Updated Imaging/Physiology-Guided PCI Tuning 2021

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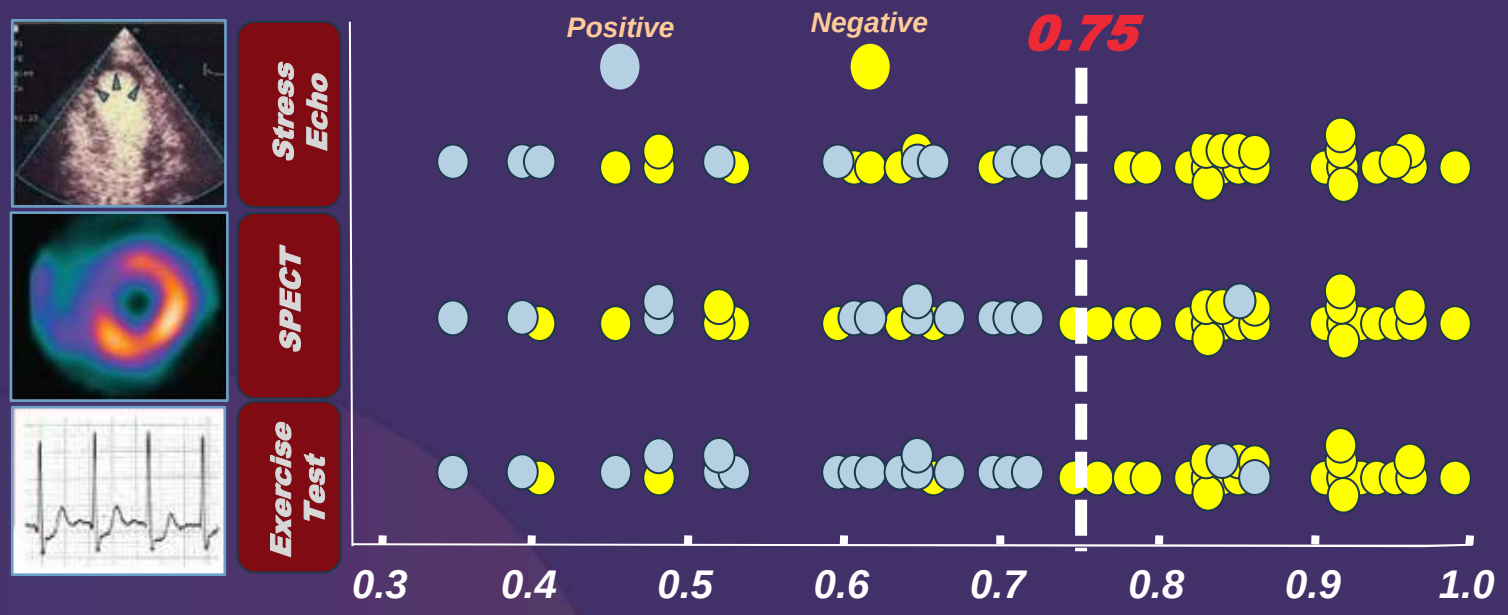
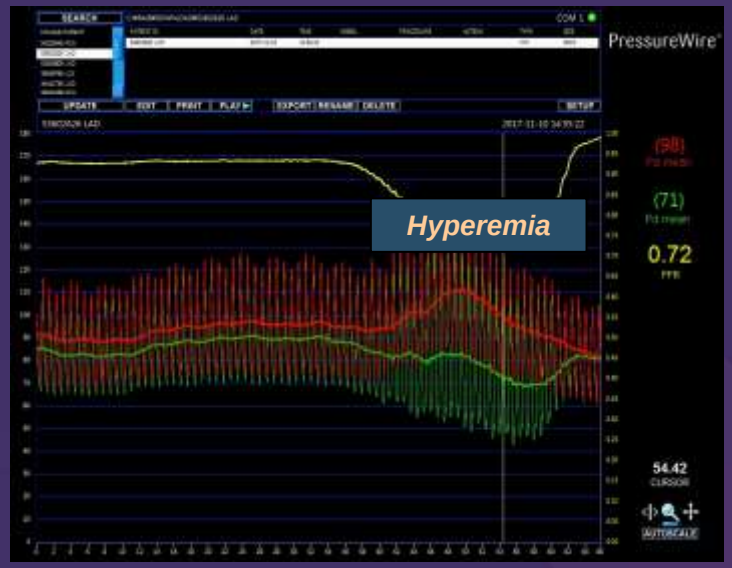
Pressure Measurement For Coronary Stenosis

N H Pijls et al. N Engl J Med 1996;334:1703-8,

FFR as A Non-Invasive Functional Study In Cath Lab

Comparison with 3 Non-Invasive Functional Studies



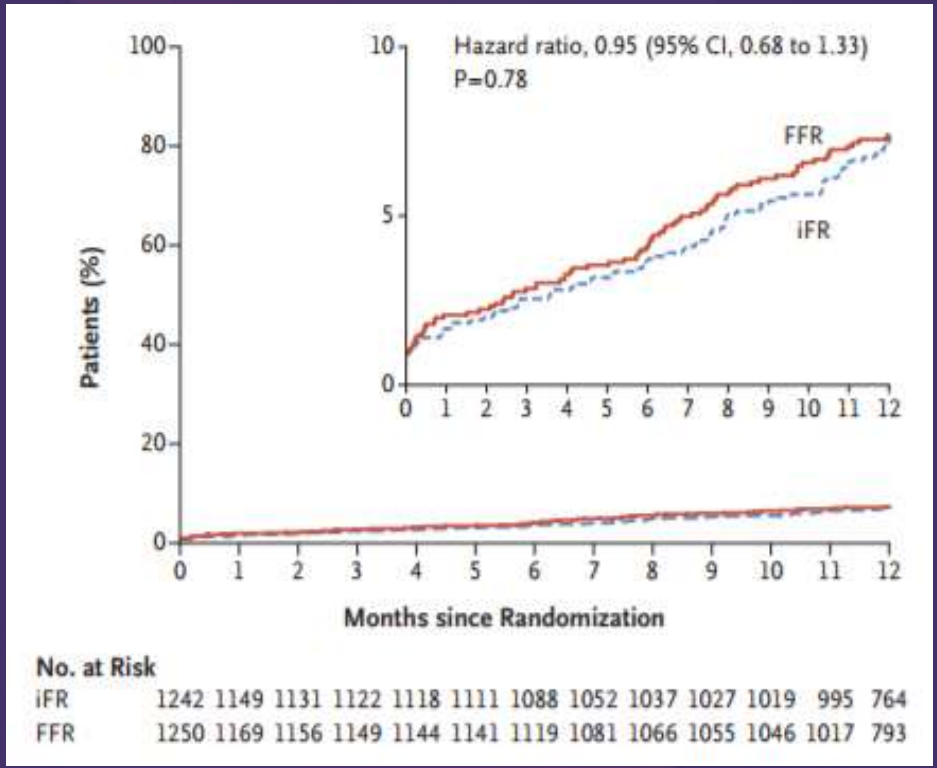


- *N = 45 patients*
- *Sensitivity 88%, Specificity 100%, PPV 100%, NPV 88%*

ACC 2017

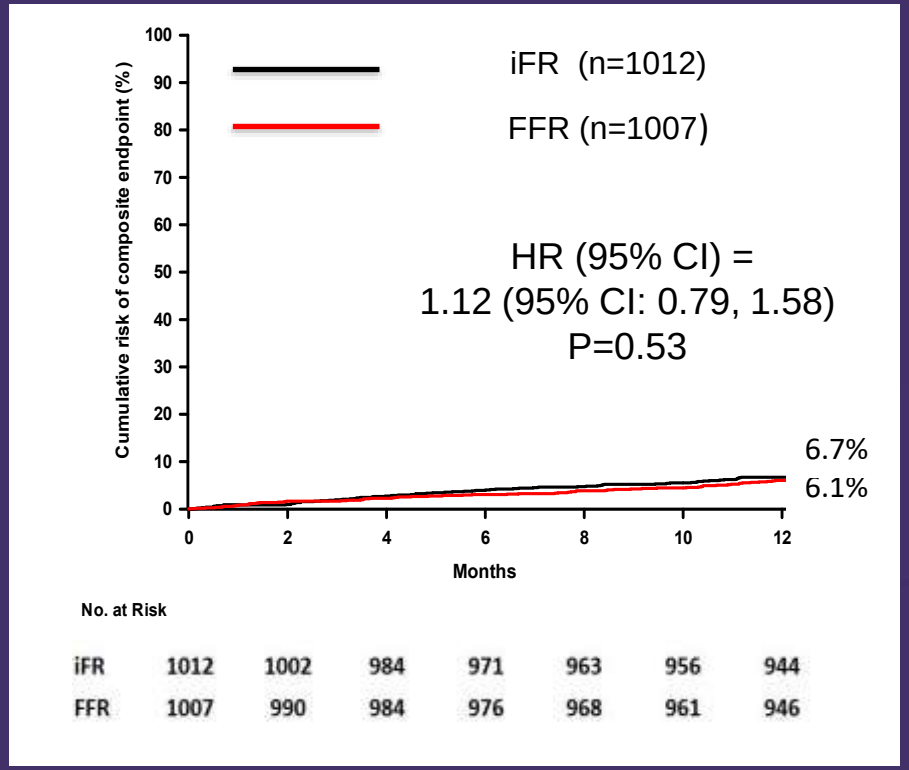
iFR is Non-Inferior to FFR

DEFINE-FLAIR



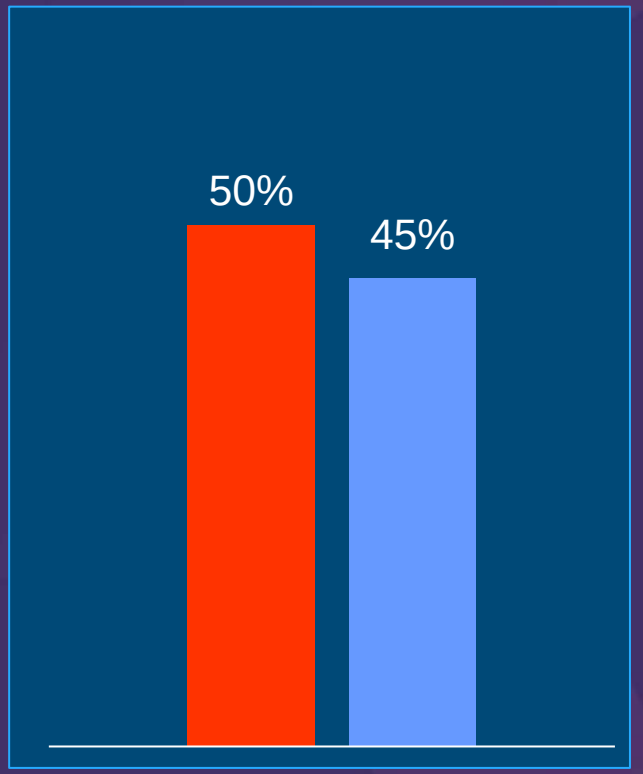
N Engl J Med. 2017 May 11;376(19):1824-1834

iFR-SWEDEHEART



N Engl J Med. 2017 May 11;376(19):1813-1823

Deferred Revascularization



AUC 2017

ARTICLE IN PRESS

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APPROPRIATE USE CRITERIA

ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/ STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease

A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, American Society of Nuclear Cardiology, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society of Thoracic Surgeons

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ESC Guideline 2018

Recommendations	Class[a]	Level[b]
When evidence of ischaemia is not available, FFR or iwFR are recommended to assess the haemodynamic relevance of intermediate-grade stenosis.[15,17,18,39]	I	A
FFR-guided PCI should be considered in patients with multivessel disease undergoing PCI.[29,31]	IIa	B
IVUS should be considered to assess the severity of unprotected left main lesions.[35–37]	IIa	B

JCS Guidelines 2019

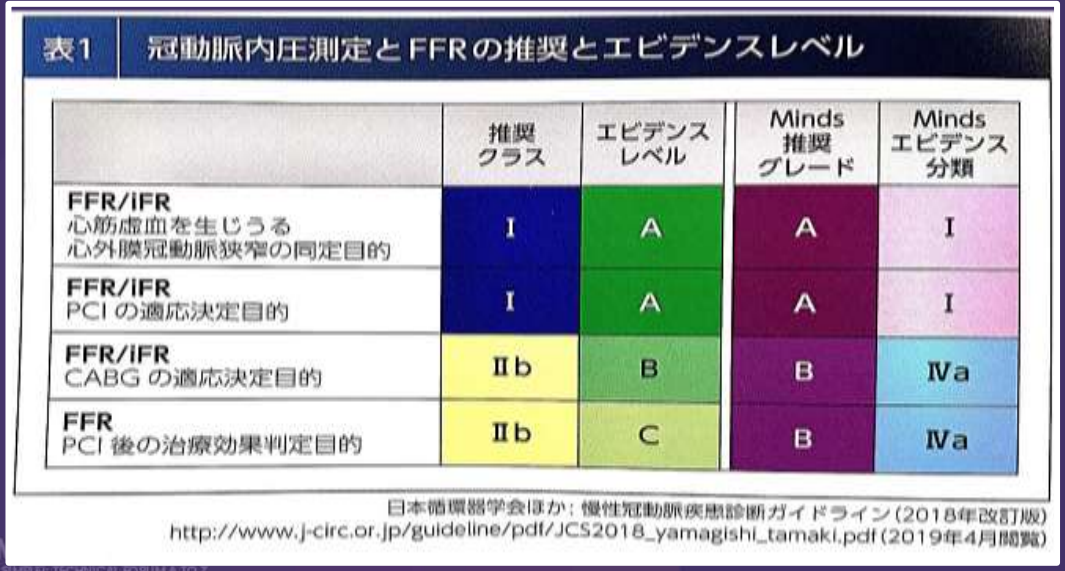


表1 冠動脈内圧測定とFFRの推奨とエビデンスレベル

	推奨クラス	エビデンスレベル	Minds推奨グレード	Minds エビデンス分類
FFR/iFR 心筋虚血を生じうる心外膜冠動脈狭窄の同定目的	I	A	A	I
FFR/iFR PCIの適応決定目的	I	A	A	I
FFR/iFR CABGの適応決定目的	IIb	B	B	IVa
FFR PCI後の治療効果判定目的	IIb	C	B	IVa

日本循環器学会ほか：慢性冠動脈疾患診断ガイドライン（2018年改訂版）
http://www.j-circ.or.jp/guideline/pdf/JCS2018_yamagishi_tamaki.pdf（2019年4月閲覧）

CCS Guideline 2019

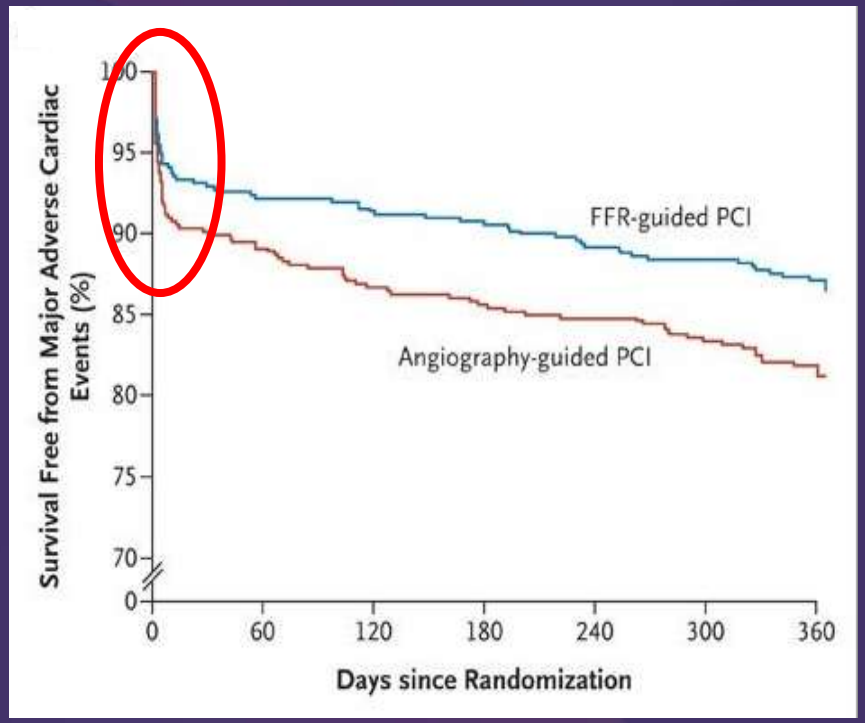
Recommendations	Class[a]	Level[b]
Risk stratification is recommended based on clinical assessment and the result of the diagnostic test initially employed to diagnose CAD.[6,75,102,103]	I	B
Resting echocardiography is recommended to quantify LV function in all patients with suspected CAD.	I	C
Risk stratification, preferably using stress imaging or coronary CTA (if permitted by local expertise and availability), or alternatively exercise stress ECG (if significant exercise can be performed and the ECG is amenable to the identification of ischaemic changes), is recommended in patients with suspected or newly diagnosed CAD.[6,75,102,106]	I	B
In symptomatic patients with a high-risk clinical profile, ICA complemented by invasive physiological guidance (FFR) is recommended for cardiovascular risk stratification, particularly if the symptoms are responding inadequately to medical treatment and revascularization is considered for improvement of prognosis.[104,107]	I	A
In patients with mild or no symptoms, ICA complemented by invasive physiological guidance (FFR/iwFR) is recommended for patients on medical treatment, in whom non-invasive risk stratification indicates a high event risk and revascularization is considered for improvement of prognosis.[104,107]	I	A
ICA complemented by invasive physiological guidance (FFR) should be considered for risk-stratification purposes in patients with inconclusive or conflicting results from non-invasive testing.[74]	IIa	B
If coronary CTA is available for event risk stratification, additional stress imaging should be performed before the referral of a patient with few/no symptoms for ICA.[108,109]	IIa	B
Echocardiographic assessment of global longitudinal strain provides incremental information to LVEF and may be considered when LVEF is >35%.[110–114]	IIb	B
Intravascular ultrasound may be considered for the risk stratification of patients with intermediate LM stenosis.[115,116]	IIb	B
ICA is not recommended solely for risk stratification.	III	C

FAME I

FFR- vs. CAG guided PCI in Multivessel Disease

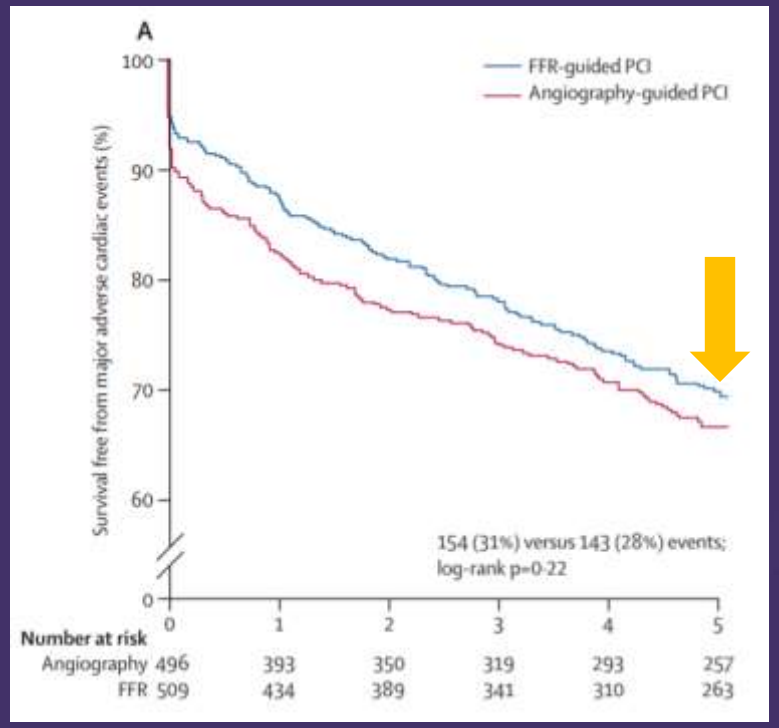
Primary Endpoint: Death, MI, and Repeat Revascularization

1 Year Follow-up



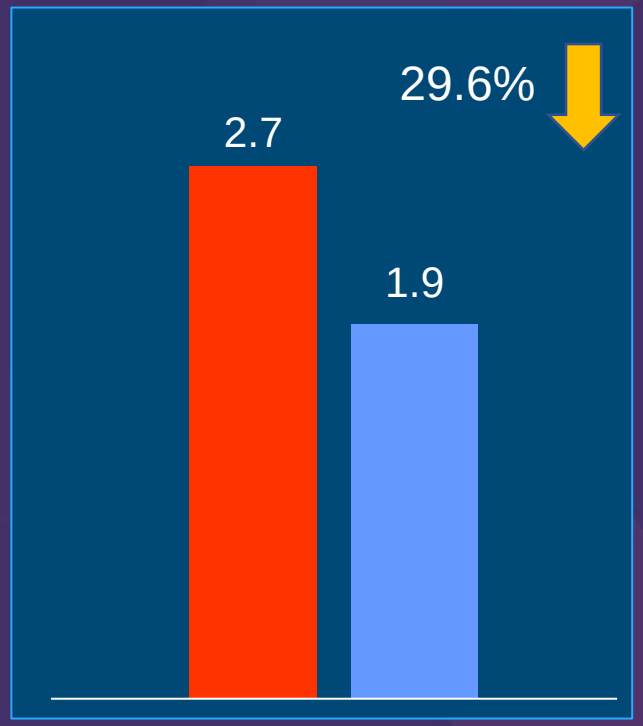
N Engl J Med 2009; 360:213-224

5 Year Follow-up



Lancet. 2015;386(10006):1853-60

Number of stents per patient

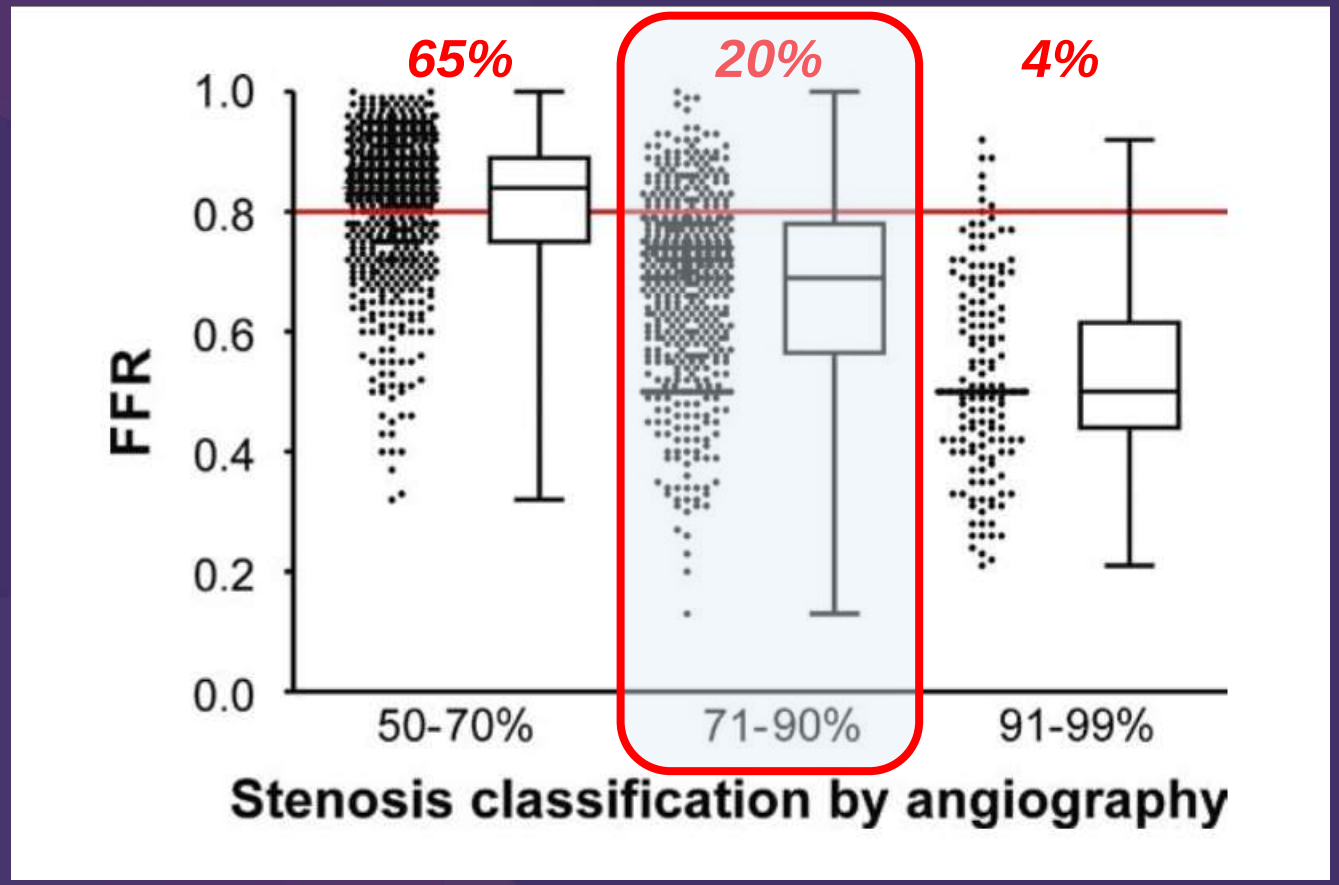


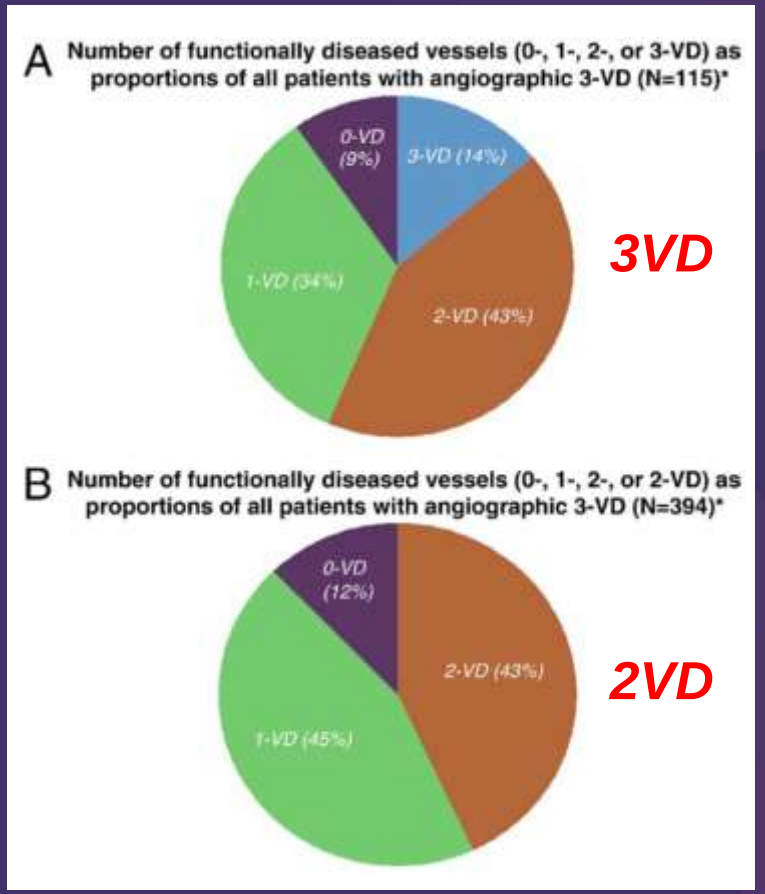
Deferred lesion related MI (0.2%) and repeat revascularization (3.2%) at 2-year FU

J Am Coll Cardiol 2010;56:177–84

FAME I

Visual Functional Mismatch

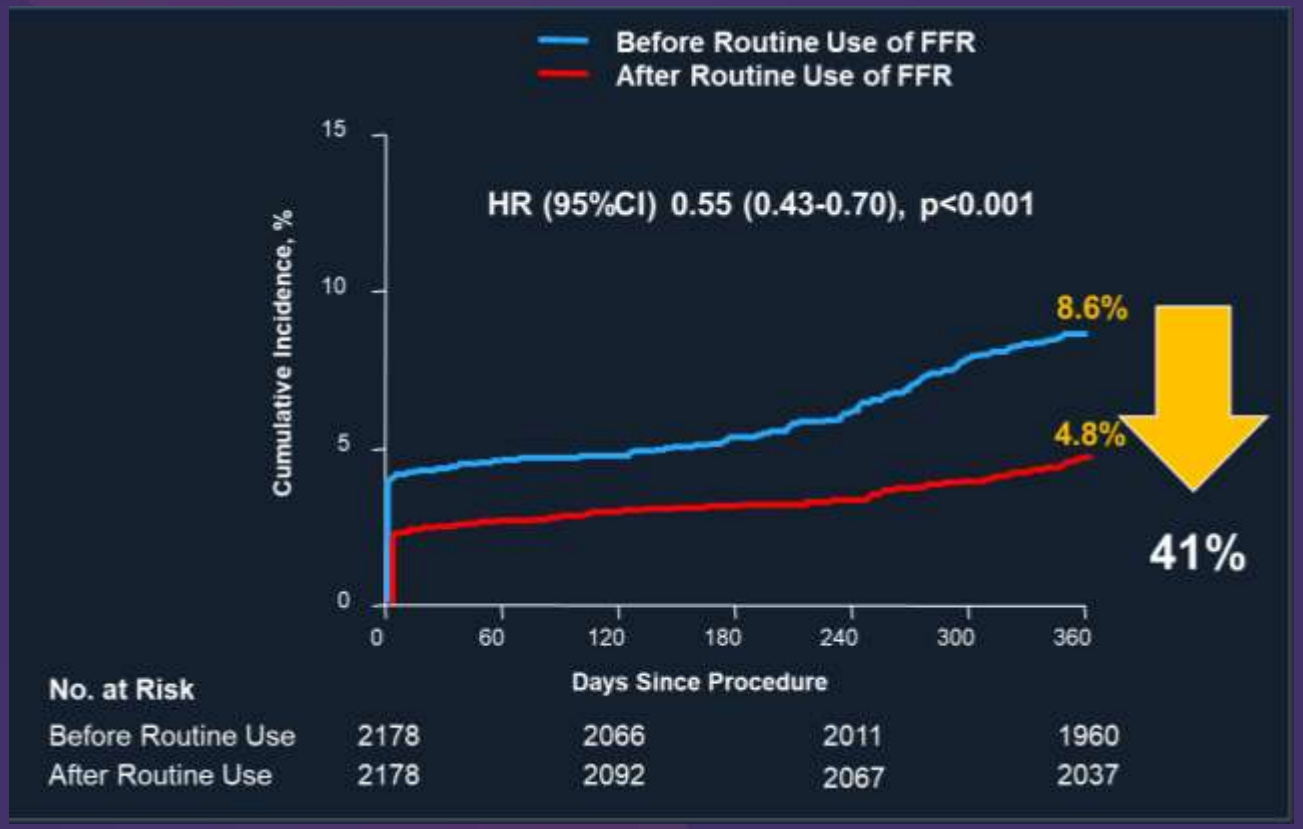


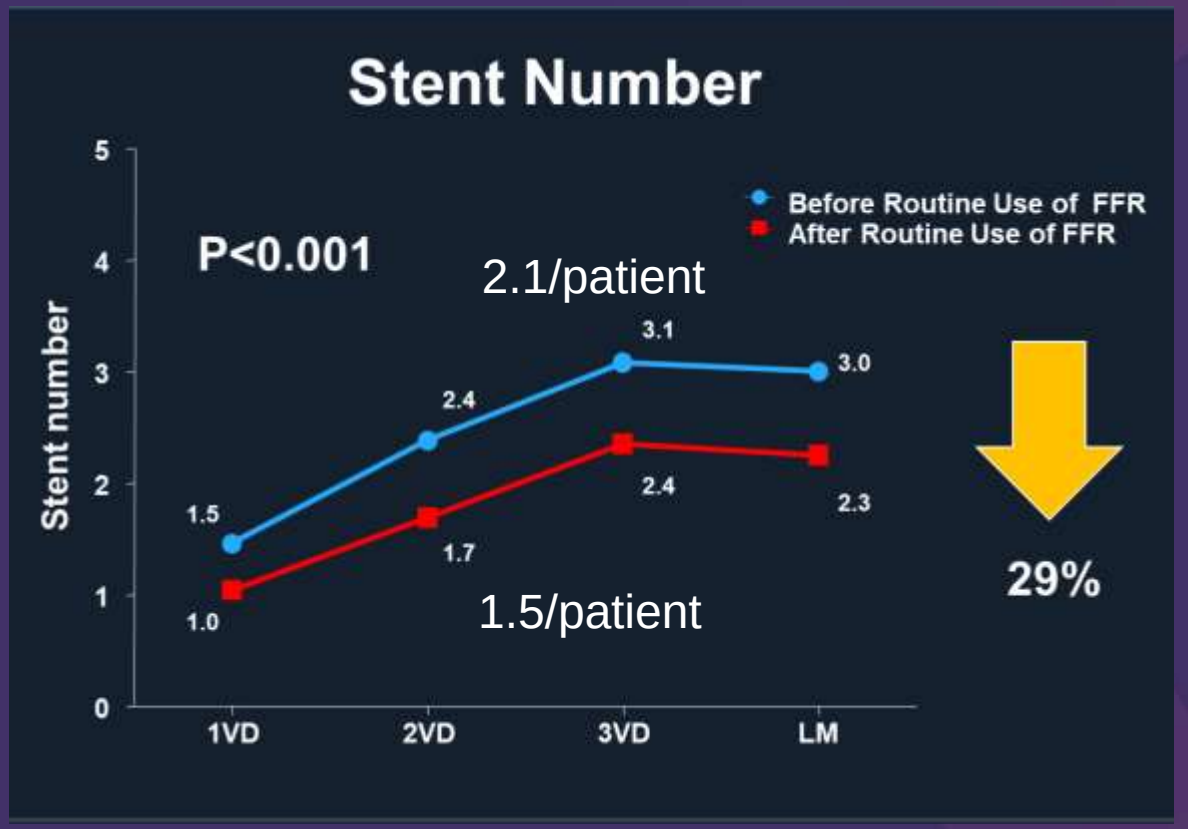


J Am Coll Cardiol 2010;55:2816–21

ASAN PCI Registry

Primary Endpoint: Death, MI, and Repeat Revascularization

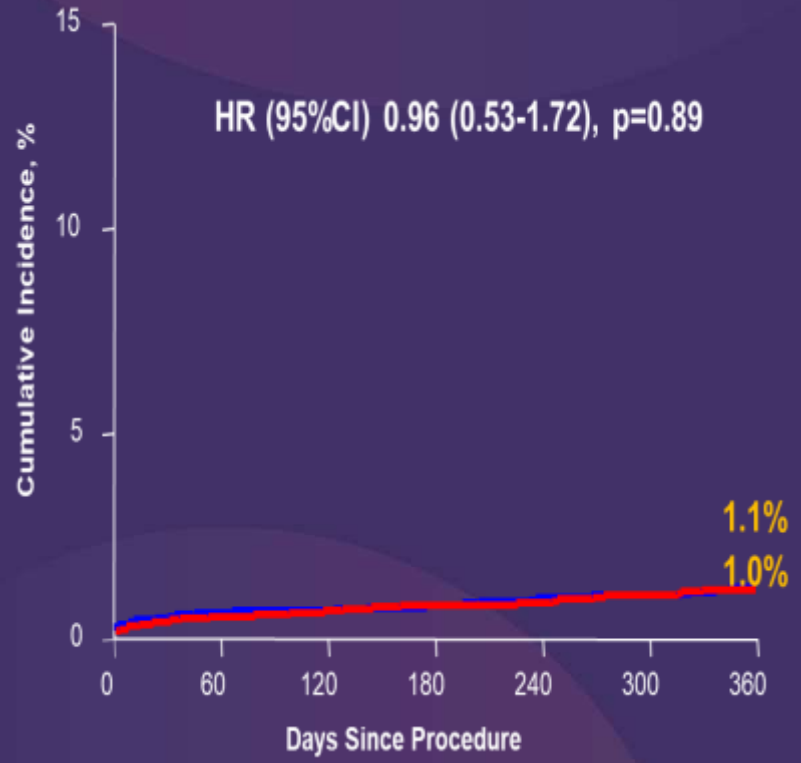




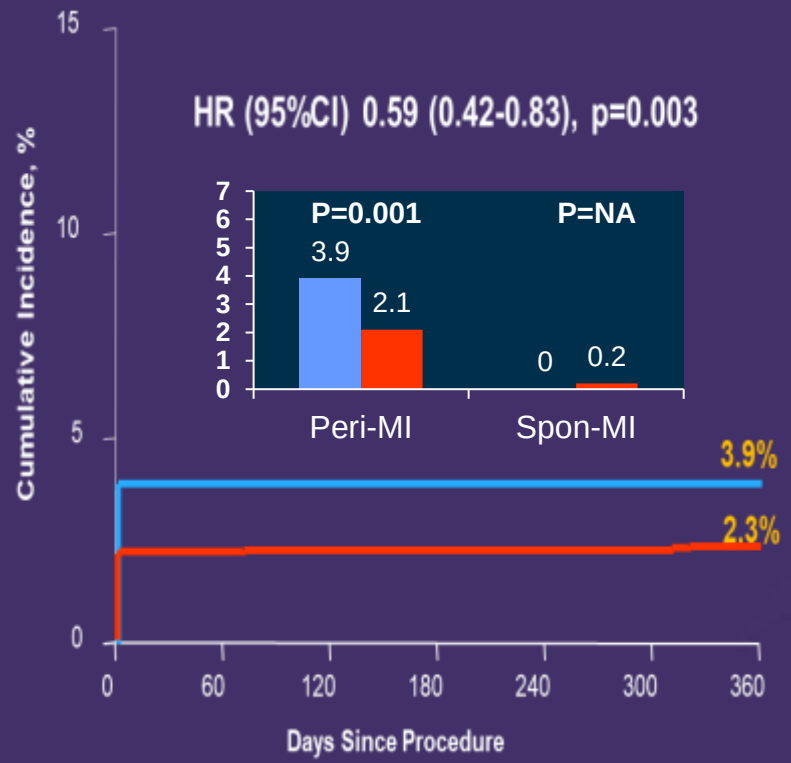
Park SJ, Ahn JM et al. Eur Heart J. 2013 Nov;34(43):3353-61

ASAN PCI Registry

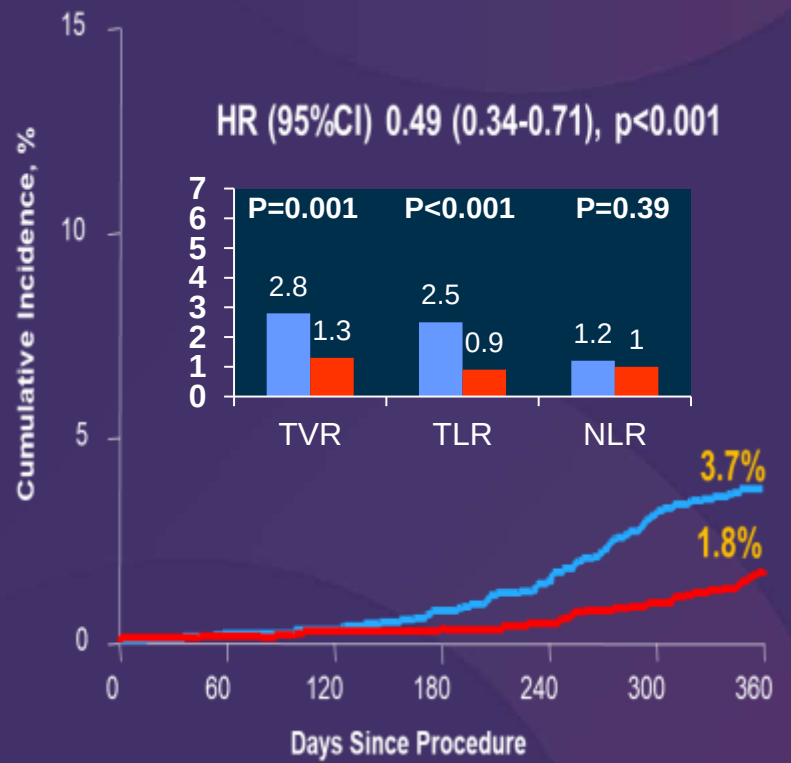
Death



MI



Repeat Revascularization



Park SJ, Ahn JM et al. Eur Heart J. 2013 Nov;34(43):3353-61

The Major Benefit of FFR(iFR) measurement

The benefit of FFR guided PCI is primarily due to

1) The reduced number of stents used per patient

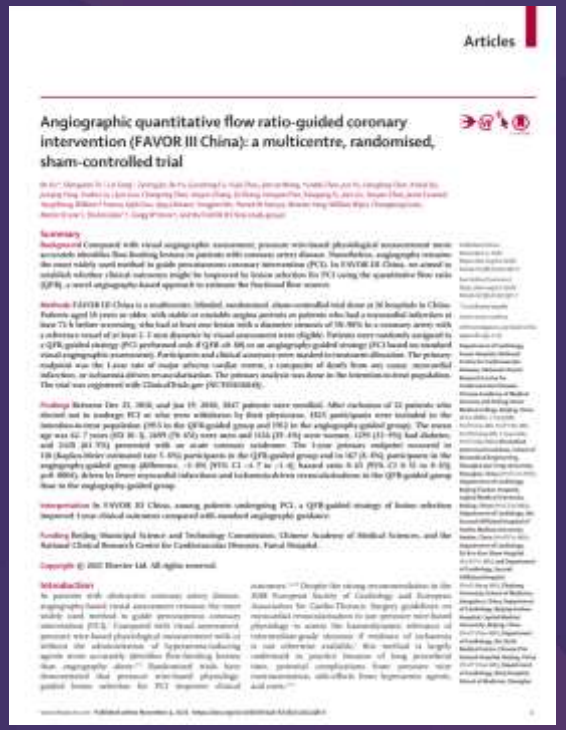
2) Avoid unnecessary PCI, and

3) The subsequent decreased risk of

peri-procedural MI and (urgent) repeat revascularization

Positive and Negative (?) Physiology Studies in 2021

FAVOR III



Articles

Angiographic quantitative flow ratio-guided coronary intervention (FAVOR III China): a multicentre, randomised, sham-controlled trial

FLOWER-MI

The NEW ENGLAND JOURNAL of MEDICINE

Multivessel PCI Guided by FFR or Angiography for Myocardial Infarction

FUTURE

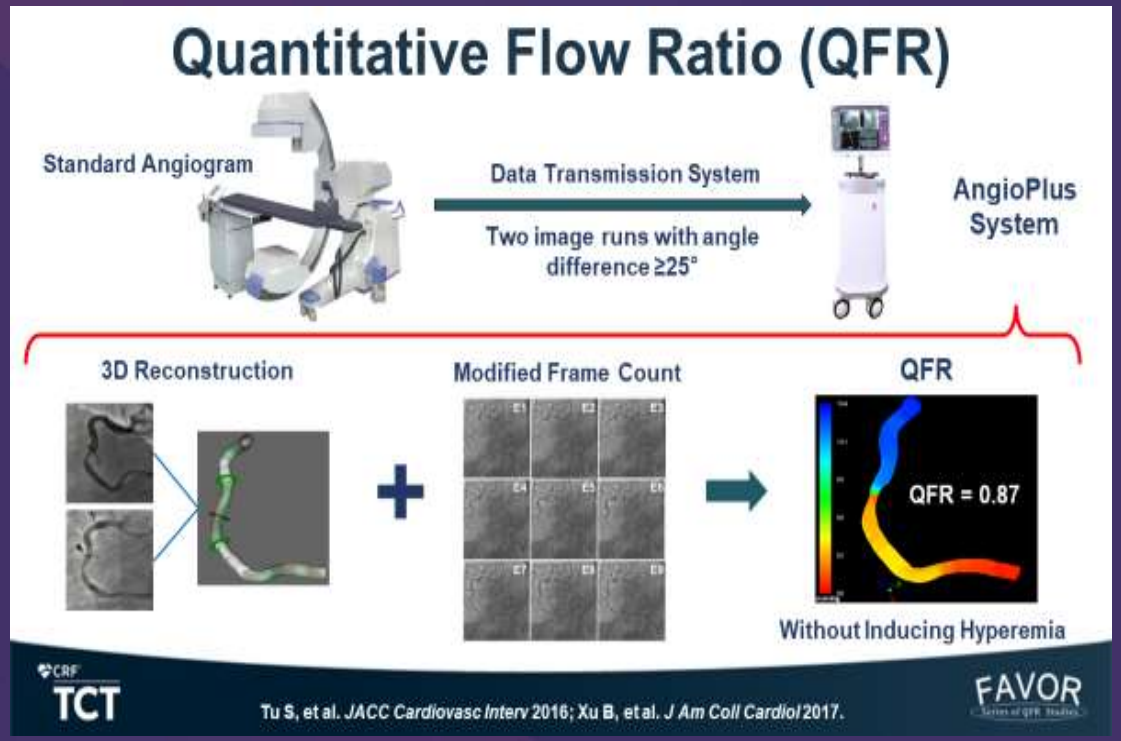
Fractional Flow Reserve to Guide Treatment of Patients With Multivessel Coronary Artery Disease

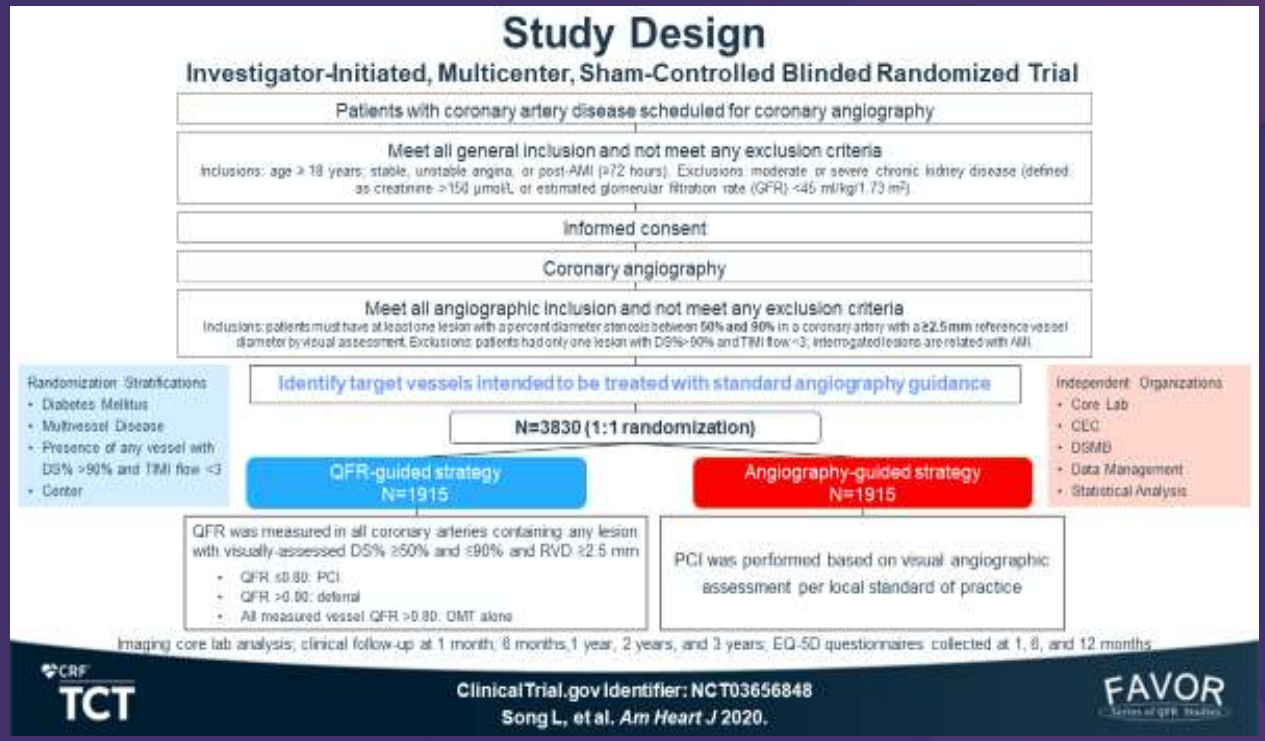
FAME 3

ORIGINAL ARTICLE

Fractional Flow Reserve–Guided PCI as Compared with Coronary Bypass Surgery

FAVOR III China Randomized Trial

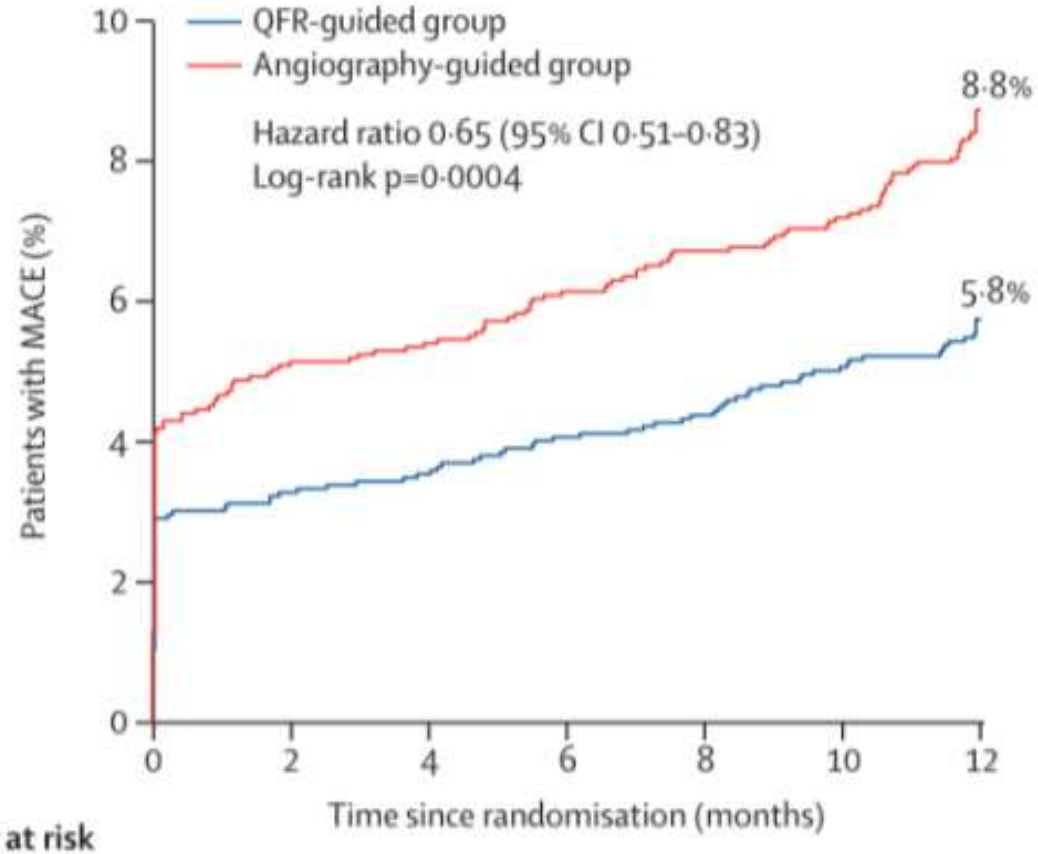




Combination of Coronary Imaging and Physiology

FAVOR III China Randomized Trial

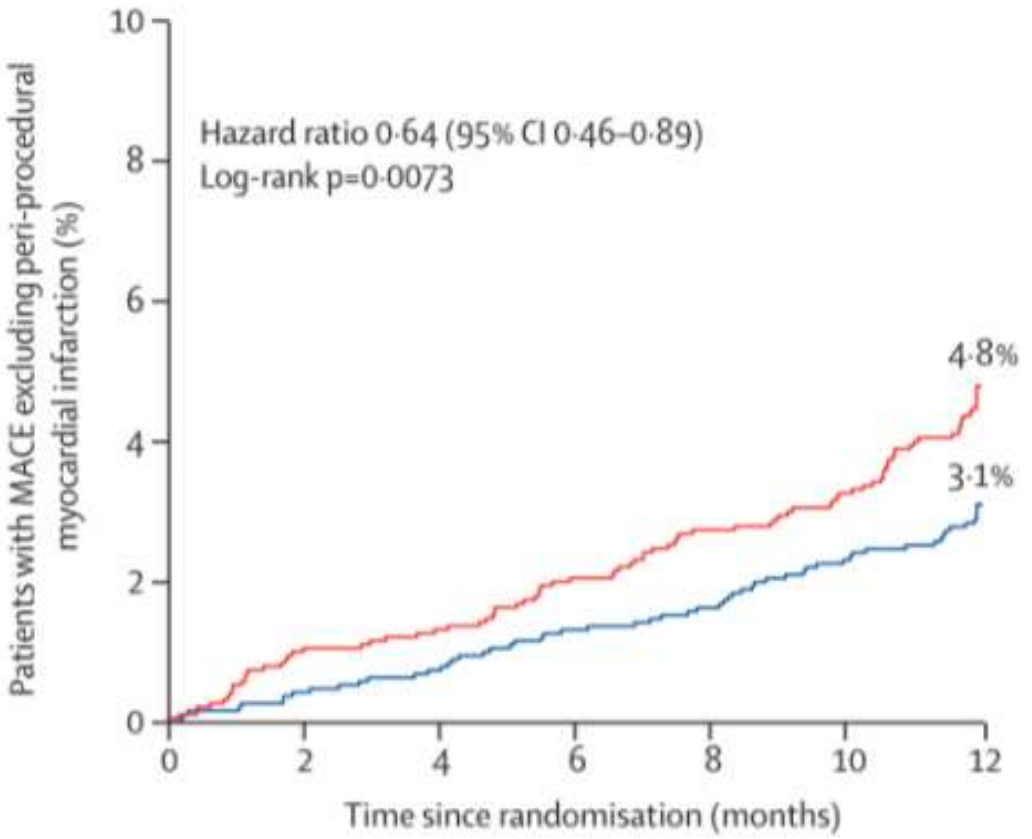
Death, MI, Ischemia-driven Revascularization



Number at risk

QFR-guided group	1913	1845	1840	1828	1821	1809	1795
Angiography-guided group	1912	1804	1798	1783	1770	1762	1732

Excluding peri-procedural MI



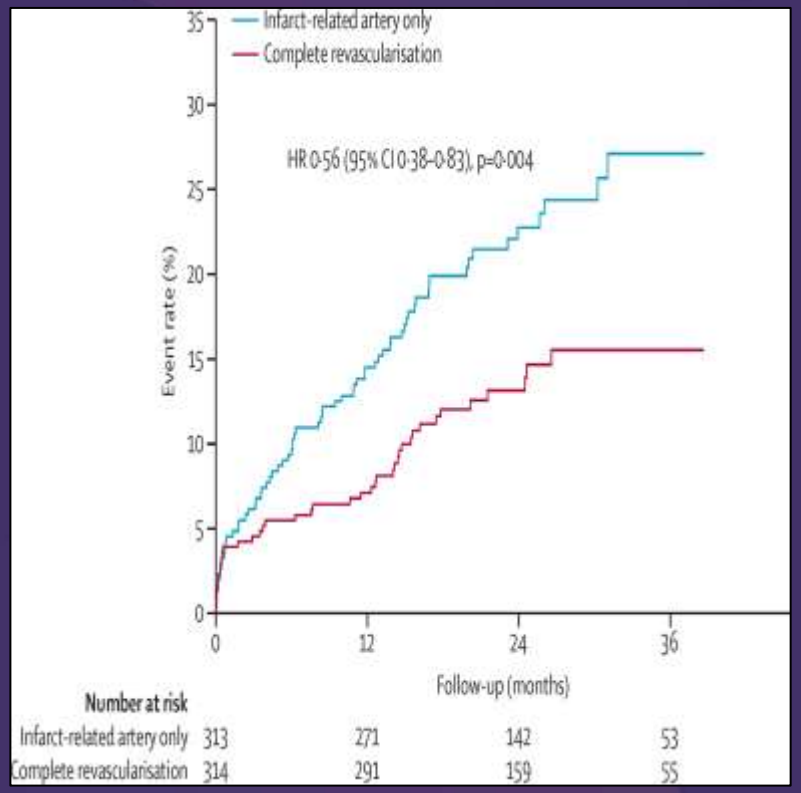
	1913	1900	1894	1881	1874	1862	1846
	1912	1883	1877	1862	1847	1839	1808

Lancet. 2021 Nov 3;S0140-6736(21)02248-0

Complete Revascularization in STEMI

DANAMI-3 PRIMULTI Trial

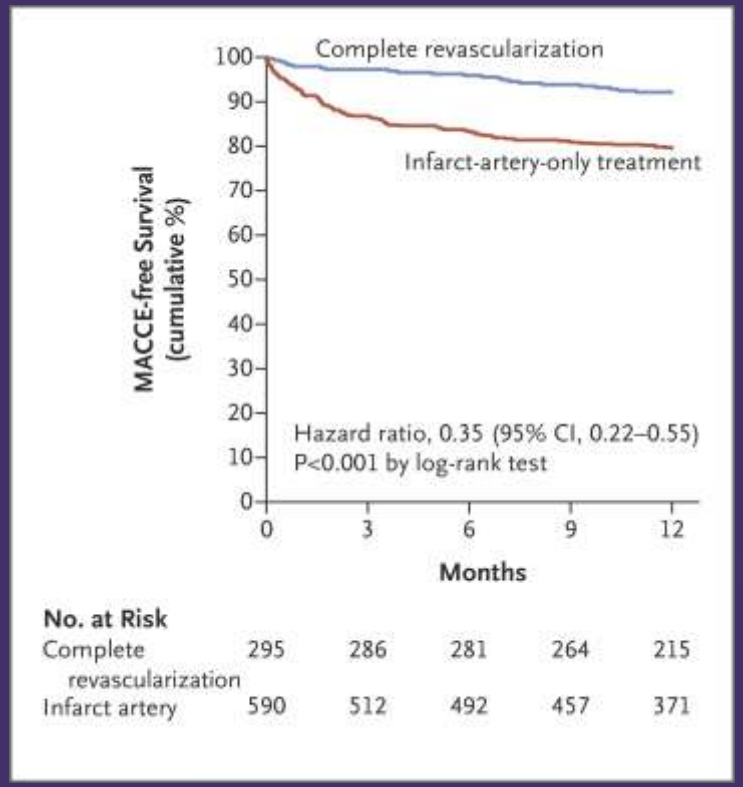
CAG Guided PCI



Lancet. 2015;386(9994):665-71.

COMPARE ACUTE Trial

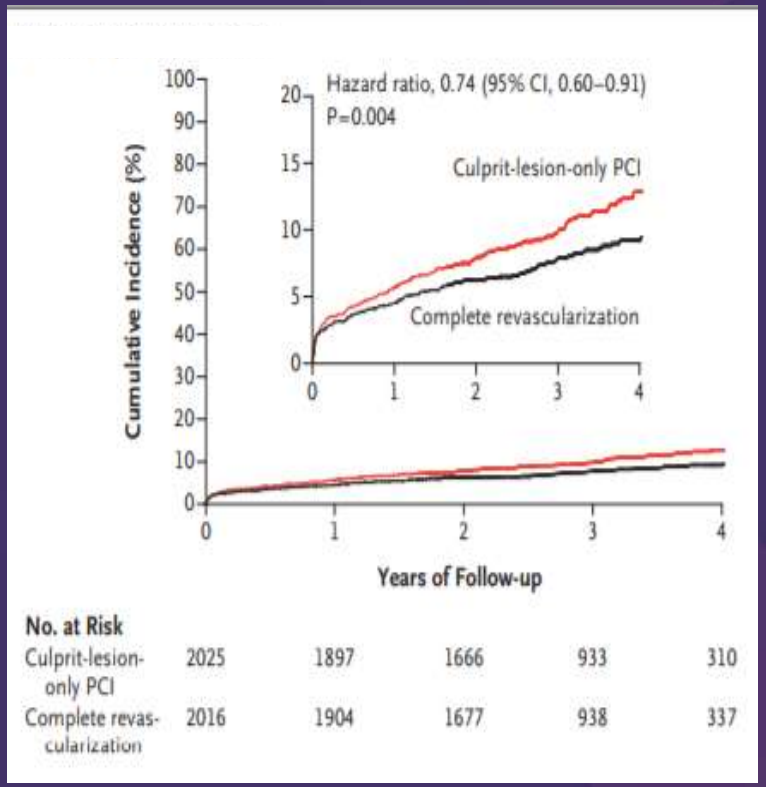
FFR Guided PCI



N Engl J Med 2017; 376:1234-1244

COMPLETE Trial

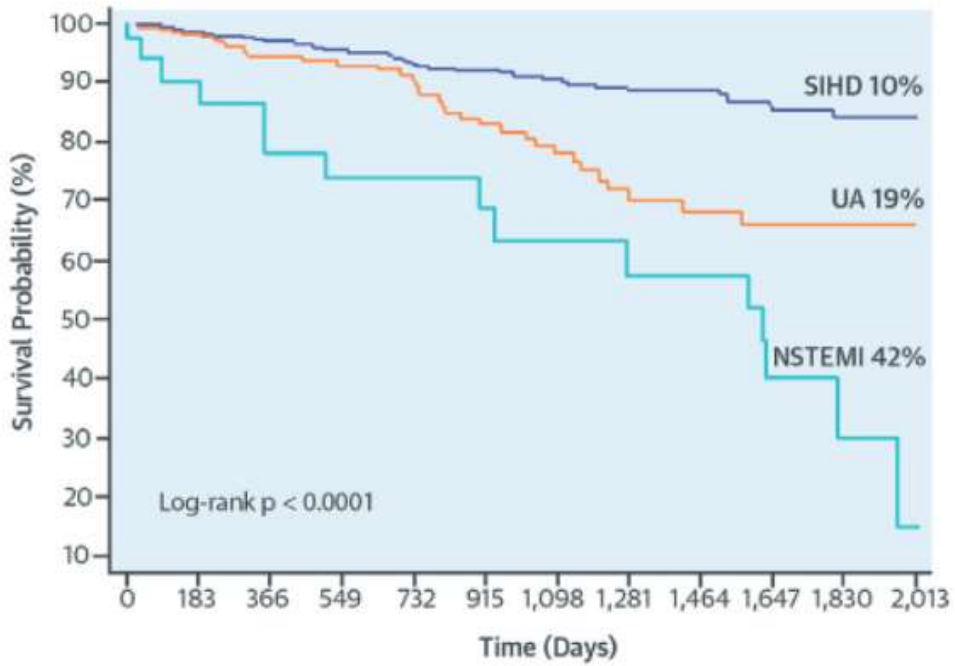
CAG Guided PCI



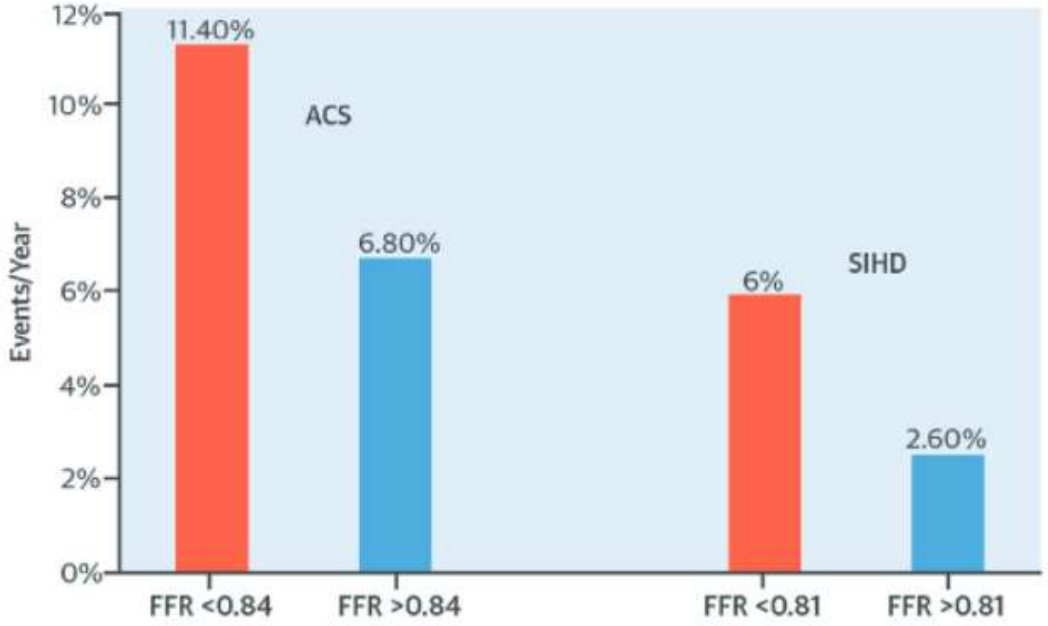
N Engl J Med 2019; 381:1411-1421

Long-Term Prognosis of Deferred ACS Lesions

MI/TVF in SIHD, UA, and NSTEMI Subgroups



Annualized MI/TVF Rates on the Basis of Optimal FFR Cutoffs for ACS and SIHD



J Am Coll Cardiol 2016 Sep 13;68(11):1181-1191

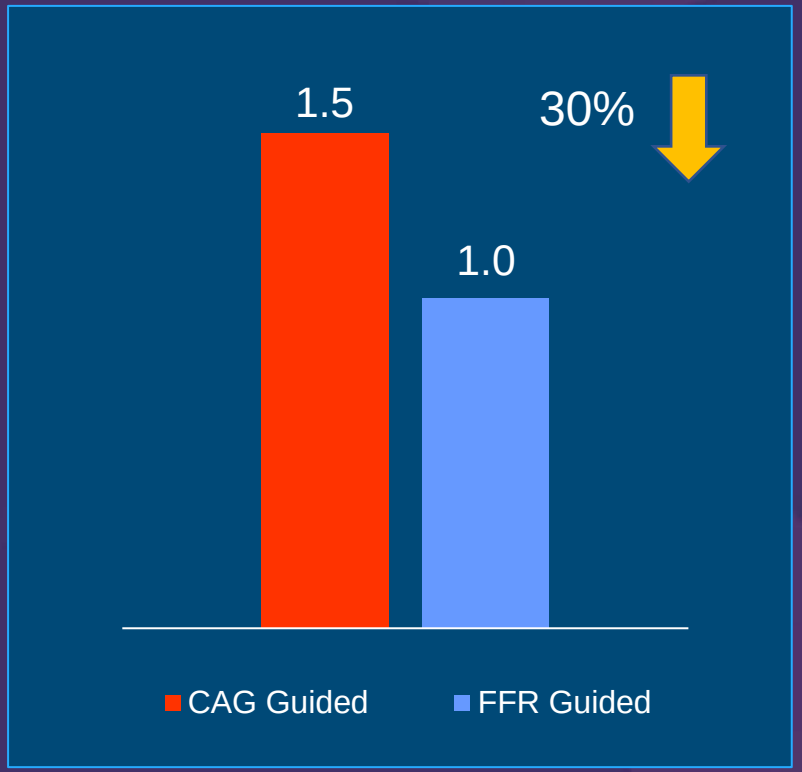
FLOWER-MI

Primary Endpoint

Death, nonfatal MI, or unplanned hospitalization

Outcomes	FFR-Guided Group (N=586)	Angiography-Guided Group (N=577)	Hazard Ratio or Difference (95% CI)†	P Value
Primary outcome				
Composite outcome — no. (%)‡	32 (5.5)	24 (4.2)	1.32 (0.78–2.23)	0.31
Death from any cause	9 (1.5)	10 (1.7)	0.89 (0.36–2.20)	
Nonfatal myocardial infarction§	18 (3.1)	10 (1.7)	1.77 (0.82–3.84)	
Unplanned hospitalization leading to urgent revascularization				
Patients with condition — no. (%)	15 (2.6)	11 (1.9)	1.34 (0.62–2.92)	
Treatment of target lesions in nonculprit artery by urgent revascularization — no./total no. (%)	8/15 (53.3)	3/11 (27.3)	—	

Number of stents per patient



N Engl J Med 2021;385:297-308

FUTURE Trial

In multivessel disease, does FFR help to guide treatment strategy (PCI, CABG, or medical treatment) and thereby improve clinical prognosis ?

AHA Late Breaking Trial at 2016

Study design 1728 patients

All-comer Patient with stable or stabilized angina Multivx-disease (>50% stenosis) including LAD at the time of angiography

exclusion criteria
STEMI<12h
no LAD disease
CI to FFR

Randomisation 1:1

FFR-guided

FFR on all target lesions

Only lesions with FFR≤0.80 included in stratification

PCI + OMT | CABG + OMT | OMT only

FFR>0.80 lesions disregarded for TT

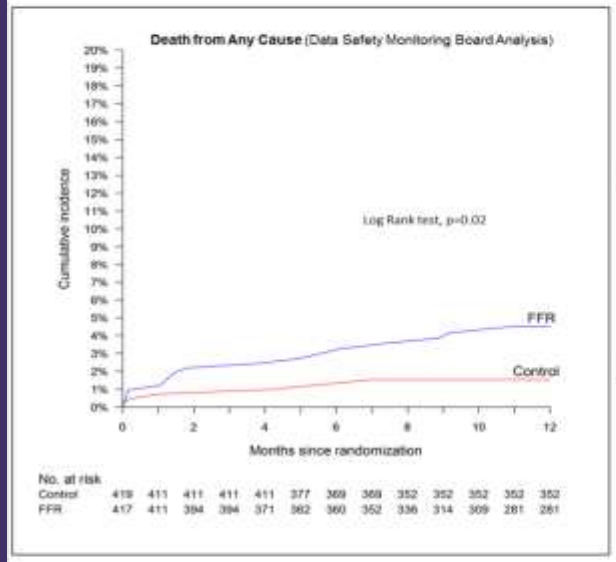
Angio-guided

non-invasive tests allowed

All lesions with %S>50 included in stratification

PCI + OMT | CABG + OMT | OMT only

DSMB: unexpected excess mortality in FFR group compared to control during safety analysis



Over n = 836 first patients

All-cause deaths at 12 months(n=24):
- control : 7 (2%)
- FFR : 17 (4%

HR 2.39, P=0.0193

Cardiovascular death: 72% of all deaths

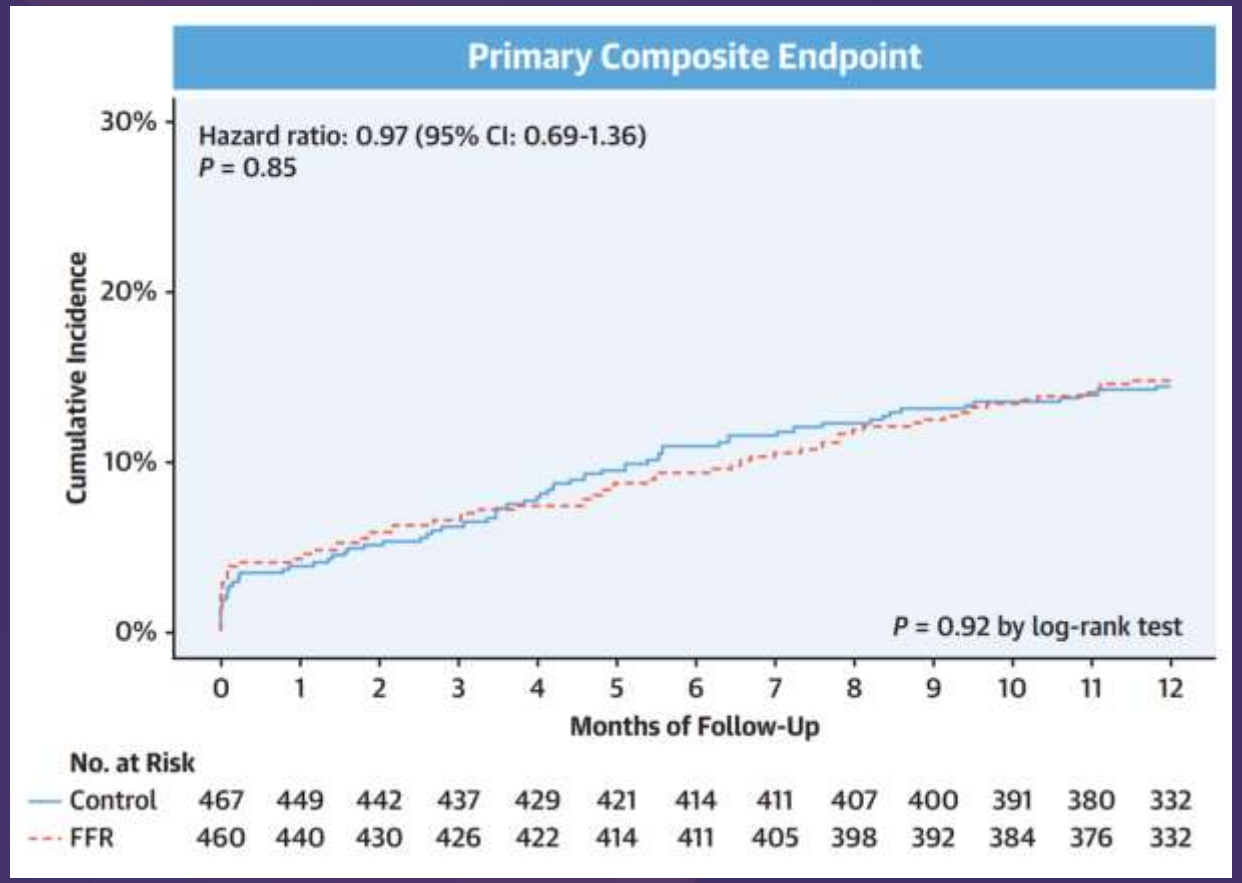
Sponsor and Steering Committee decided to follow DSMB recommendation and stopped recruitement at n=936 patients

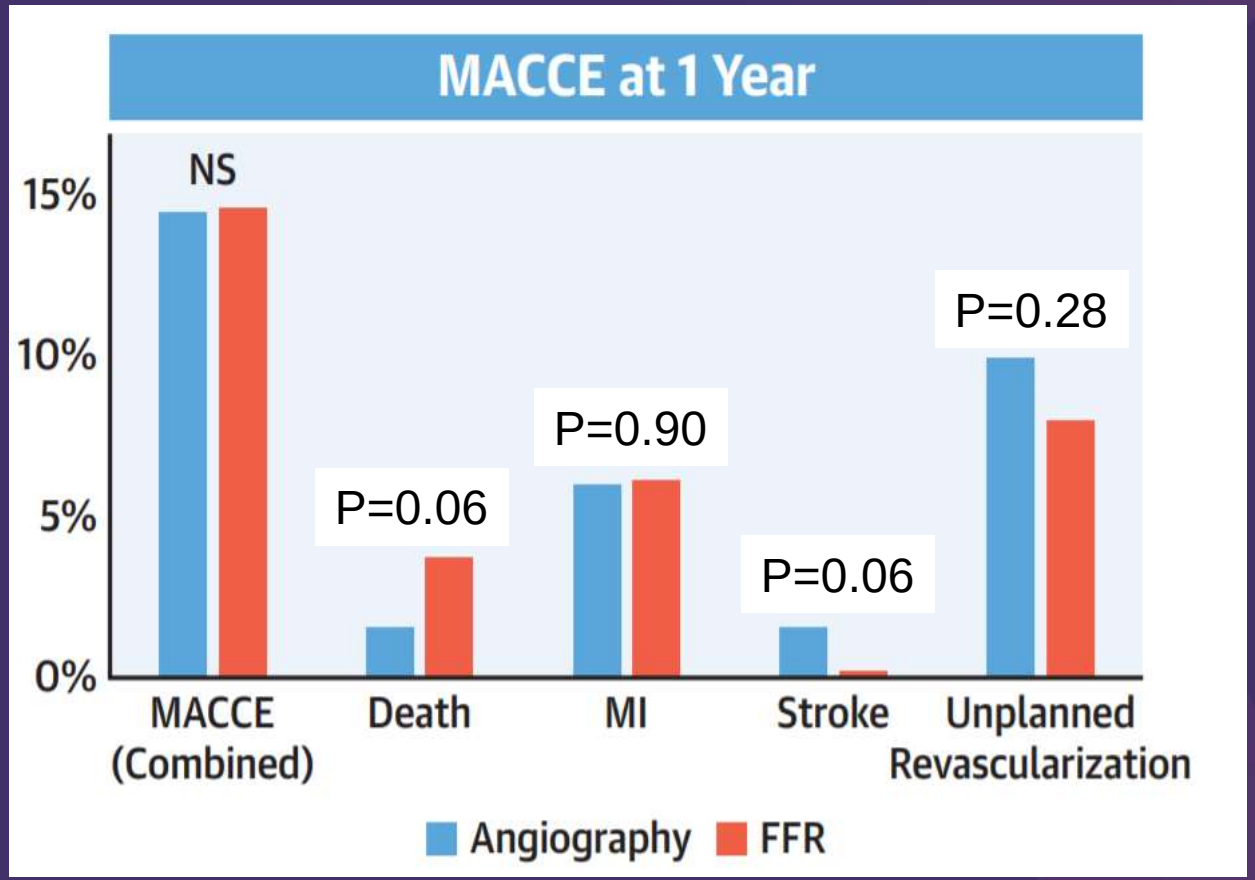
Results and follow-up are presented at cute of date of June 20th 2016

FUTURE Trial

Primary Endpoint

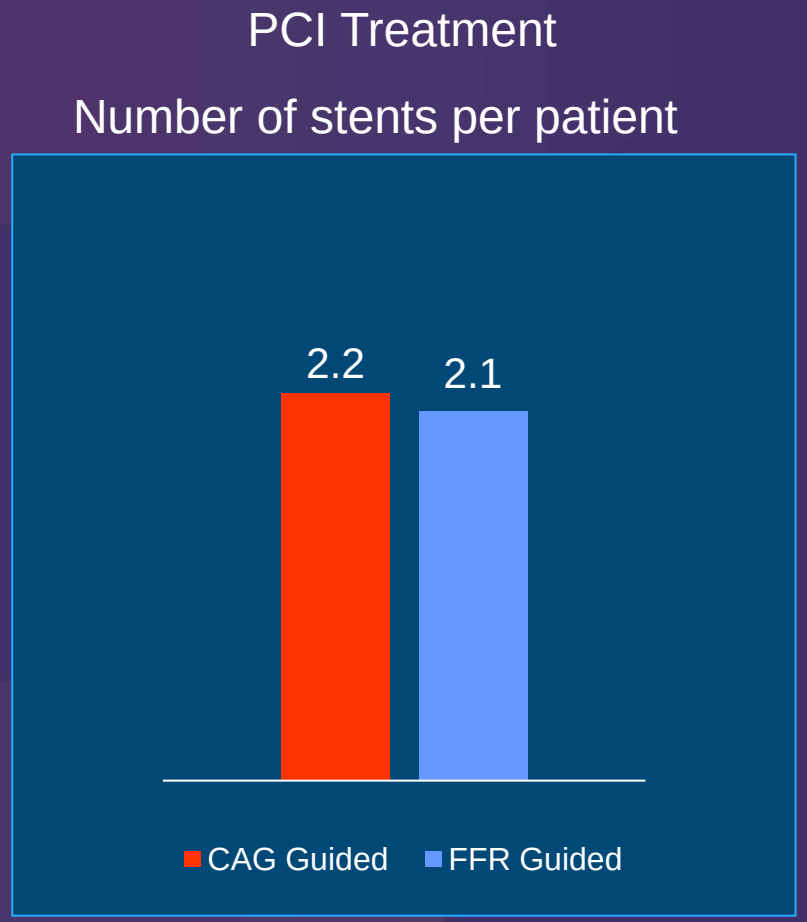
Death, nonfatal MI, stroke or unplanned hospitalization

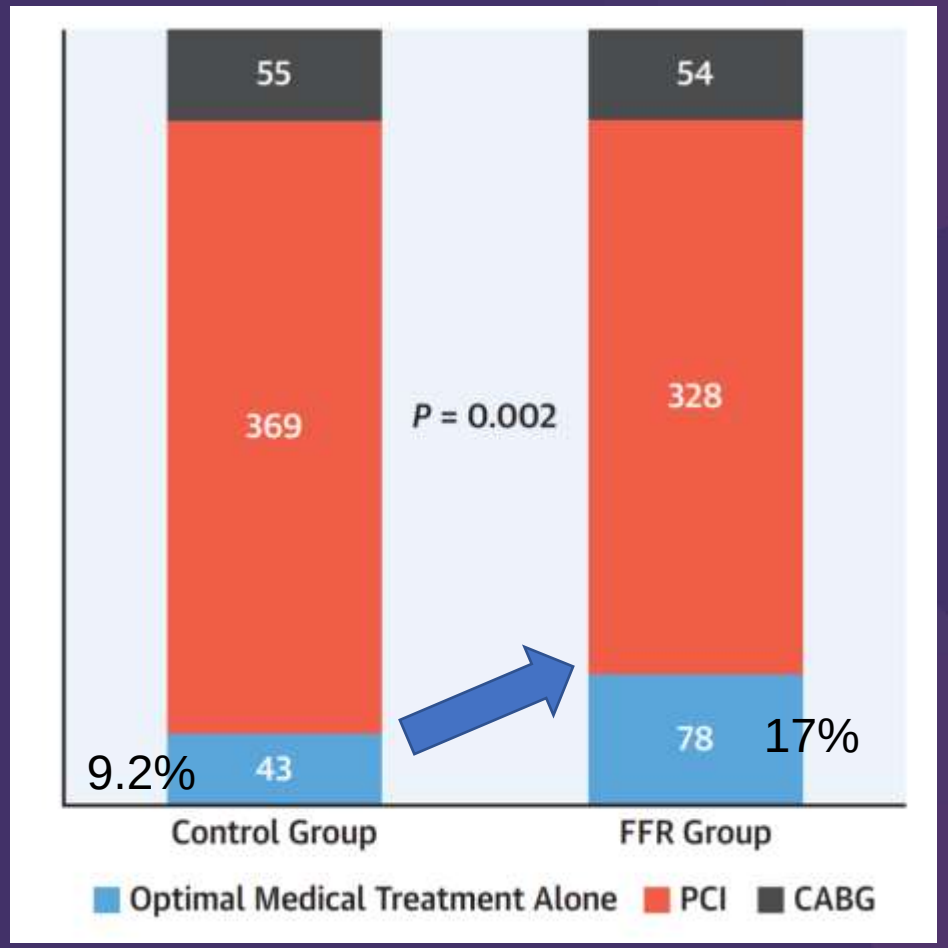




J Am Coll Cardiol 2021;78:1875–1885

Treatment Strategy





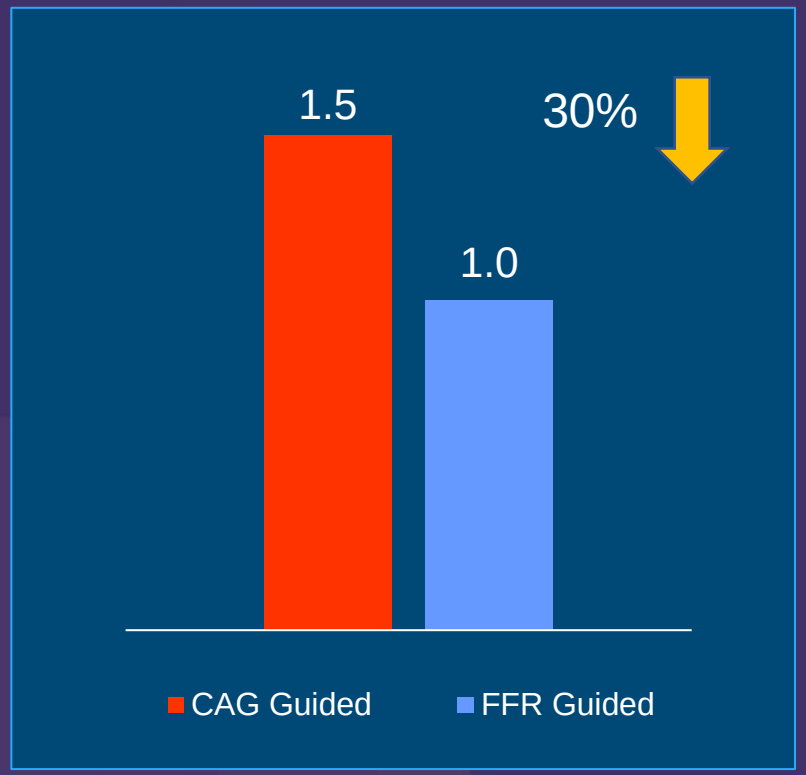
J Am Coll Cardiol 2021;78:1875–1885

Treatment Strategy

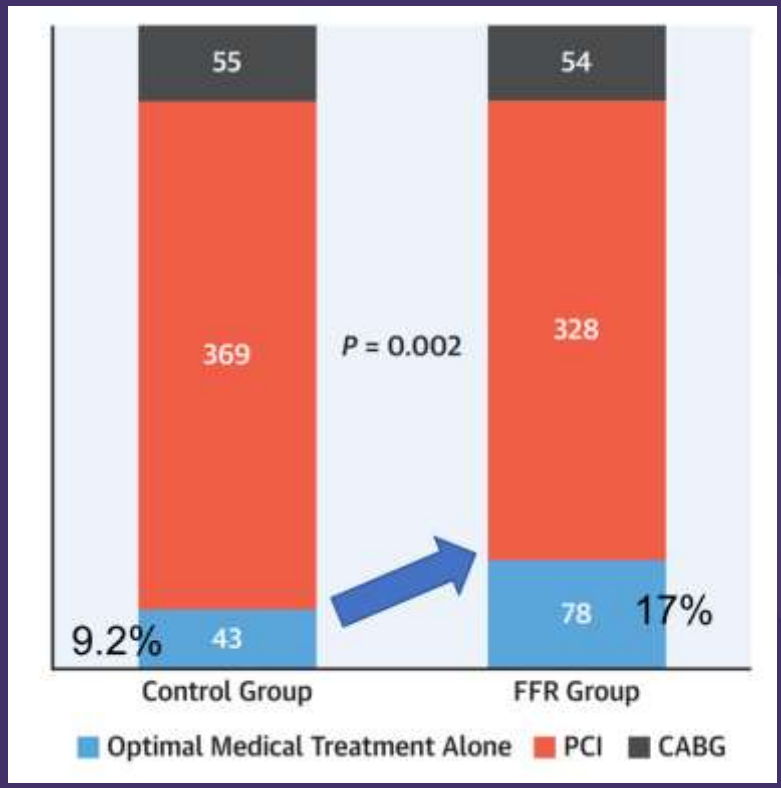
Reduced Stent Number and Increased Medical Treatment

FLOWER-MI

Number of stents per patient

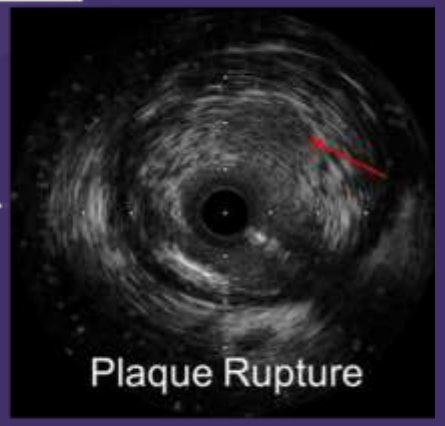


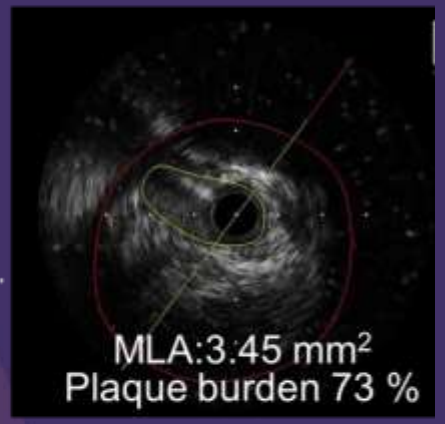
FUTURE Trial



Is Deferral Safe?

RCA, IVUS





FFR 0.89

Preventive PCI for FFR > 0.80 but vulnerable plaque

PREVENT Trial

Any Epicardial Coronary Stenosis **with**
FFR > 0.80 **and with** ***Two*** **of the following**

1. TCFA by OCT or VH-IVUS
2. IVUS MLA <4.0mm²
3. IVUS Plaque Burden >70%
4. Lipid-Rich Plaque on NIRS ($_{max}LCBI_{4mm}$>315)

R

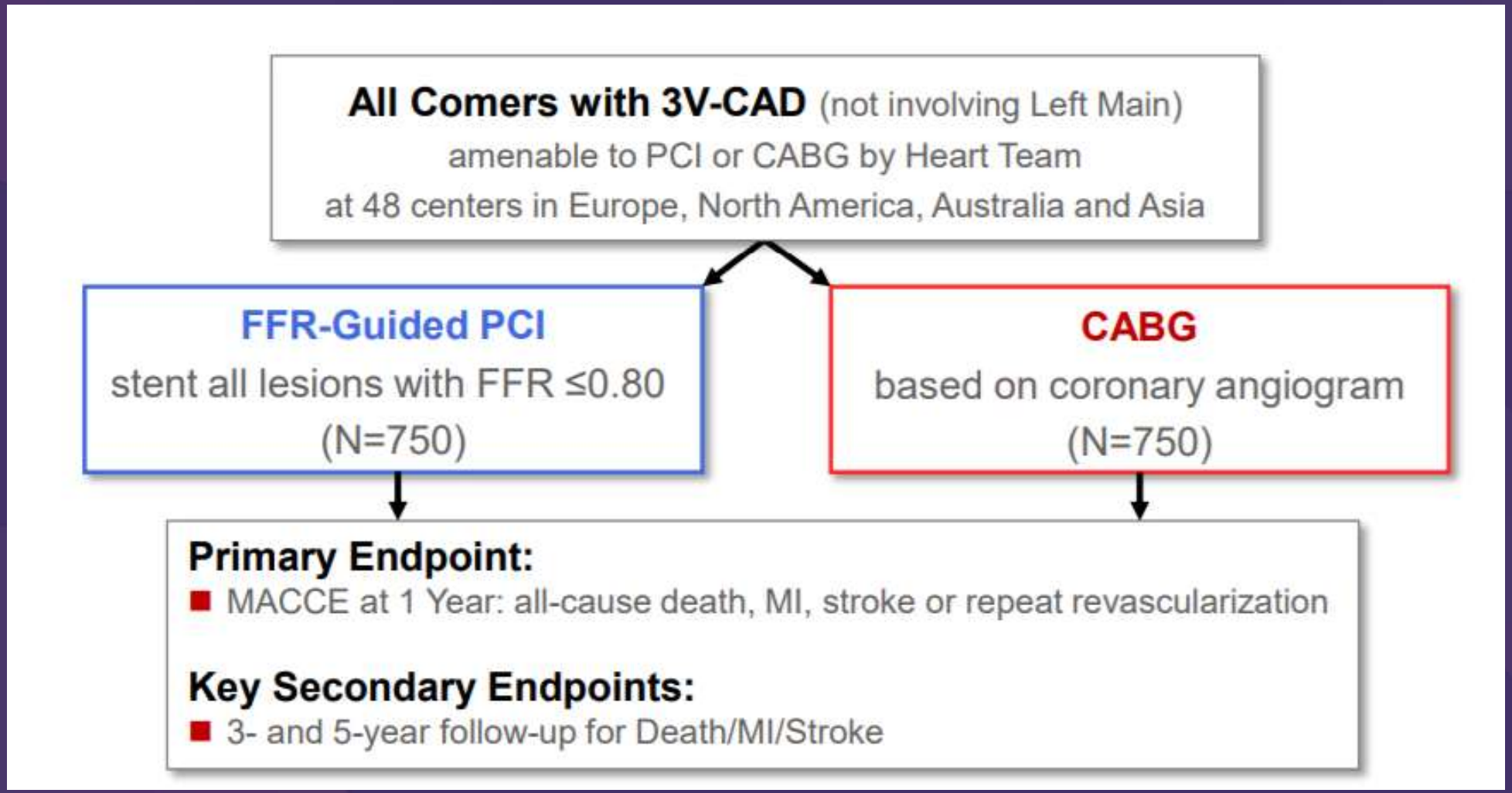
PCI+OMT
N=800

OMT
N=800

Primary endpoint *at 2 years*:
CV death, MI, Hospitalization d/t unstable angina

OCT sub-study/ NIRS sub-study, (300 patients in each arm at 2 years)

FAME3: FFR-Guided PCI vs. CABG

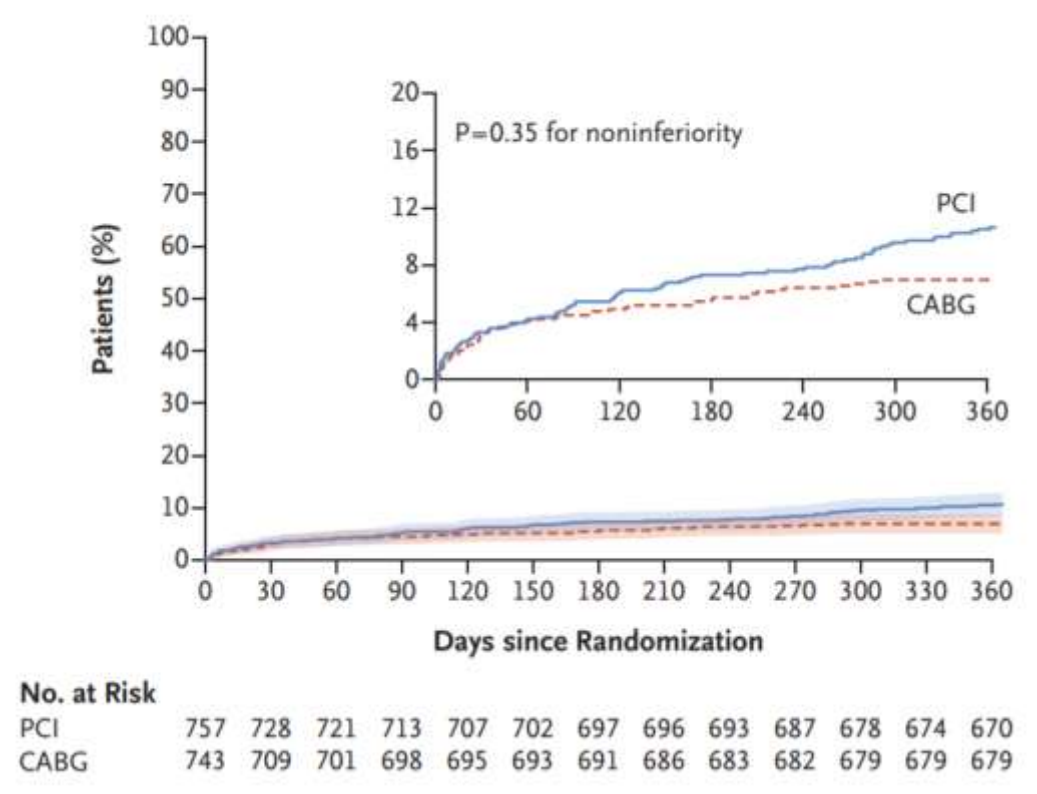


DOI: 10.1056/NEJMoa2112299

FAME3: FFR-Guided PCI vs. CABG

Primary Endpoint

Death, MI, stroke or Repeat revascularization



Endpoint	PCI (n=757)	CABG (n=743)	Hazard Ratio
Death	1.6%	0.9%	1.7 (0.7-4.3)
Cardiac death	0.8%	0.5%	
MI	5.2%	3.5%	1.5 (0.9-2.5)
Procedural	1.7%	1.2%	
Spontaneous	3.3%	2.3%	
Stroke	0.9%	1.1%	0.9 (0.3-2.4)
Repeat Revascularization	5.9%	3.9%	1.5 (0.9-2.3)
Death, MI or Stroke	7.3%	5.2%	1.4 (0.9-2.1)

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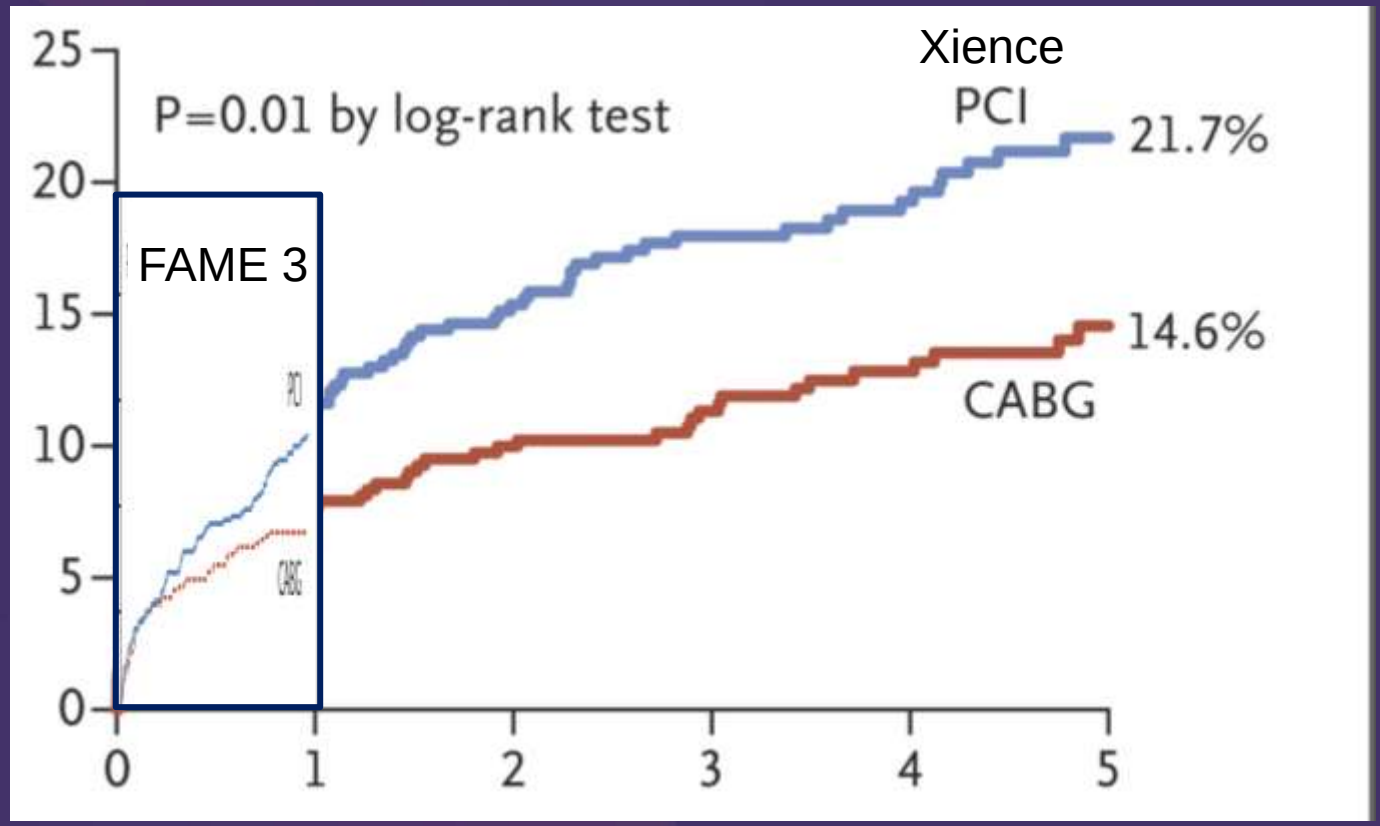
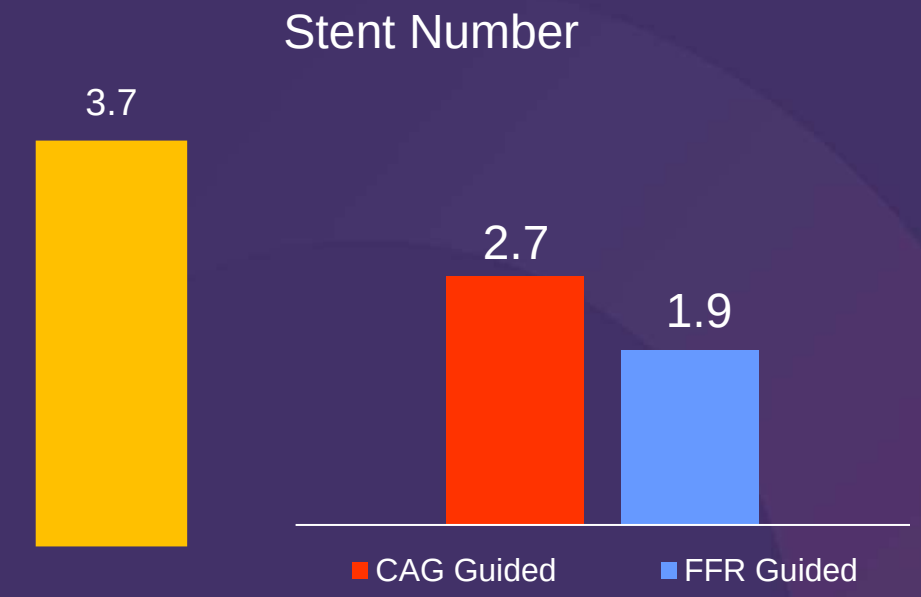
FAME3: FFR-Guided PCI vs. CABG

BEST Trial (PCI with 2nd DES)



N Engl J Med 2015; 372:1204-1212

% Lesions FFR measured	82%
FFR>0.80	24%
Staged procedure	22%
Number of stents	3.7±1.9
Total stent length	80 mm
Intravascular imaging	12%
FFR measured after PCI	60%



FAME 3 (3VD only)

FAME 1 (MVD)