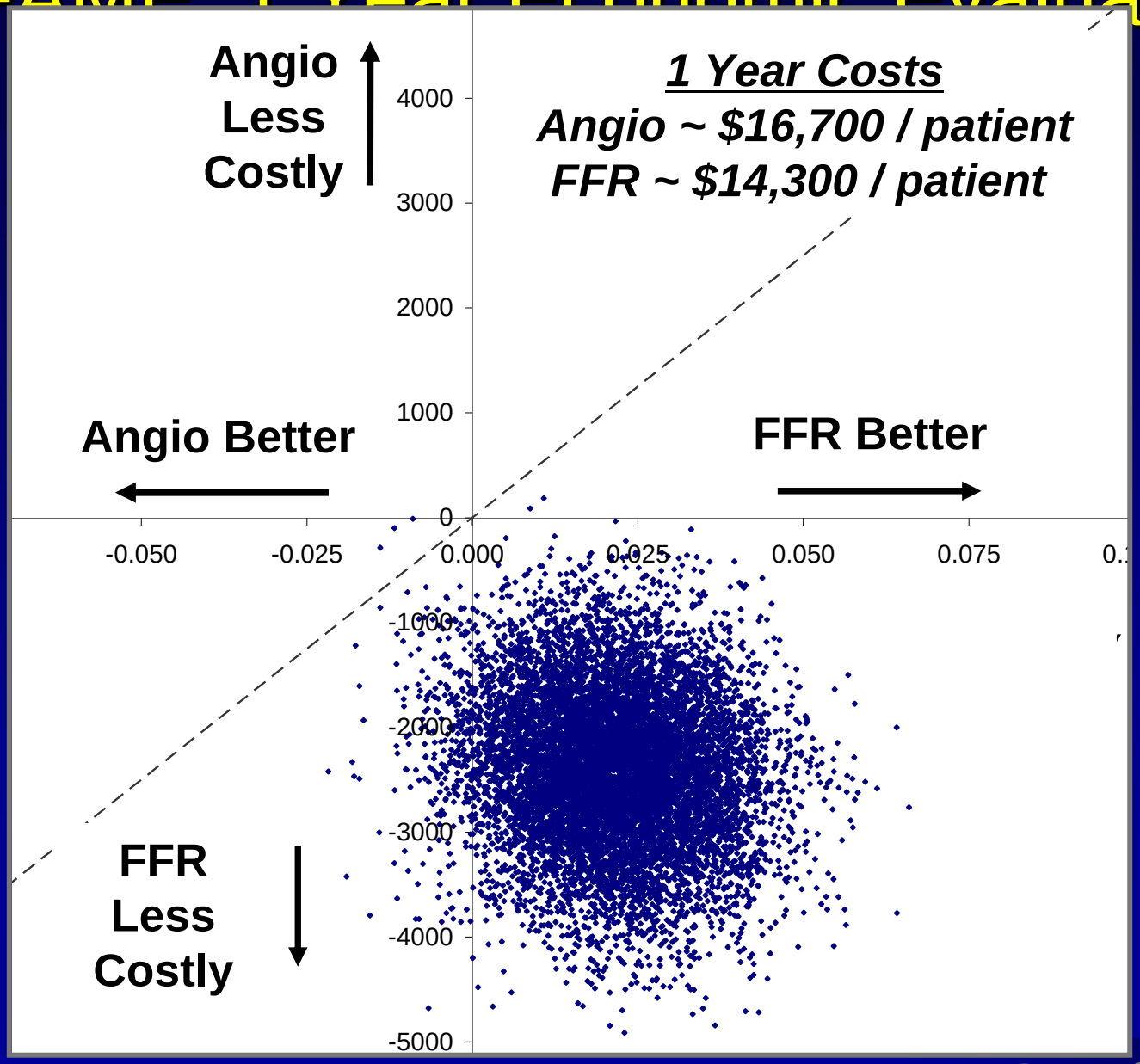
FAME: 1 Year Economic Evaluation



Fearon, et al. Circulation 2010; (in press)

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- FFR-guided PCI can simplify a procedure and may increase PCI volume

Should we perform PCI in *all* intermediate lesions?

Drug-Eluting Stents in the Treatment of Intermediate Lesions

Pooled Analysis From Four Randomized Trials

Jeffrey W. Moses, MD, FACC,* Gregg W. Stone, MD, FACC,* Eugenia Nikolsky, MD, PHD, FACC,* Gary S. Mintz, MD, FACC,* George Dangas, MD, PHD, FACC,* Eberhard Grube, MD,† Stephen G. Ellis, MD, FACC,‡ Alexandra J. Lansky, MD, FACC,* Giora Weisz, MD,* Martin Fahy, MSC,* Yingbo Na, MSC,* Mary E. Russell, MD, FACC,§ Dennis Donohoe, MD,‖ Martin B. Leon, MD, FACC,* Roxana Mehran, MD, FACC*

New York, New York; Siegburg, Germany; Cleveland, Ohio; Natick, Massachusetts; and Warren, New Jersey

92 lesions with QCA < 50% stenosis treated with DES

Moses JW, et al. J Am Coll Cardiol 2006;47:2164-71.

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What is the Expected MACE in DES-Treated Intermediate Lesions?

1 year events in 92 intermediate lesions treated with DES

1-yr (cumulative)	
Cardiac death, n (%)	0 (0)
Myocardial infarction, n (%)	3 (3.4)
Q-wave	0 (0)
Non–Q-wave	3 (3.4)
Stent thrombosis, n (%)	0 (0)
Target lesion revascularization, n (%)	1 (1.2)
Target vessel revascularization, n (%)	3 (3.4)
Composite adverse cardiac events, n (%)*	5 (5.6)

1 Year Cardiac Death and MI rate of 3.4%

Moses JW, et al. J Am Coll Cardiol 2006;47:2164-71.

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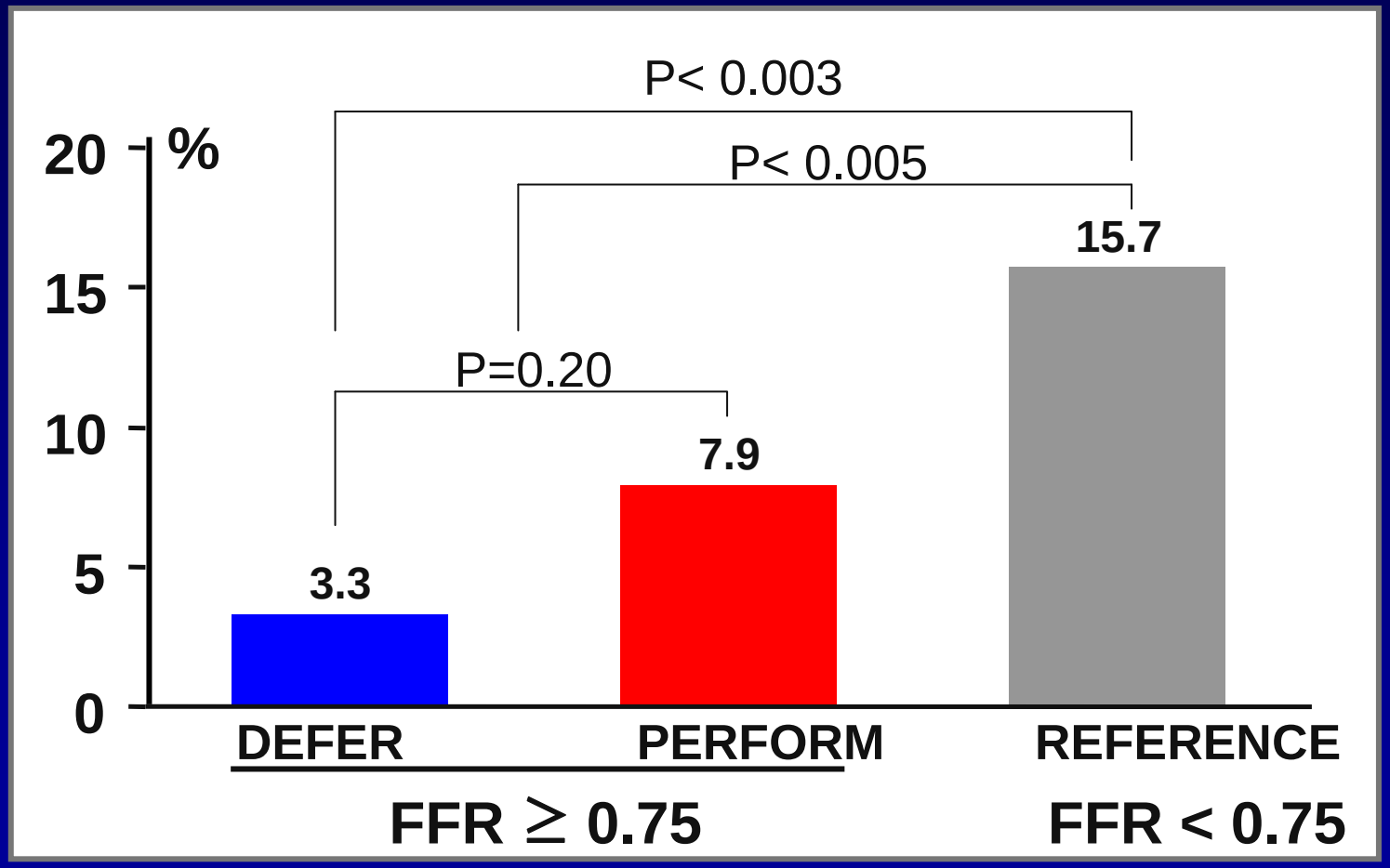
5 Year Cardiac Death / MI in DEFER study

181 patients with intermediate lesions and FFR ≥0.75 randomized to PCI or deferral



Pijls et al. J Am Coll Cardiol 2007;49:2105-11

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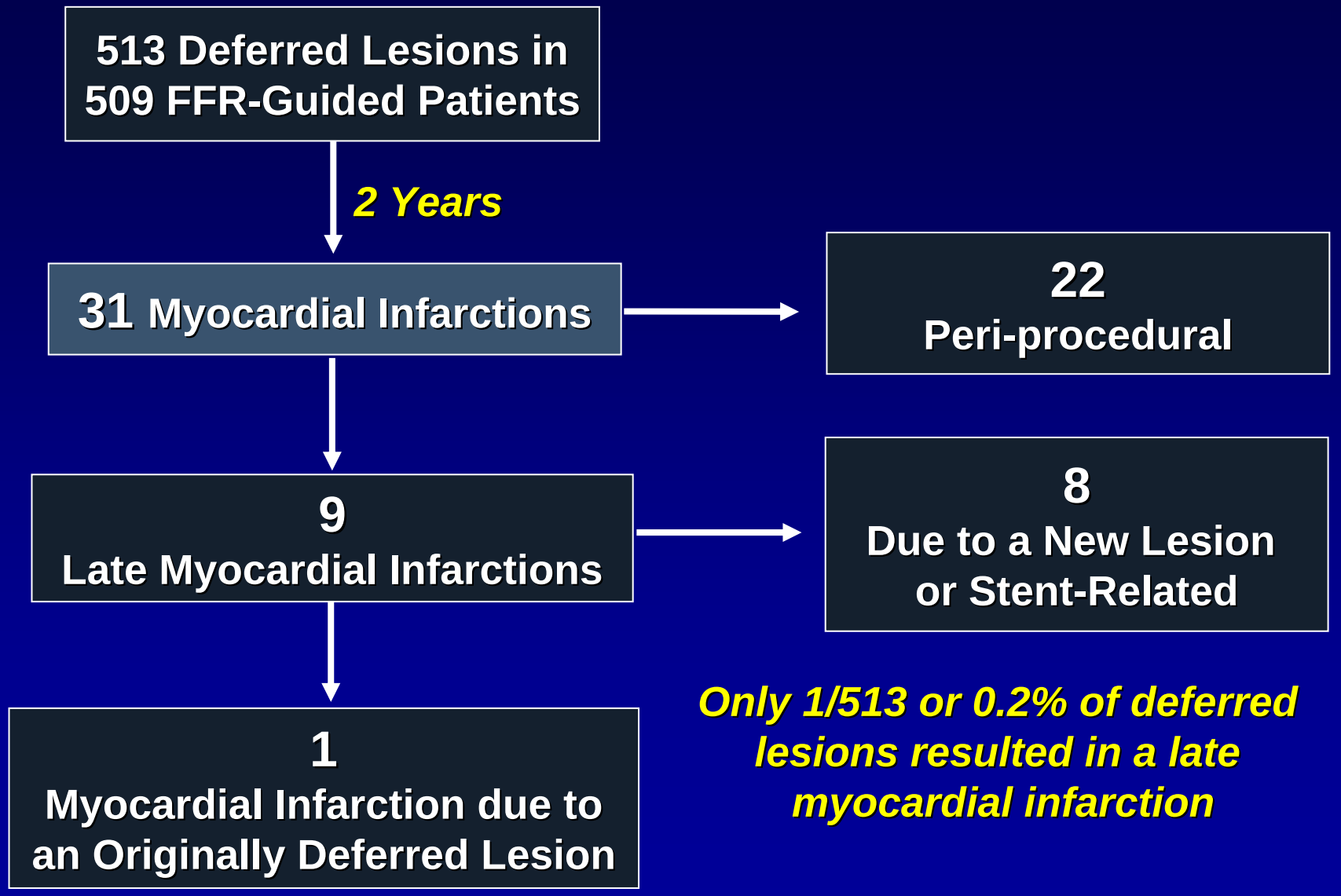
2 Year Outcome of Deferred Lesions in FAME



Only 1/513 or 0.2% of deferred lesions resulted in a late myocardial infarction

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Why should FFR Guide PCI?

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Recent Case: “Mr. H.”

- 79 year old retired physicist with angina
- Risk factors include HTN and dyslipidemia
- Stress echo revealed anteroseptal and apical ischemia
- Referred for coronary angiography on September 10th, 2010…

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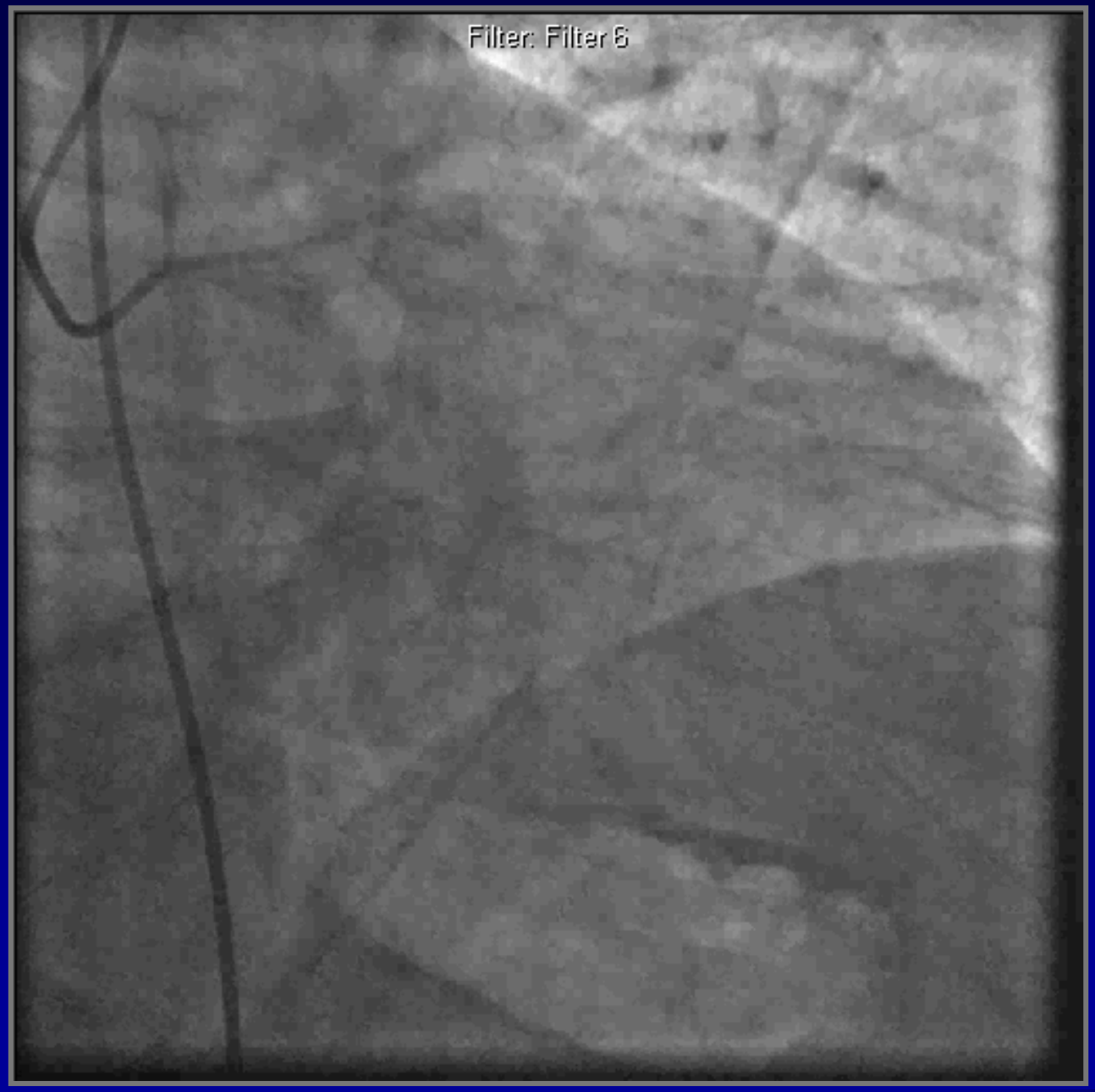

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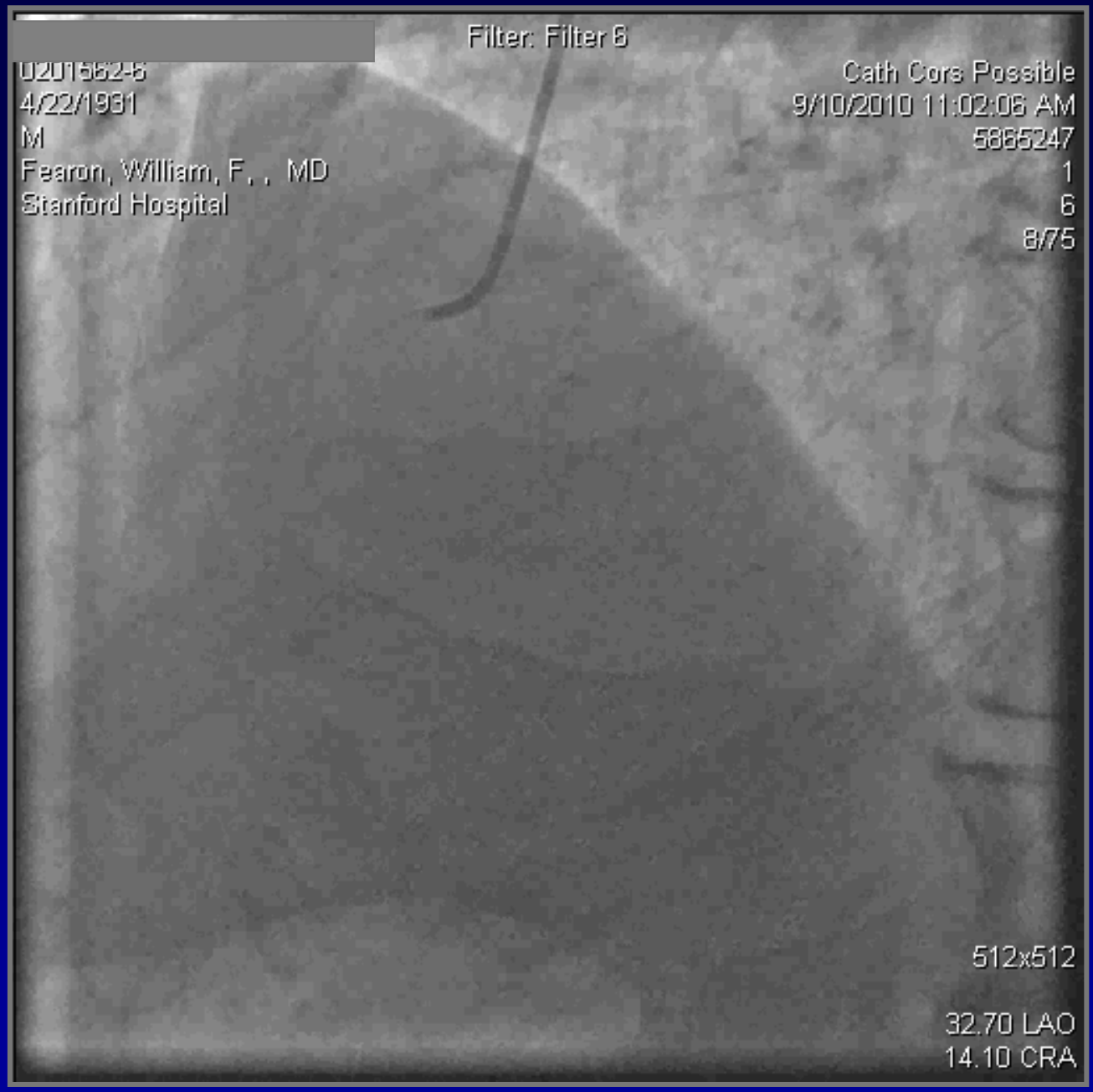
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How should we handle this case?

Recently published European guidelines for revascularization

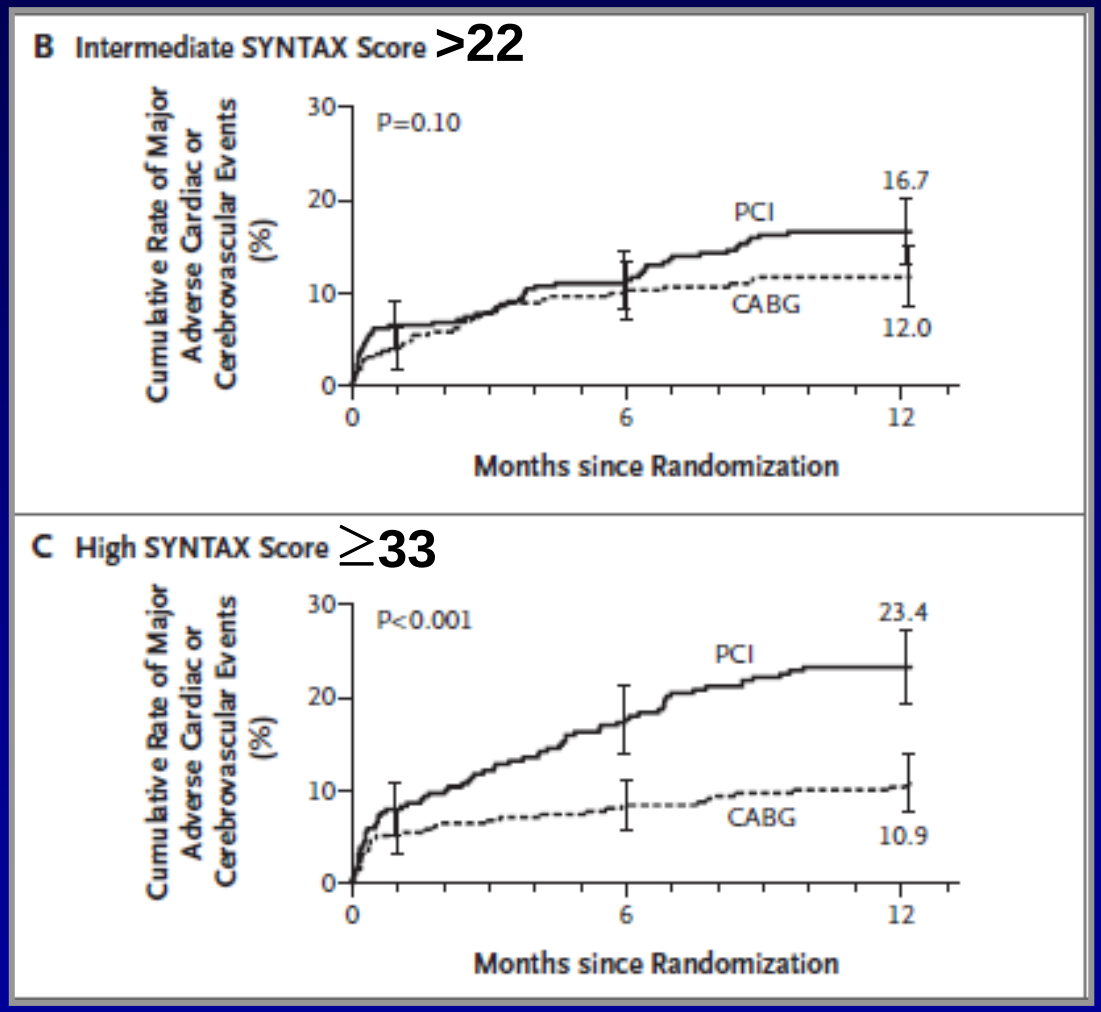
Calculated SYNTAX score = 25.5

Subset of CAD by anatomy	Favours CABG	Favours PCI	Ref.
1VD or 2VD - non-proximal LAD	IIb C	I C	—
1VD or 2VD - proximal LAD	I A	IIa B	30, 31, 50, 51
3VD simple lesions, full functional revascularization achievable with PCI, SYNTAX score ≤22	I A	IIa B	4, 30–37, 53
3VD complex lesions, incomplete revascularization achievable with PCI, SYNTAX score >22	I A	III A	4, 30–37, 53
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B	4, 54
Left main (isolated or 1VD, distal bifurcation)	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≤32	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≥33	I A	III B	4, 54

Wijns W, Kolh P, et al. Eur Heart J 2010; in press

PCI vs. CABG Outcomes Based on Syntax Score

Worse outcomes with PCI vs CABG with higher SYNTAX score



Serruys et al. N Engl J Med 2009;360:961-72

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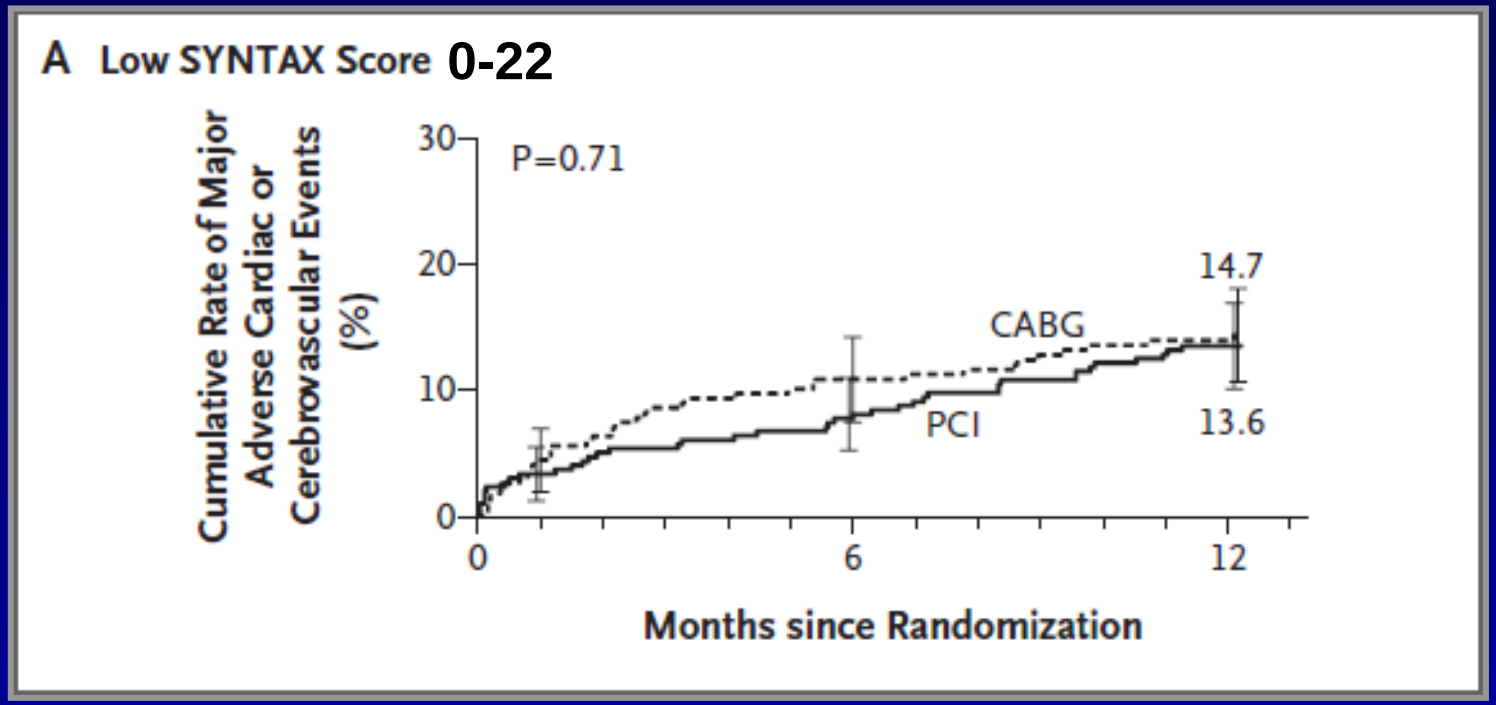
PCI vs. CABG Outcomes Based on Syntax Score

Similar outcomes with PCI vs CABG with lower SYNTAX score



Serruys et al. N Engl J Med 2009;360:961-72

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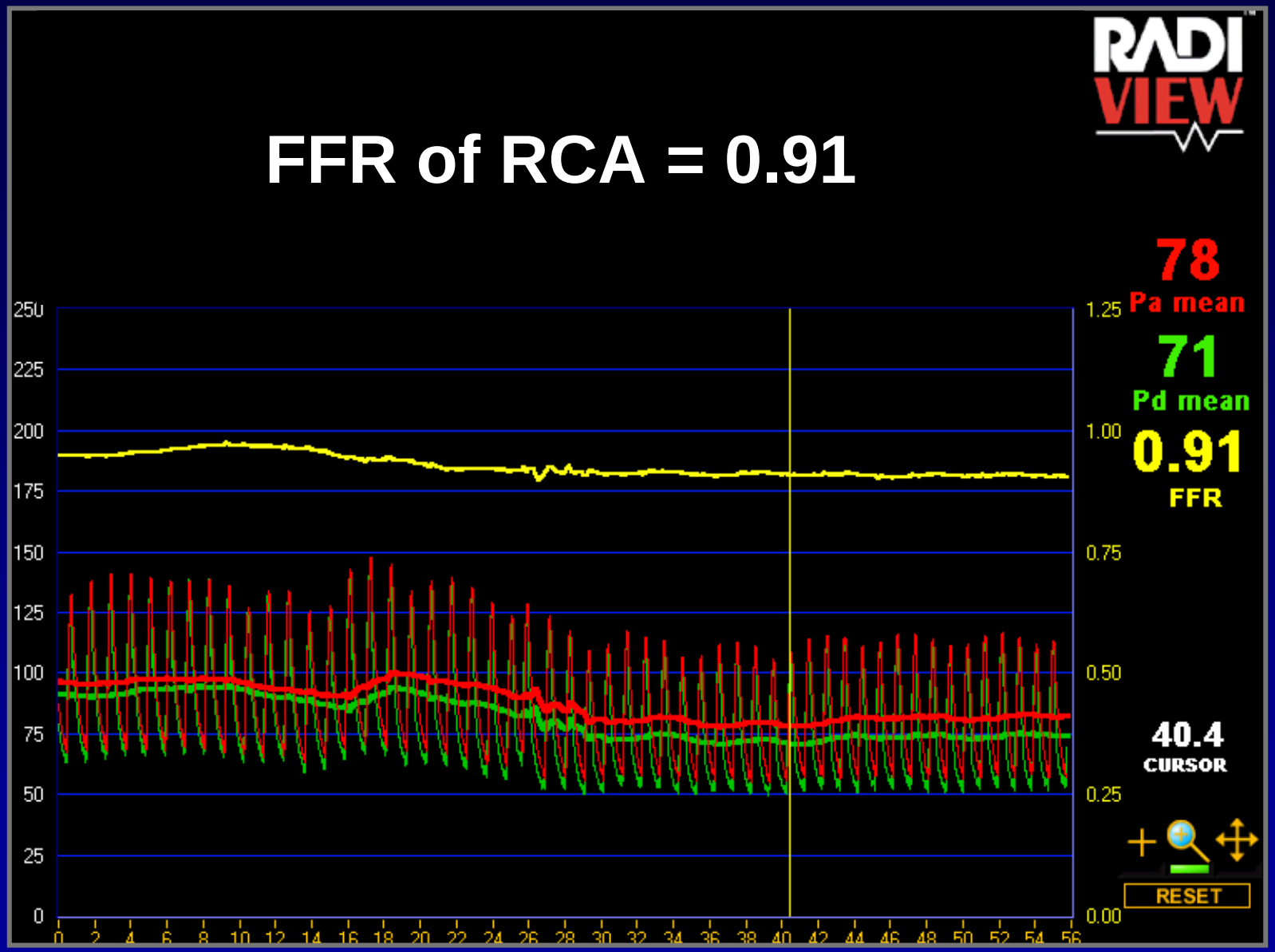
FFR of RCA = 0.91



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How should we handle this case?

Recently published European guidelines for revascularization

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Left main + 2VD or 3VD, SYNTAX score ≥33	I A	III B	4, 54

Recalculated SYNTAX score after FFR = 18.5

Wijns W, Kolh P, et al. Eur Heart J 2010; in press

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e-mail from Mr. H.

Sept. 19th, 2010:

Dr. Fearon....this is from New Mexico. Yesterday we were walking around on the base of the Santa Fe ski area at over 10,300 feet. Not too strenuous but then not too much air there. Feeling great and just wanted to tell you and say thanks...Bill

Anatomic vs. Functional CAD

Patients with angiographically 3VD (N=115), proportions per number of diseased vessels after assessment by FFR

Tonino et al., JACC 2010;55:2816-21

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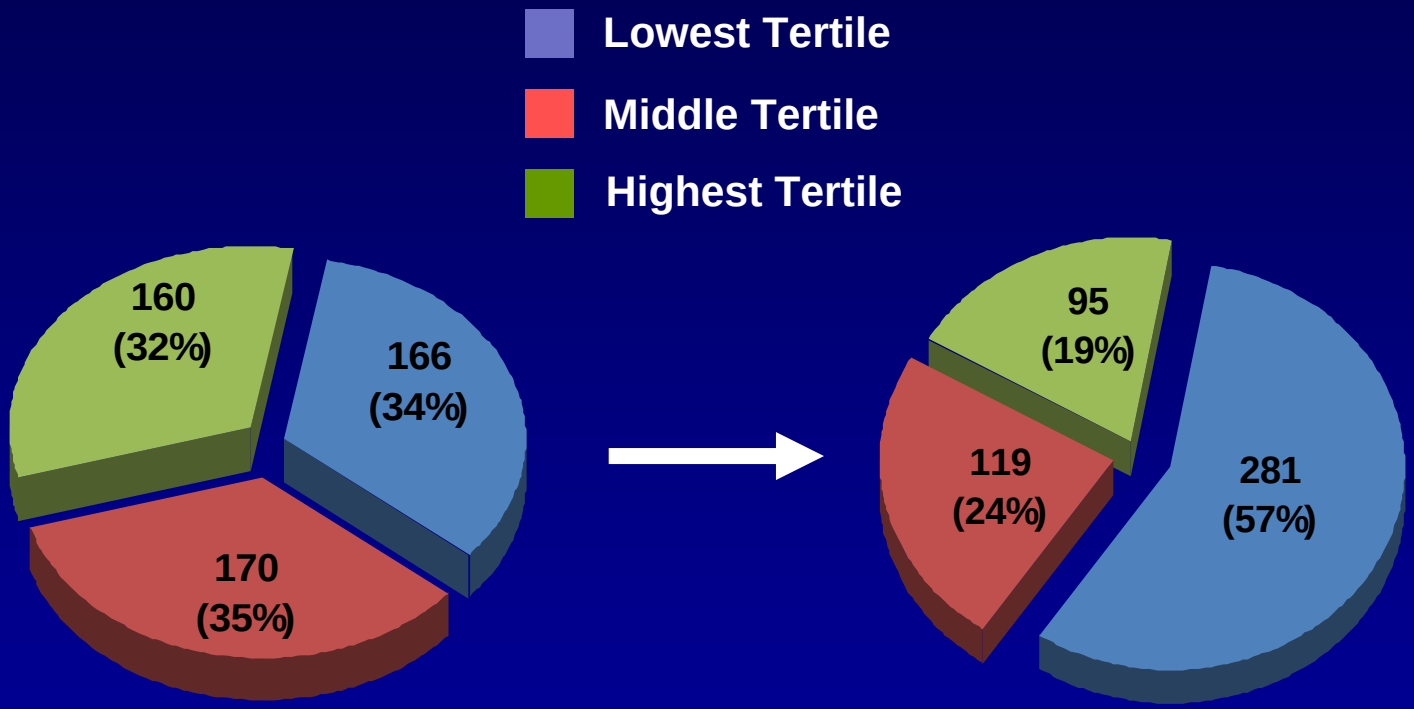
Change in SYNTAX score after FFR

SYNTAX score in roughly 500 FAME patients before and after FFR



Without FFR ***With FFR***

CW Nam, MD (preliminary data)

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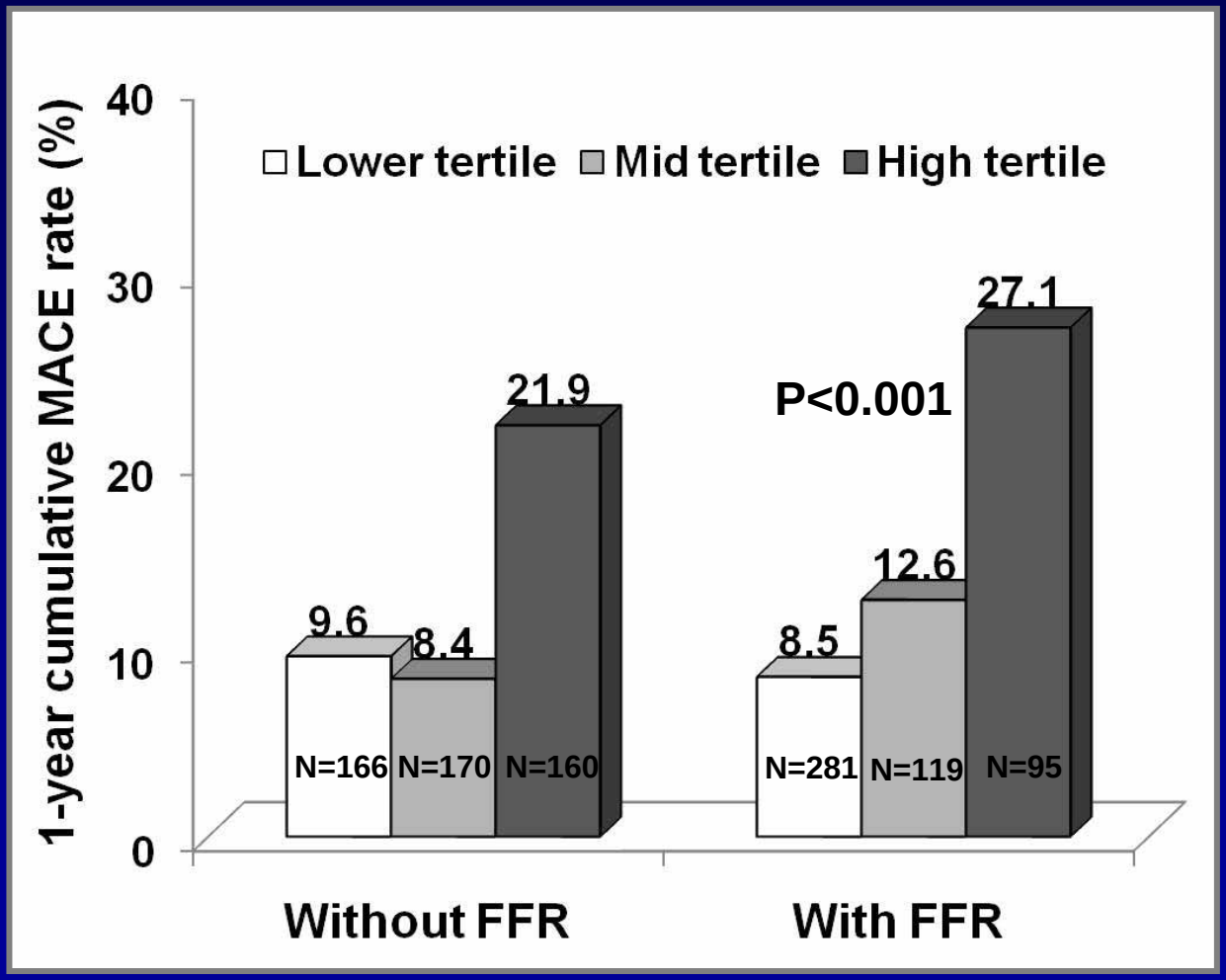
Impact of FFR on SYNTAX Score

Prognostic value of SYNTAX score improves after incorporating FFR



CW Nam, MD (preliminary data)

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2009 U.S. PCI Guidelines Update

Table 10. Recommendations for Use of Fractional Flow Reserve

2004/2005/2007 Recommendation: 2005 PCI Guideline, Section 5.6.2.	2009 PCI Focused Update Recommendations	Comments
Class IIa		
1. It is reasonable to use intracoronary physiologic	1. Coronary pressure (fractional flow reserve [FFR]) or Doppler	Modified recommendation (level of

1. **FFR can be useful to determine if PCI is warranted, particularly if the noninvasive test is absent or equivocal. It is reasonable to use FFR for assessing the need for PCI of intermediate lesions (IIa)**

2. **FFR is not warranted to assess an angiographically significant stenosis if there is angina present and an unequivocally positive stress test in a concordant vascular distribution (III)**

the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study is not recommended. (*Level of Evidence: C*)

concordant vascular distribution in patients with angina *and a positive, unequivocal noninvasive functional study* is not recommended. (*Level of Evidence: C*)

Circulation 2009;120:2271-2306

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2010 European PCI Guidelines

FFR Receives IA Recommendation

Table 33 Recommendations for specific percutaneous coronary intervention devices and pharmacotherapy

	Class[a]	Level[b]	Ref.[c]
FFR-guided PCI is recommended for detection of ischaemia-related lesion(s) when objective evidence of vessel-related ischaemia is not available.	I	A	15, 28
DES[d] are recommended for reduction of restenosis/re-occlusion, if no contraindication to extended DAPT.	I	A	45, 46, 55, 215

Table 1 Classes of recommendations

Classes of recommendations	Definition
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.
Class II	Conflicting evidence and/or a

Table 2 Levels of evidence

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.

Wijns W, Kolh P, et al. Eur Heart J 2010; in press

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Should FFR Guide PCI?

- Yes, in most cases, FFR will:
  - Simplify your procedure
  - Save money
  - And most importantly, improve your patient's outcome!