

Updated Imaging/Physiology-Guided PCI Tuning 2021

Jung-Min Ahn, MD

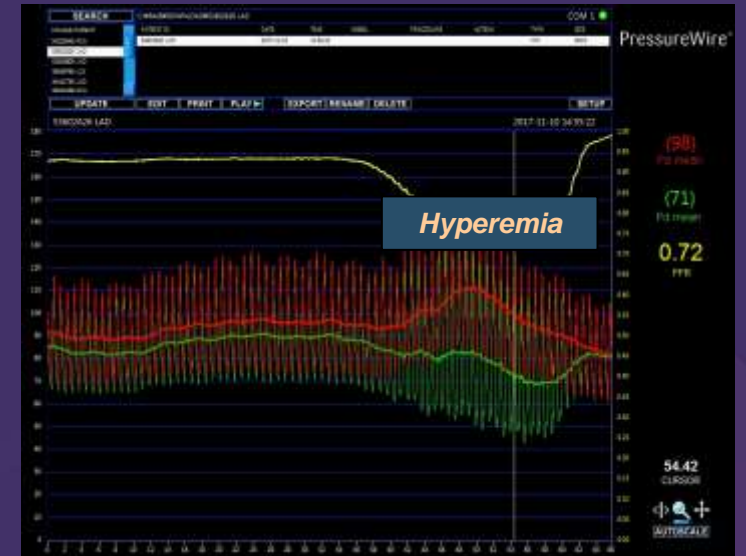
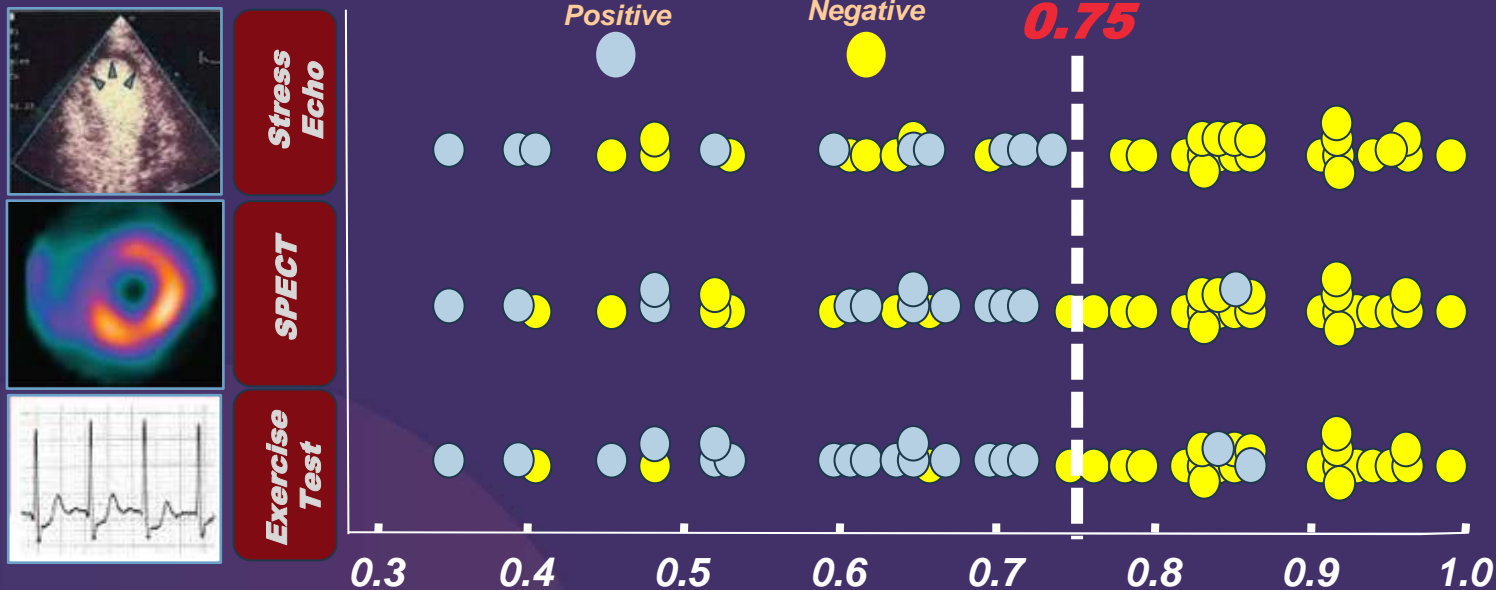
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Pressure Measurement For Coronary Stenosis

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

FFR as A Non-Invasive Functional Study In Cath Lab

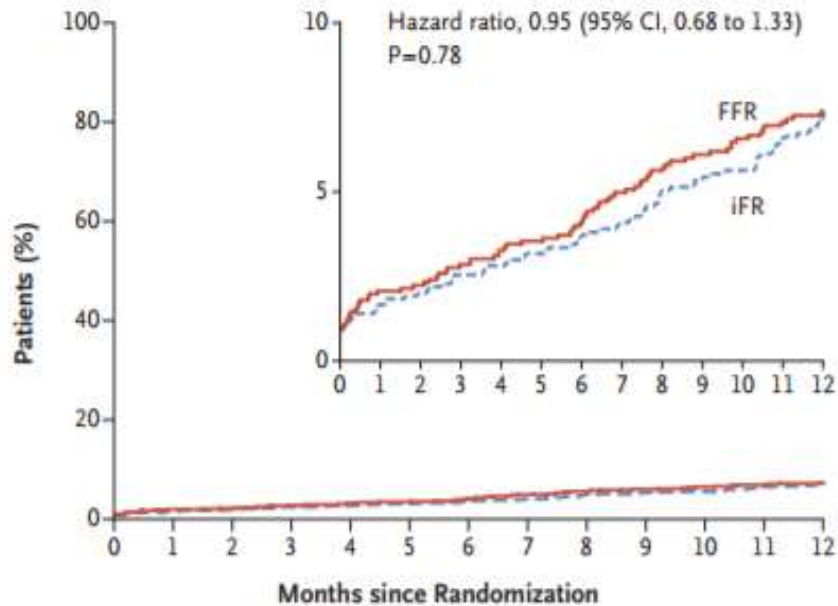
Comparison with 3 Non-Invasive Functional Studies



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

iFR is Non-Inferior to FFR

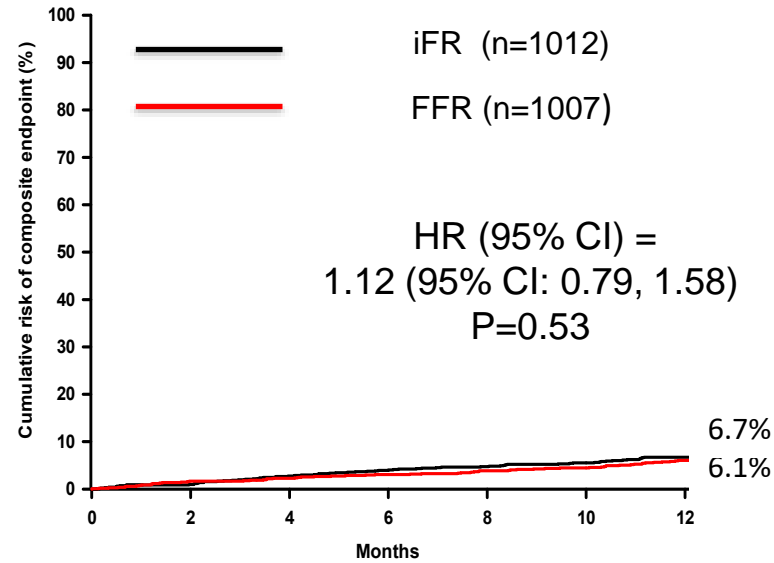
DEFINE-FLAIR



No. at Risk	0	1	2	3	4	5	6	7	8	9	10	11	12
iFR	1242	1149	1131	1122	1118	1111	1088	1052	1037	1027	1019	995	764
FFR	1250	1169	1156	1149	1144	1141	1119	1081	1066	1055	1046	1017	793

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

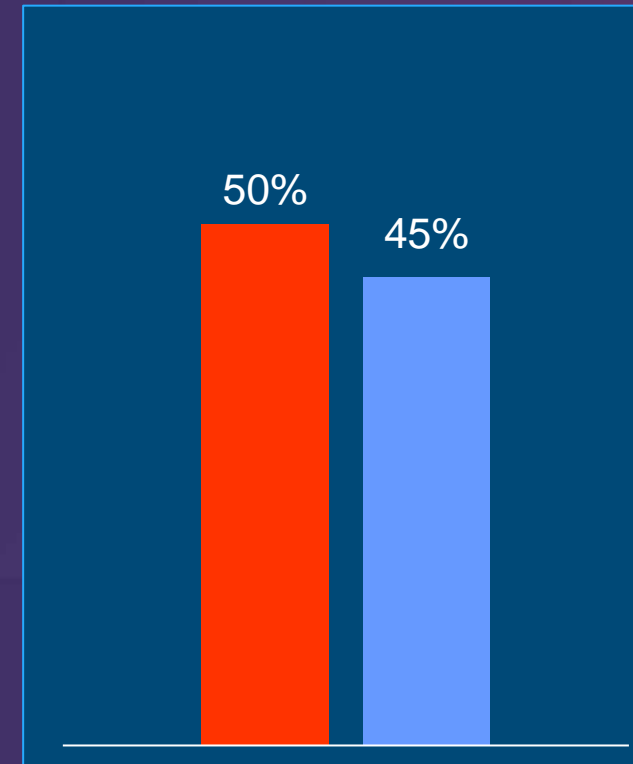
iFR-SWEDEHEART



No. at Risk	0	2	4	6	8	10	12
iFR	1012	1002	984	971	963	956	944
FFR	1007	990	984	976	968	961	946

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

Deferred Revascularization



■ iFR Guided ■ FFR Guided

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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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月印刷）

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

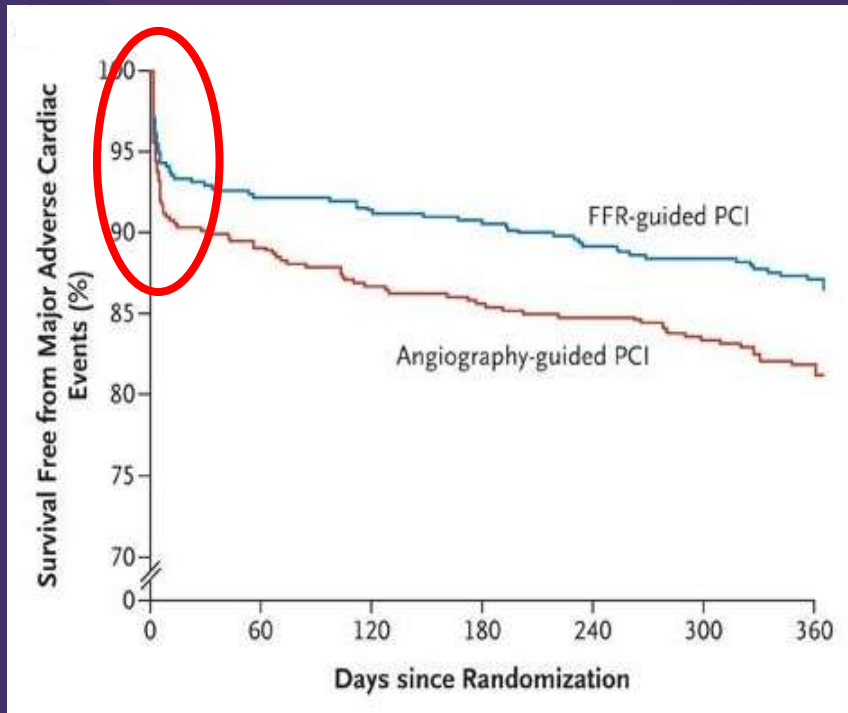
CCS Guideline 2019

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. ³⁴	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. ^{104,109}	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

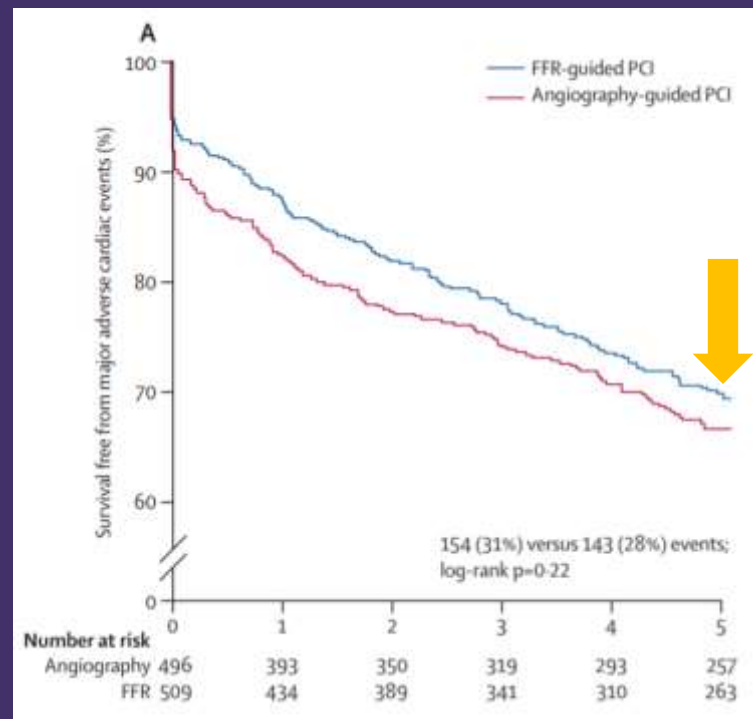
FFR- vs. CAG guided PCI in Multivessel Disease Primary Endpoint: Death, MI, and Repeat Revascularization

1 Year Follow-up



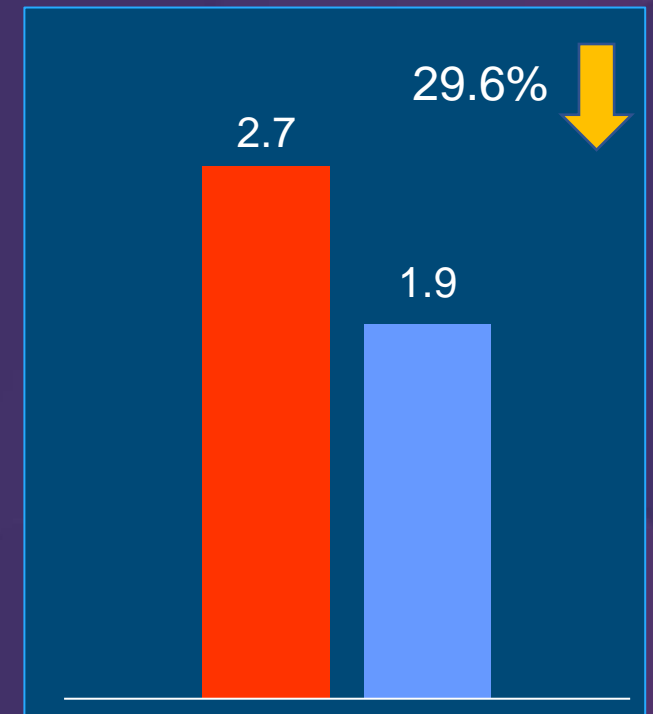
N Engl J Med 2009; 360:213-224

5 Year Follow-up



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

Number of stents per patient



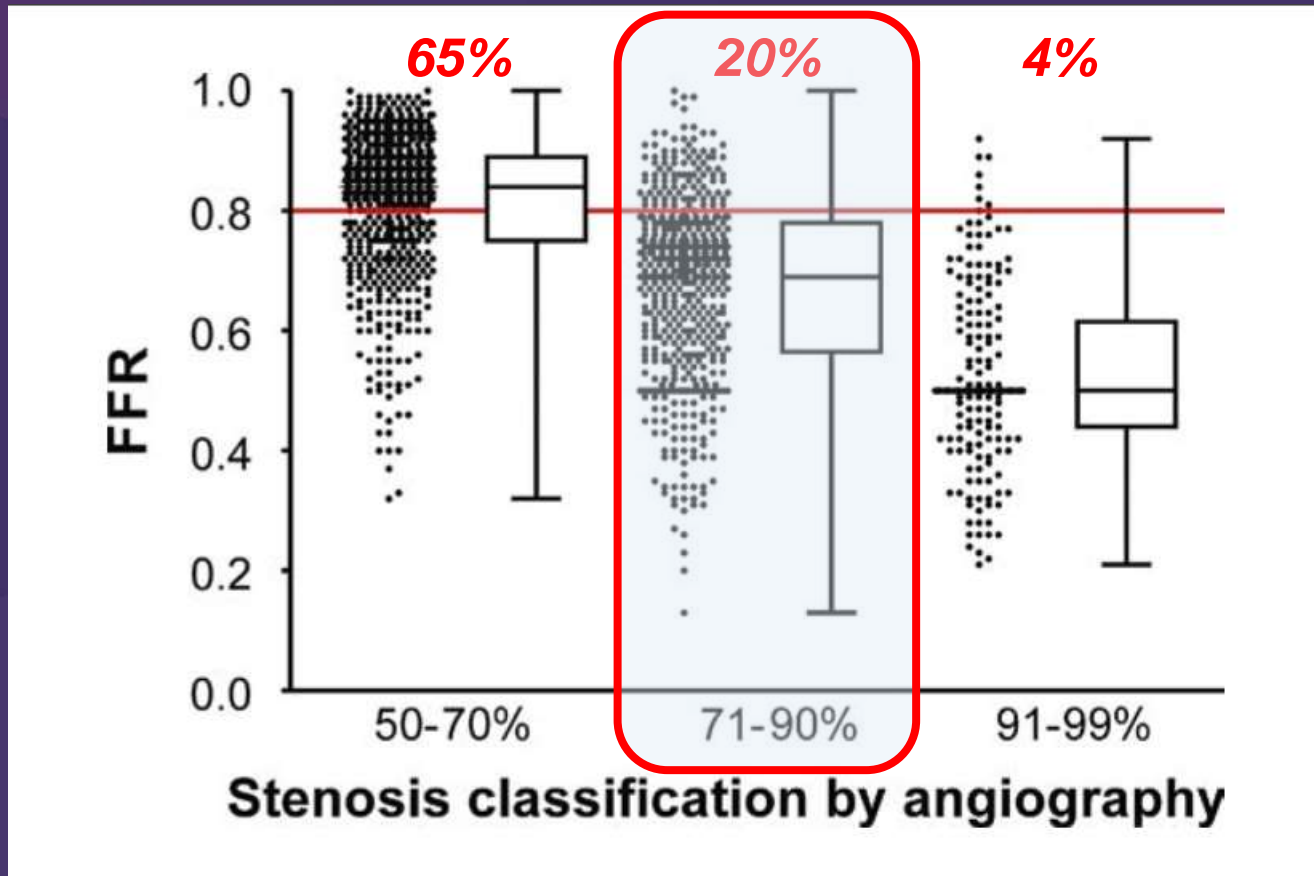
■ CAG Guided ■ FFR Guided

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

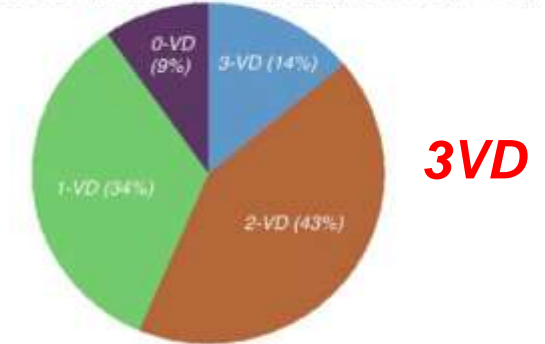
J Am Coll Cardiol 2010;56:177-84

FAME I

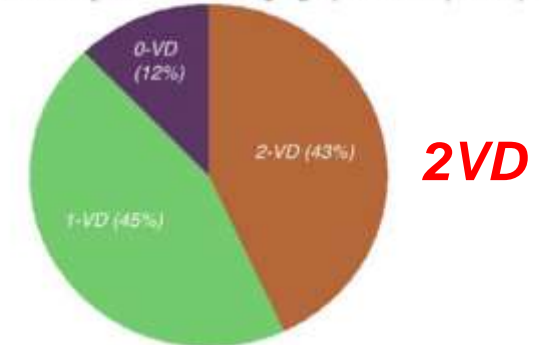
Visual Functional Mismatch



A Number of functionally diseased vessels (0-, 1-, 2-, or 3-VD) as proportions of all patients with angiographic 3-VD (N=115)*



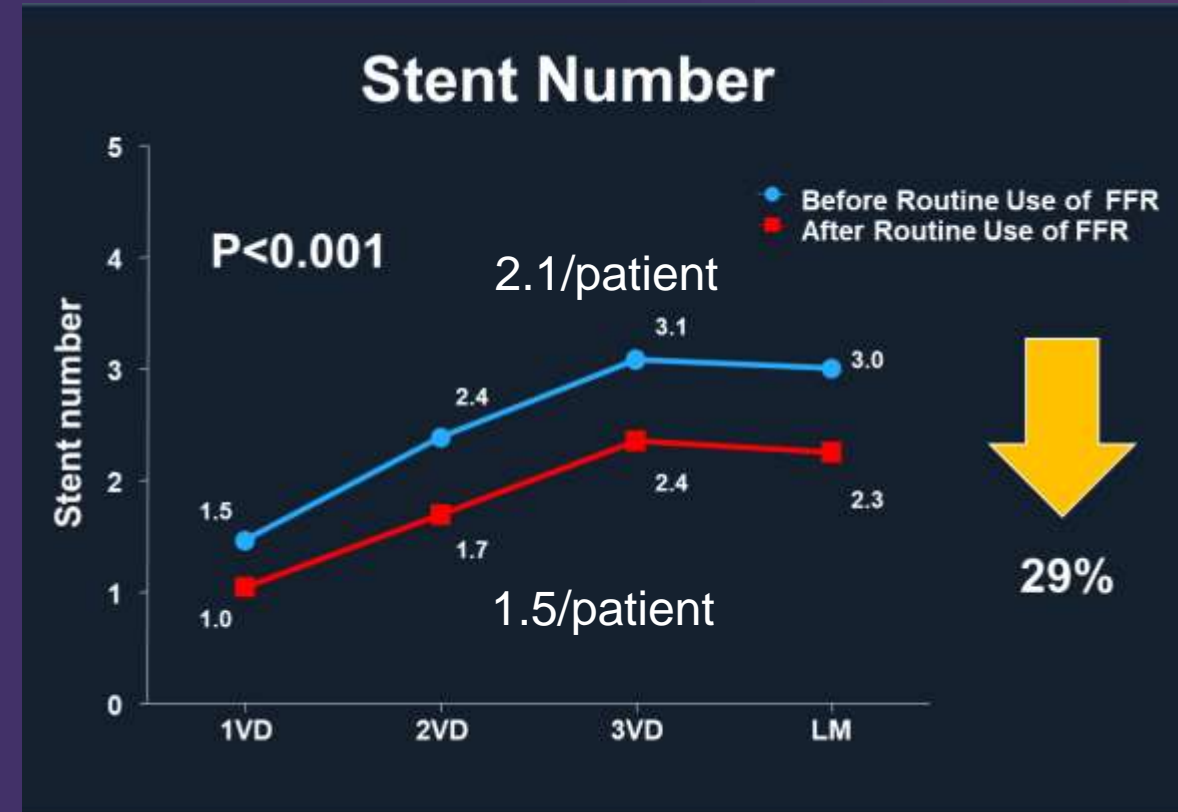
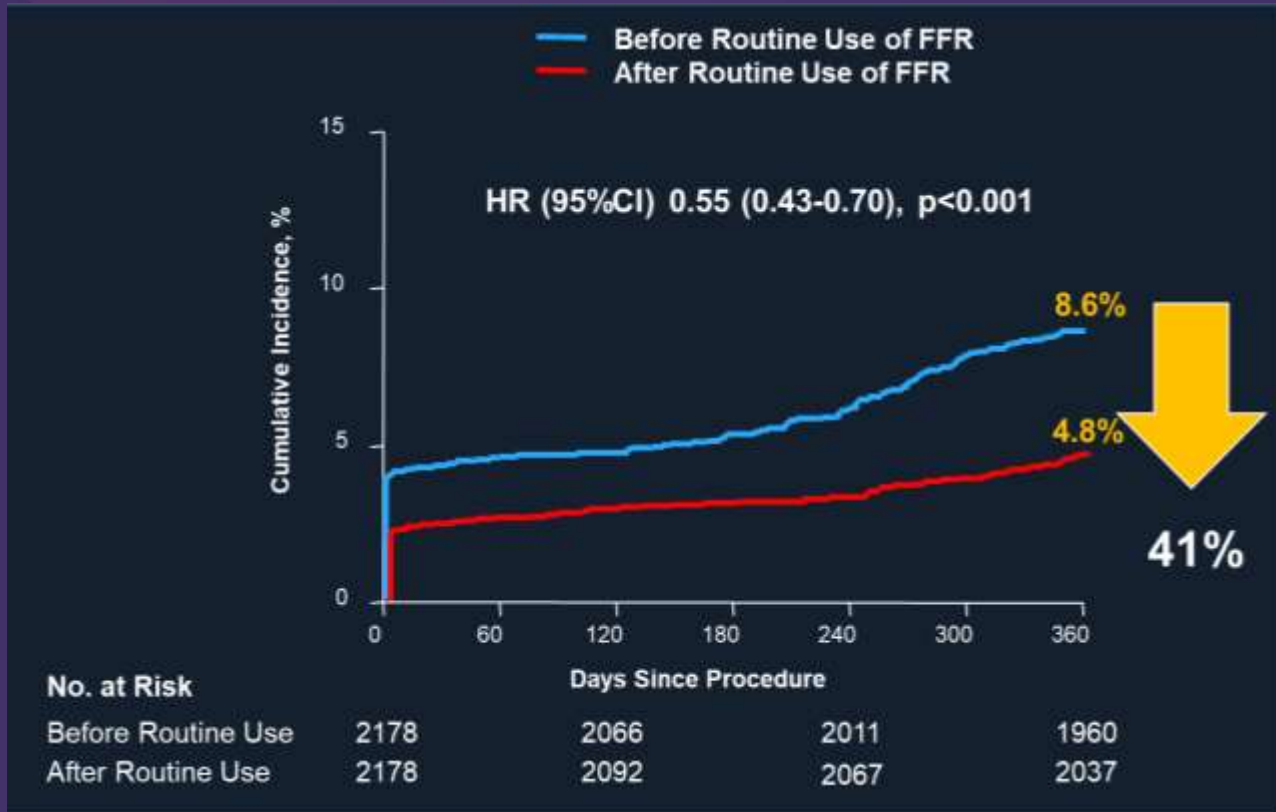
B Number of functionally diseased vessels (0-, 1-, 2-, or 2-VD) as proportions of all patients with angiographic 3-VD (N=394)*



J Am Coll Cardiol 2010;55:2816–21

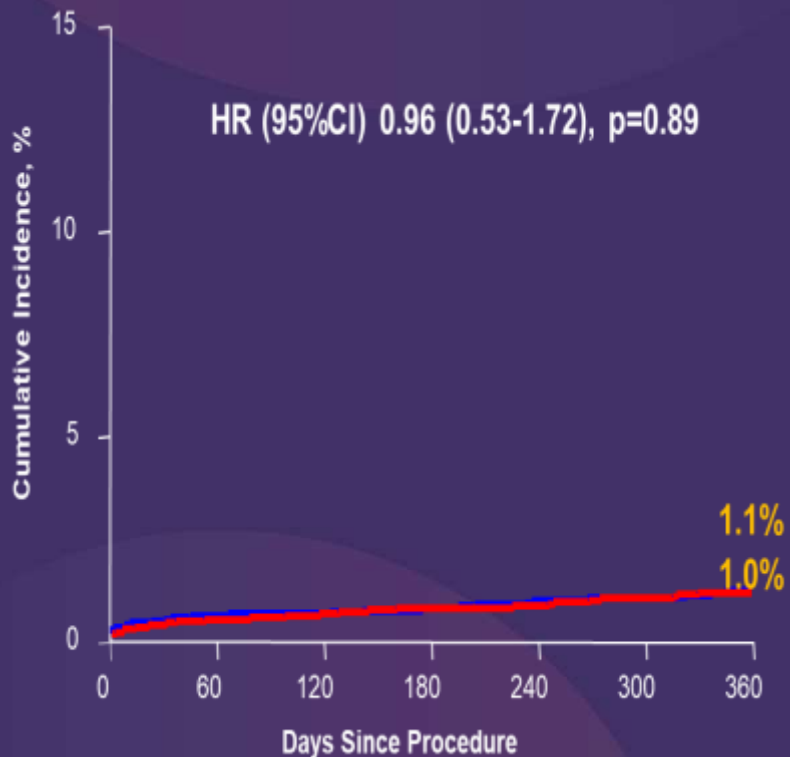
ASAN PCI Registry

Primary Endpoint: Death, MI, and Repeat Revascularization

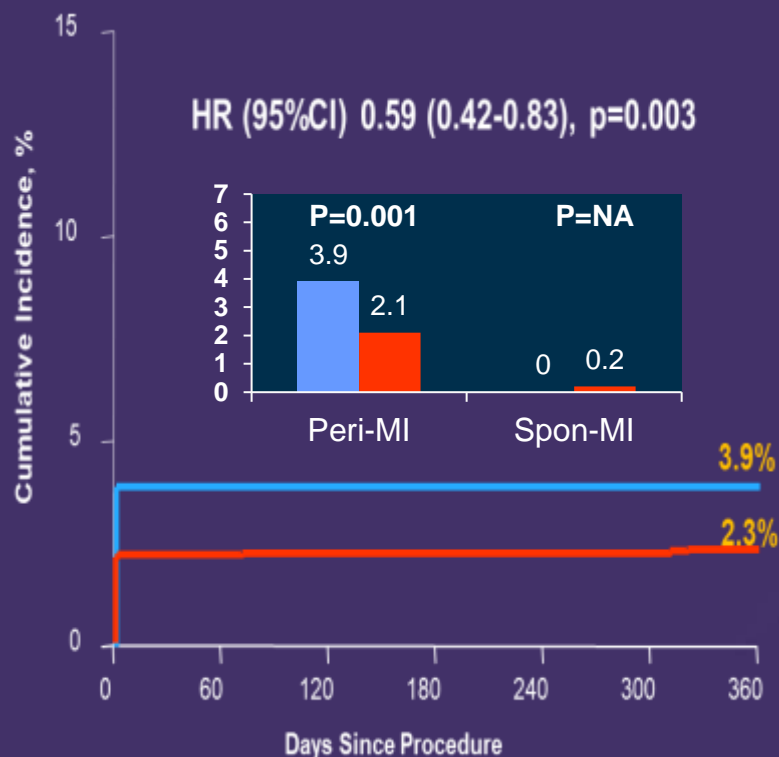


ASAN PCI Registry

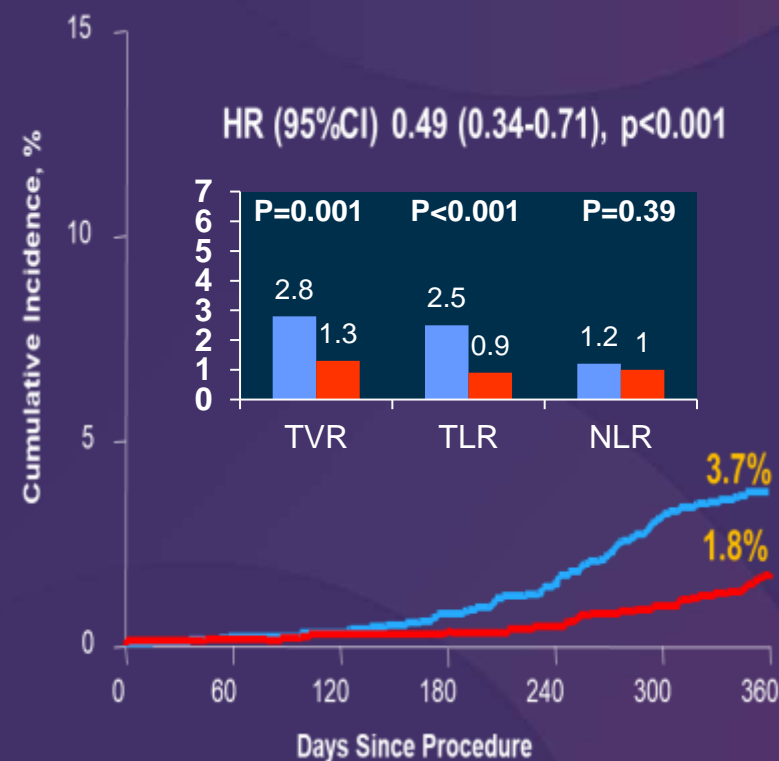
Death



MI



Repeat Revascularization



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

FLOWER-MI

FUTURE

FAME 3

Articles

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

Abstract **Background** FAVOR III China is a multicentre, randomised, sham-controlled trial done in 30 hospitals in China. Patients aged 18 years or older, with stable or unstable angina pectoris or patients who had a myocardial infarction at least 7 days before screening, who had at least one lesion with a diameter stenosis of 50–70% in a coronary artery with a reference vessel of at least 2.5 mm diameter by visual assessment were eligible. Patients were randomly assigned to a QFR-guided strategy (QFR-guided) or a standard angiography-guided strategy (standard). The primary endpoint was the 1-year rate of major adverse cardiac events, a composite of death from any cause, myocardial infarction, or ischaemic stroke. The primary analysis was done in the intention-to-treat population. The trial was registered with ClinicalTrials.gov (NCT04303884).

Results From May 23, 2018, and Jan 19, 2020, 847 patients were enrolled. After exclusion of 12 patients who did not fit angiographic QFR or other reasons by their physicians, 835 participants were included in the intention-to-treat population (418 in the QFR-guided group and 417 in the angiography-guided group). The mean age was 62.7 years (SD 10.3, 2009 (24.0) were men and 1634 (19.4) were women. 1295 (15.1%) had diabetes, and 1208 (14.3%) presented with an acute coronary syndrome. The lesion primary endpoint occurred in 118 (28.2%) patients in the QFR-guided group and in 147 (35.0%) patients in the angiography-guided group (difference, 7.8% [95% CI -1.7 to 14.6, hazard ratio 0.81 [95% CI 0.56 to 1.16], *p*=0.24). There were fewer myocardial infarctions and ischaemic stroke events in the QFR-guided group than in the angiography-guided group.

Interpretation In FAVOR III China, among patients undergoing PCI, a QFR-guided strategy of lesion selection improved 1-year clinical outcomes compared with standard angiography-guided.

Keywords Randomised trial, coronary artery disease, quantitative flow ratio, angiography-guided, sham-controlled trial.

Introduction In patients with obstructive coronary artery disease, angiography-based (visual assessment) lesion severity is widely used to guide percutaneous coronary intervention (PCI). Treatment with intracoronary stents is generally reserved for patients with angiographically significant lesions. However, the interobserver variability of visual assessment of lesions is high, and the use of quantitative flow ratio (QFR) to guide PCI has been shown to improve clinical outcomes compared with standard angiography-guided PCI. Randomised trials have demonstrated that percutaneous coronary intervention (PCI) guided by quantitative flow ratio (QFR) improved clinical outcomes compared with standard angiography-guided PCI in patients with obstructive coronary artery disease. The FAVOR III China trial was a multicentre, randomised, sham-controlled trial done in 30 hospitals in China. Patients aged 18 years or older, with stable or unstable angina pectoris or patients who had a myocardial infarction at least 7 days before screening, who had at least one lesion with a diameter stenosis of 50–70% in a coronary artery with a reference vessel of at least 2.5 mm diameter by visual assessment were eligible. Patients were randomly assigned to a QFR-guided strategy (QFR-guided) or a standard angiography-guided strategy (standard). The primary endpoint was the 1-year rate of major adverse cardiac events, a composite of death from any cause, myocardial infarction, or ischaemic stroke. The primary analysis was done in the intention-to-treat population. The trial was registered with ClinicalTrials.gov (NCT04303884).

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The NEW ENGLAND JOURNAL OF MEDICINE

Published July 22, 2021

Multivessel PCI Guided by FFR or Angiography for Myocardial Infarction

Abstract **Background** In patients with ST-segment myocardial infarction (STEMI) who have multivessel disease, percutaneous coronary intervention (PCI) for nonculprit lesions (multivessel PCI) is superior to medical treatment of the culprit lesion alone. However, whether culprit revascularization that is guided by fractional flow reserve (FFR) is superior to an angiography-guided procedure is unclear.

Methods In this multicentre trial, we randomly assigned patients with STEMI and multivessel disease who had angiographically significant PCI of the infarct-related artery to receive culprit revascularization guided by either FFR or angiography. The primary outcome was a composite of death from any cause, reinfarction, infarction, or hospitalization leading to repeat revascularization at 1 year.

Results The mean number of vessels that were placed per patient for multivessel lesions was 1.6 (SD 0.9) in the FFR-guided group and 1.6 (SD 0.9) in the angiography-guided group. During follow-up, a primary outcome event occurred in 32 of 586 patients (5.5%) in the FFR-guided group and in 24 of 577 patients (4.2%) in the angiography-guided group (hazard ratio, 1.33 [95% confidence interval, 0.75 to 2.37]; *P*=0.32). Death occurred in 9 patients (1.5%) in the FFR-guided group and in 10 (1.7%) in the angiography-guided group (hazard ratio, 1.05 [95% confidence interval, 0.35 to 3.00]; *P*=0.92). Reinfarction occurred in 15 (2.6%) in the FFR-guided group and in 11 (1.9%) in the angiography-guided group (hazard ratio, 1.33 [95% confidence interval, 0.56 to 3.14]; *P*=0.51). Hospitalization leading to repeat revascularization occurred in 23 (3.9%) in the FFR-guided group and in 17 (3.0%) in the angiography-guided group (hazard ratio, 1.33 [95% confidence interval, 0.61 to 2.90]; *P*=0.37).

Conclusions In patients with STEMI undergoing culprit revascularization, an FFR-guided strategy did not have a significant benefit over an angiography-guided strategy with respect to the risk of death, reinfarction, or hospitalization leading to repeat revascularization at 1 year. However, given the wide confidence intervals for the primary effect, the findings do not allow for a conclusive interpretation. (Funded by the French Ministry of Health and others; FLOWER-MI ClinicalTrials.gov number, NCT03499994.)

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

Abstract **Background** There is limited evidence that fractional flow reserve (FFR) is effective in guiding therapeutic strategy in multivessel coronary artery disease. We evaluated the effect of percutaneous coronary intervention of nonculprit artery lesions guided by FFR or angiography.

Methods The FUTURE-3 (Fractional Flow Reserve Guiding Treatment of Multivessel Coronary Artery Disease) trial was a multicentre, randomised, sham-controlled trial done in 10 hospitals in China. Patients aged 18 years or older, with multivessel coronary artery disease who had angiographically significant PCI of the infarct-related artery to receive culprit revascularization guided by either FFR or angiography. The primary outcome was a composite of death from any cause, reinfarction, infarction, or hospitalization leading to repeat revascularization at 1 year.

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Fractional Flow Reserve-Guided PCI Compared With Coronary Bypass Surgery

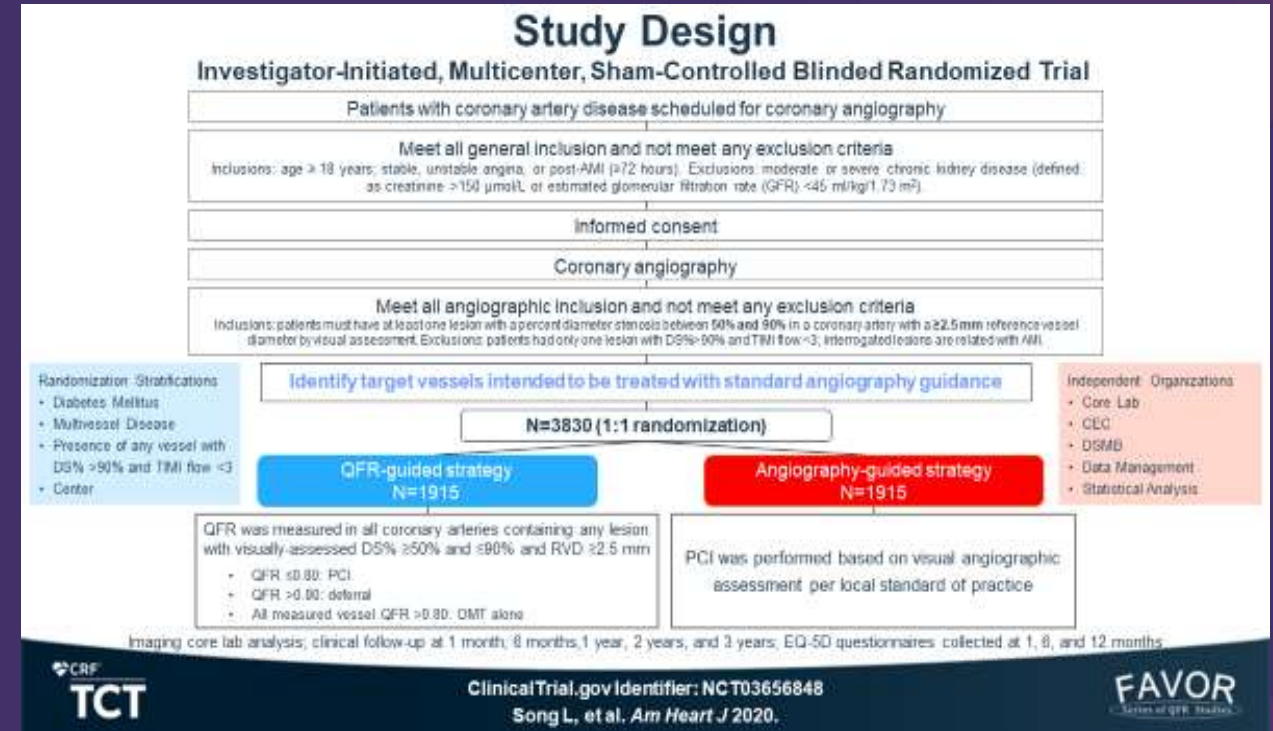
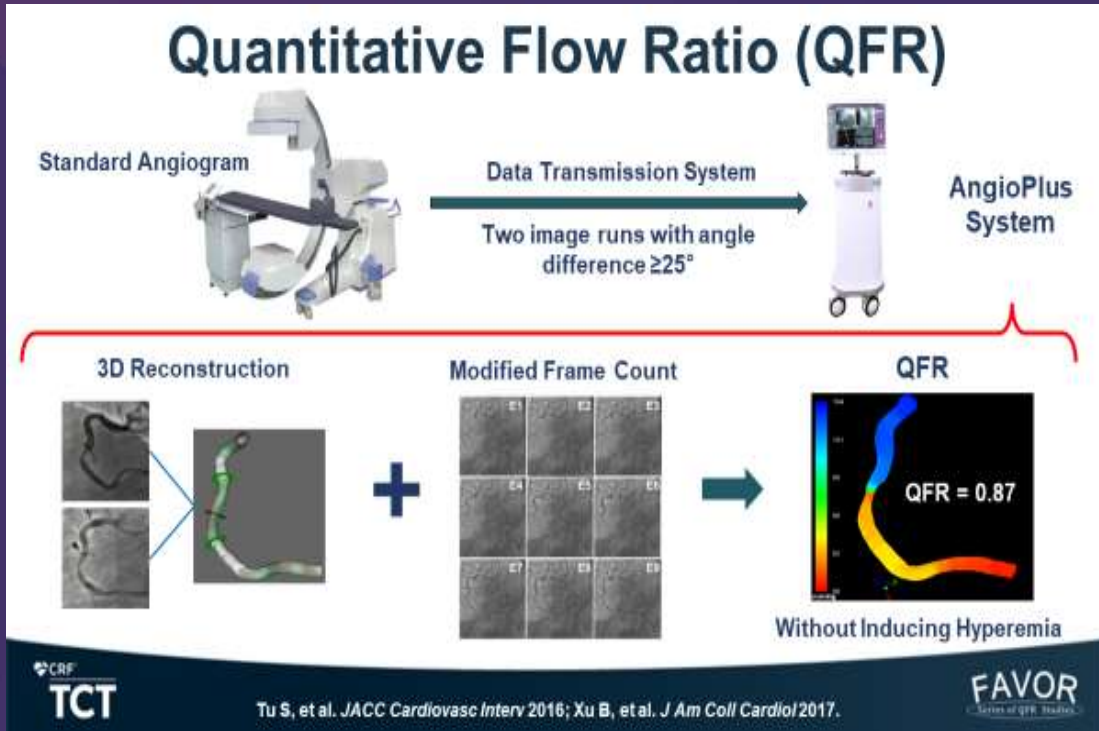
Abstract **Background** In patients with multivessel coronary artery disease, percutaneous coronary intervention (PCI) with current-generation stents is superior to medical treatment. However, whether PCI is superior to coronary artery bypass grafting (CABG) in patients with multivessel coronary artery disease who have angiographically significant PCI of the infarct-related artery to receive culprit revascularization guided by either FFR or angiography is unclear.

Methods The FAVOR III China is a multicentre, randomised, sham-controlled trial done in 30 hospitals in China. Patients aged 18 years or older, with multivessel coronary artery disease who had angiographically significant PCI of the infarct-related artery to receive culprit revascularization guided by either FFR or angiography. The primary outcome was a composite of death from any cause, reinfarction, infarction, or hospitalization leading to repeat revascularization at 1 year.

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FAVOR III China Randomized Trial

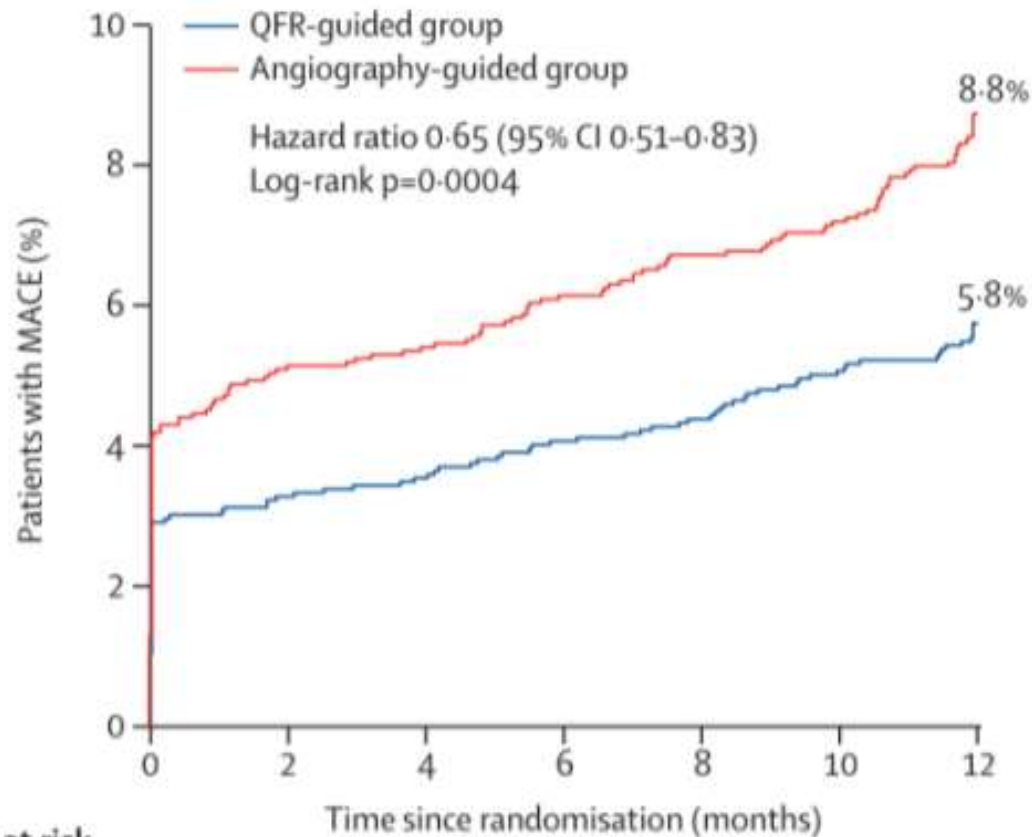


Combination of Coronary Imaging and Physiology

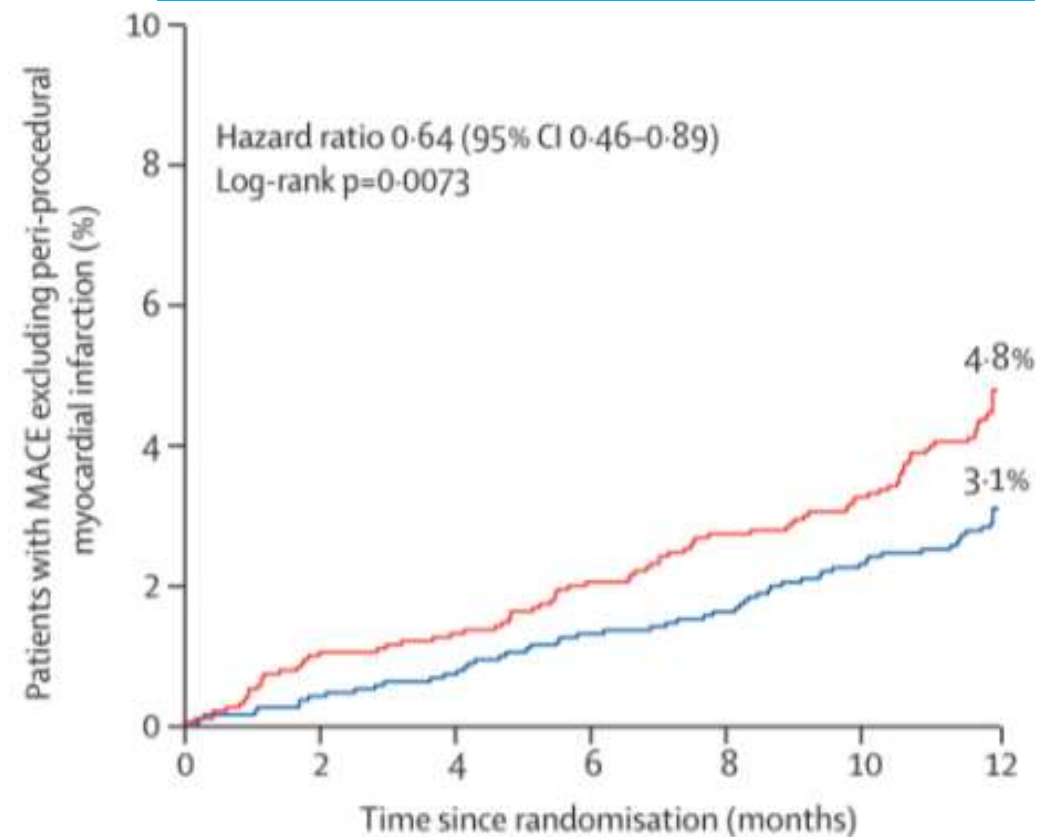
FAVOR III China Randomized Trial

Death, MI, Ischemia-driven Revascularization

Excluding peri-procedural MI



Number at risk		Time since randomisation (months)						
		0	2	4	6	8	10	12
QFR-guided group	1913	1845	1840	1828	1821	1809	1795	
Angiography-guided group	1912	1804	1798	1783	1770	1762	1732	

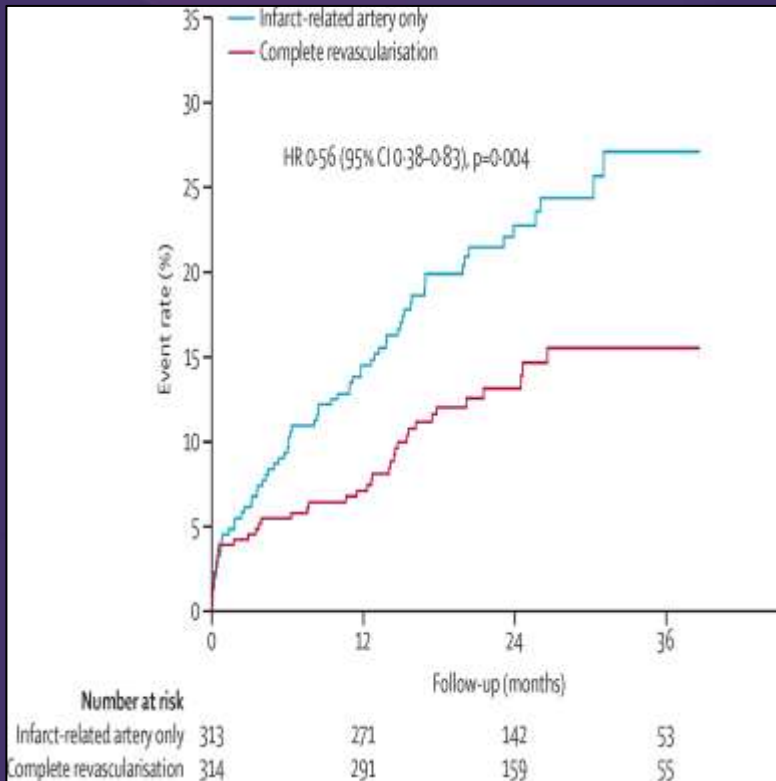


Number at risk		Time since randomisation (months)						
		0	2	4	6	8	10	12
QFR-guided group	1913	1900	1894	1881	1874	1862	1846	
Angiography-guided group	1912	1883	1877	1862	1847	1839	1808	

Complete Revascularization in STEMI

DANAMI-3 PRIMULTI Trial

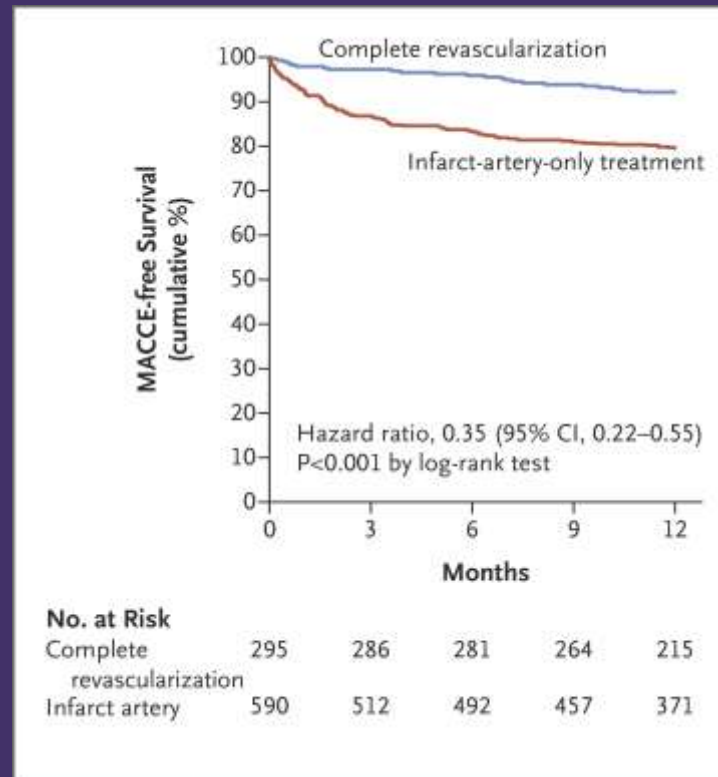
CAG Guided PCI



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

COMPARE ACUTE Trial

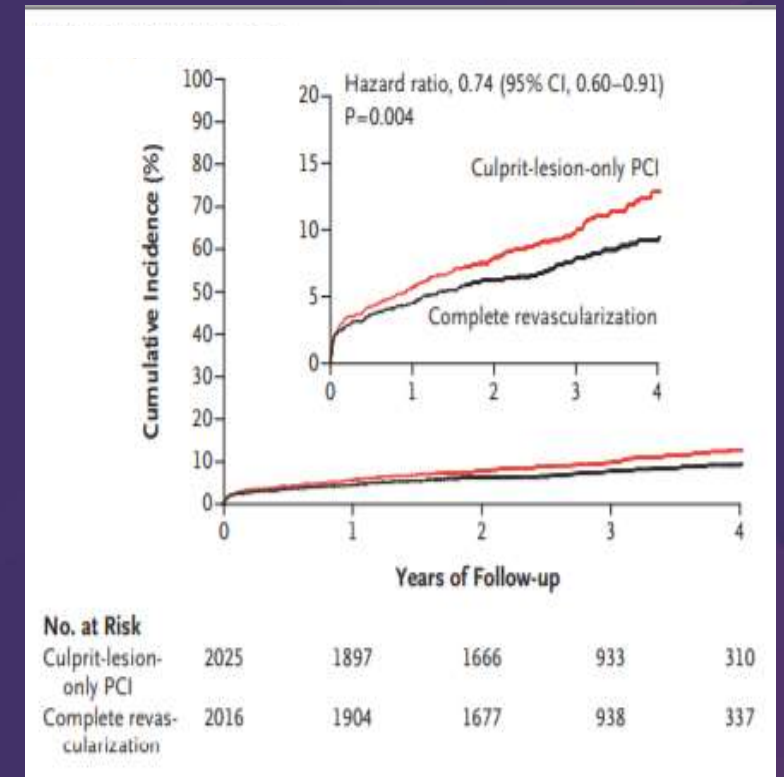
FFR Guided PCI



N Engl J Med 2017; 376:1234-1244

COMPLETE Trial

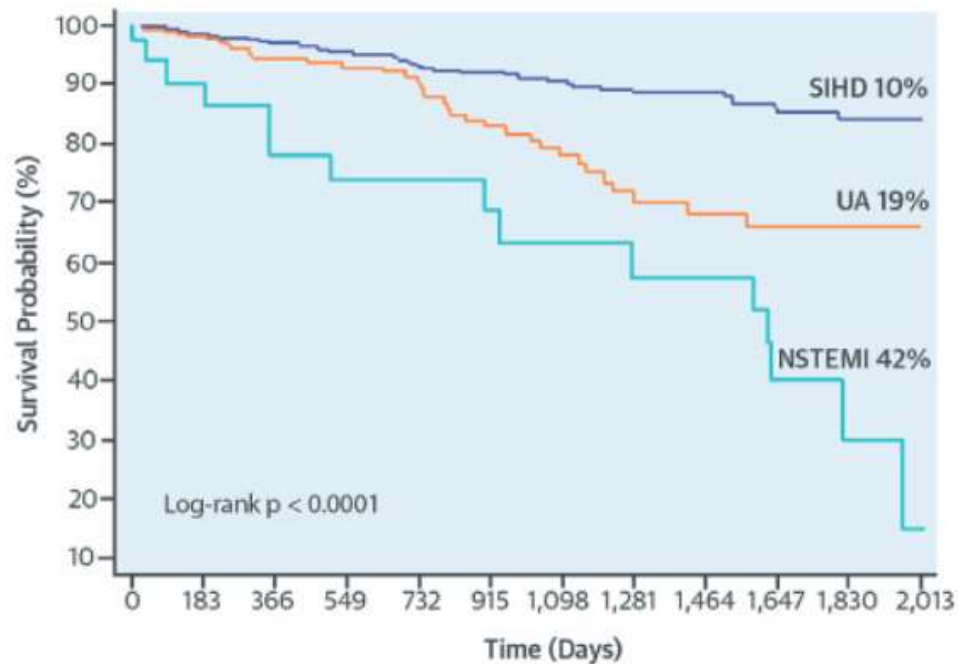
CAG Guided PCI



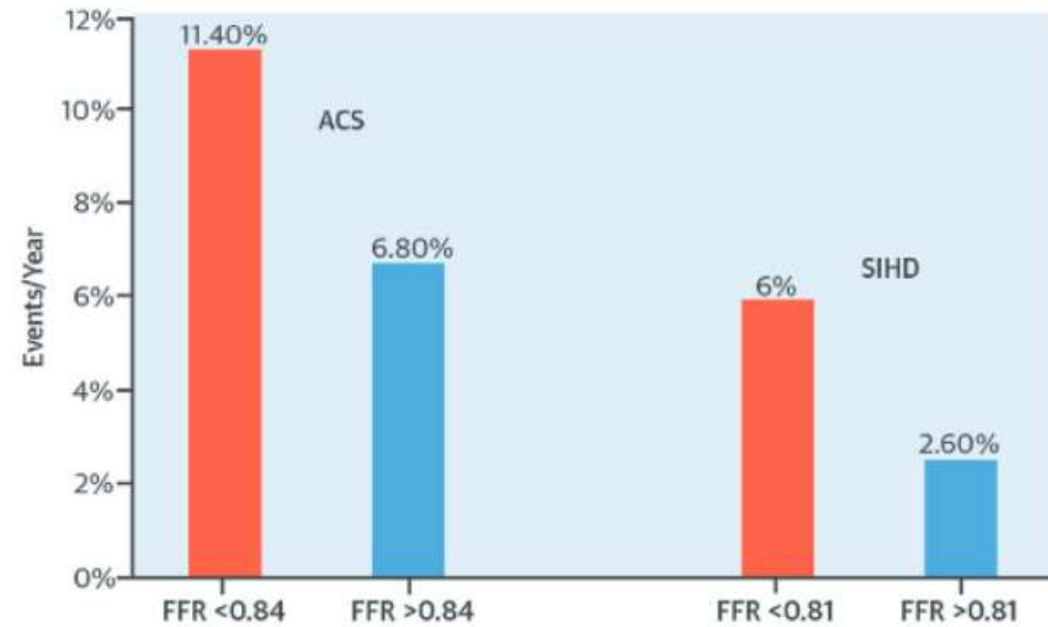
N Engl J Med 2019; 381:1411-1421

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

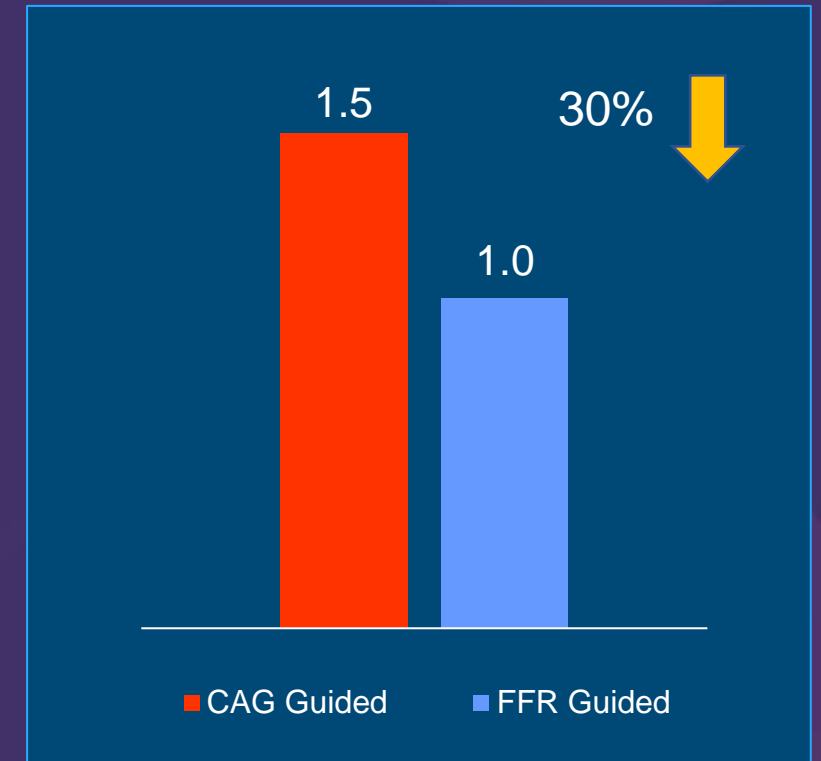
FLOWER-MI

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)	—	

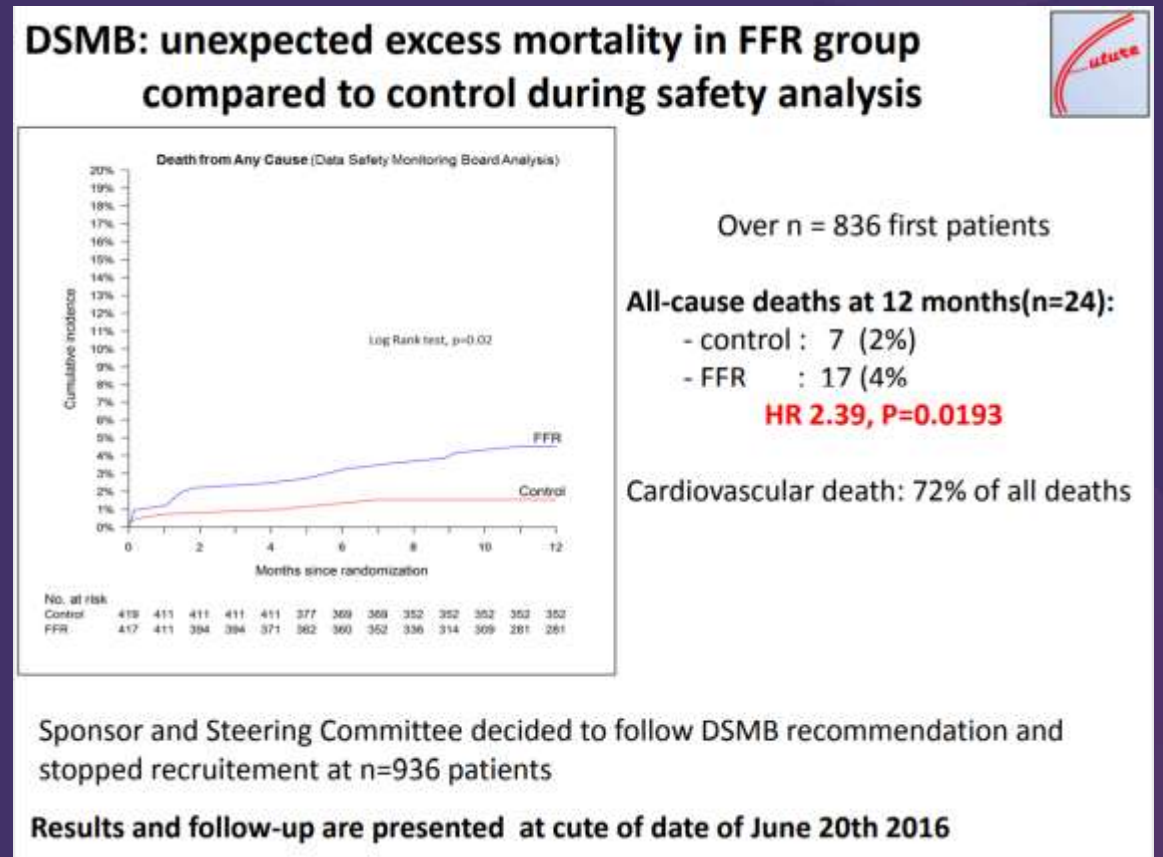
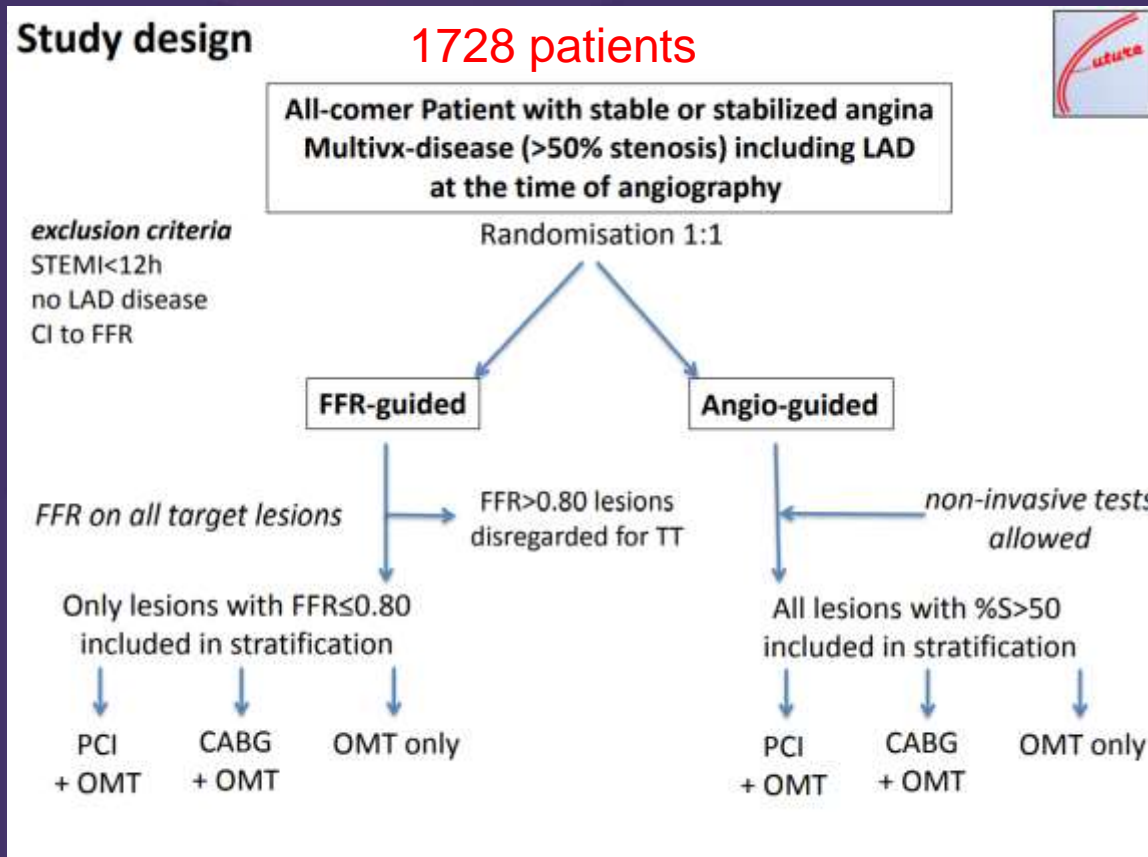
Number of stents per patient



FUTURE Trial

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

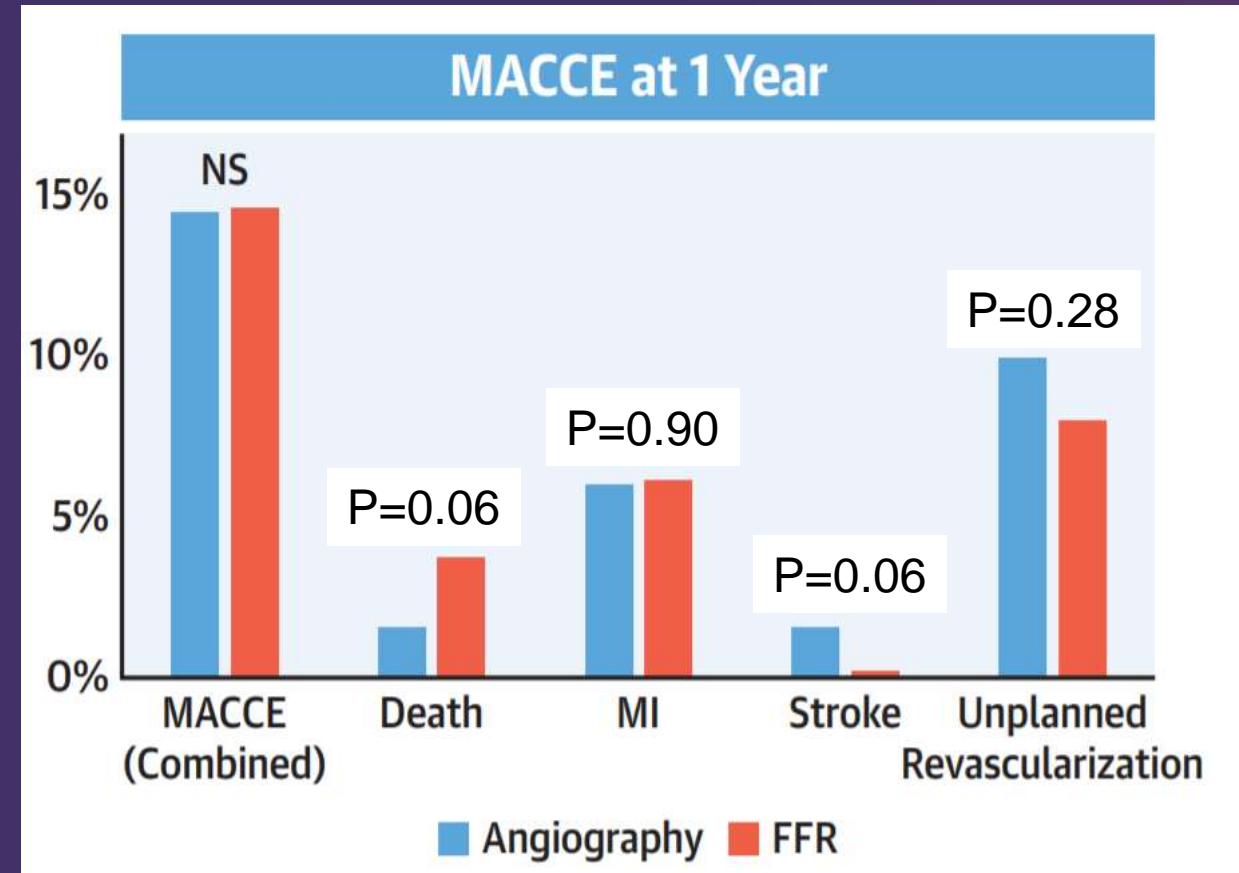
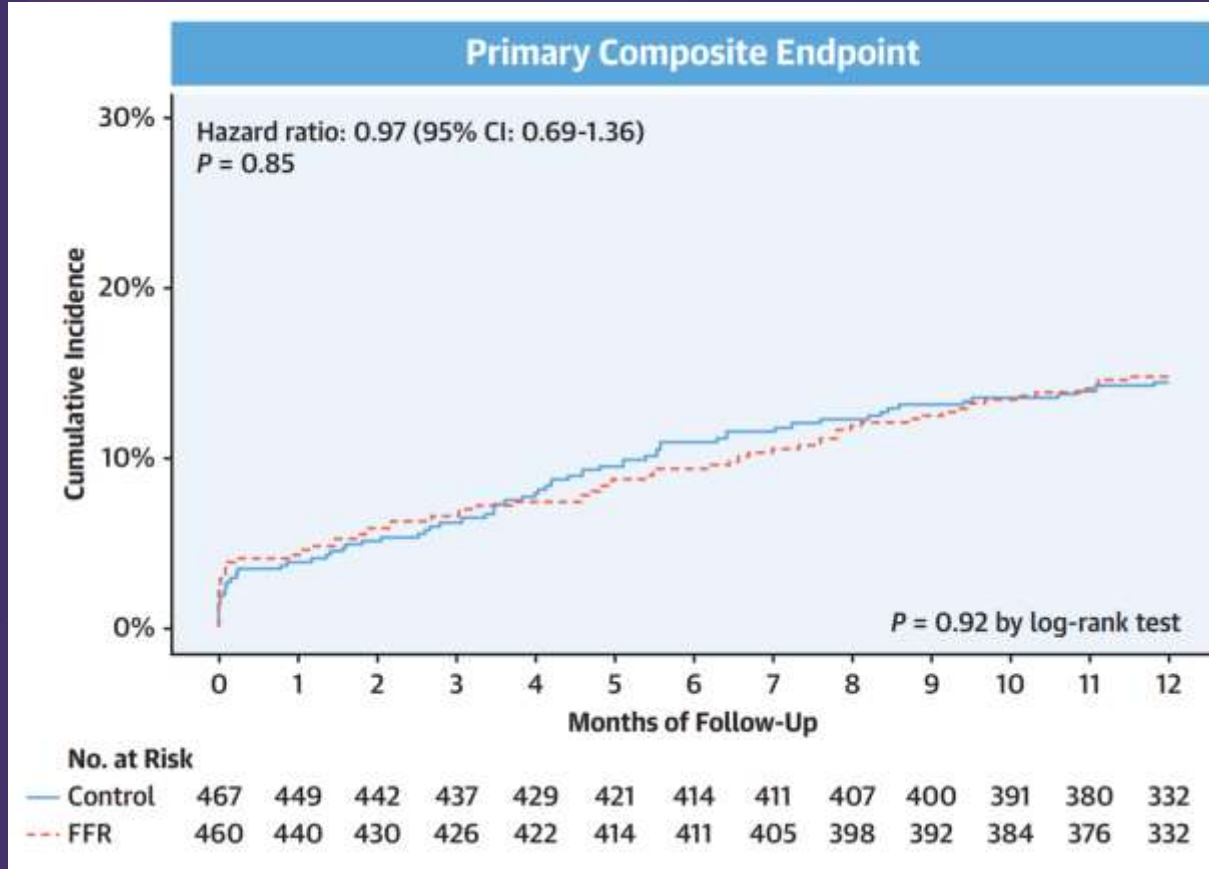
AHA Late Breaking Trial at 2016



FUTURE Trial

Primary Endpoint

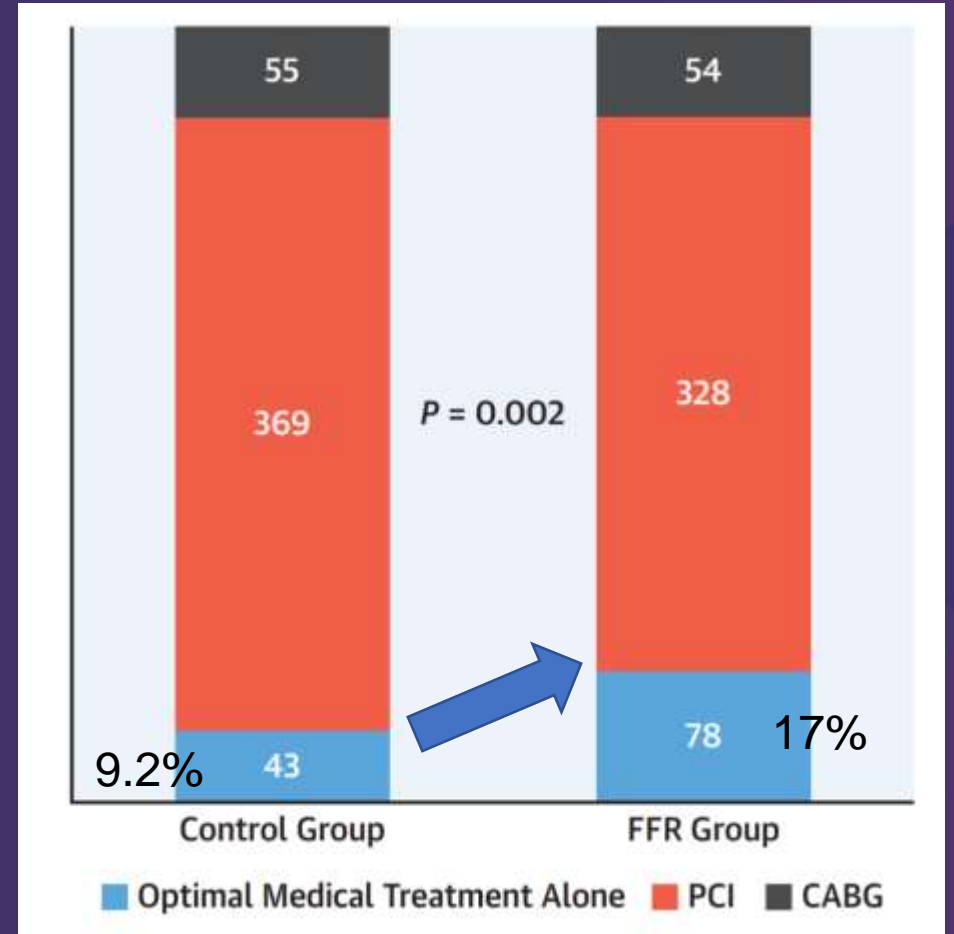
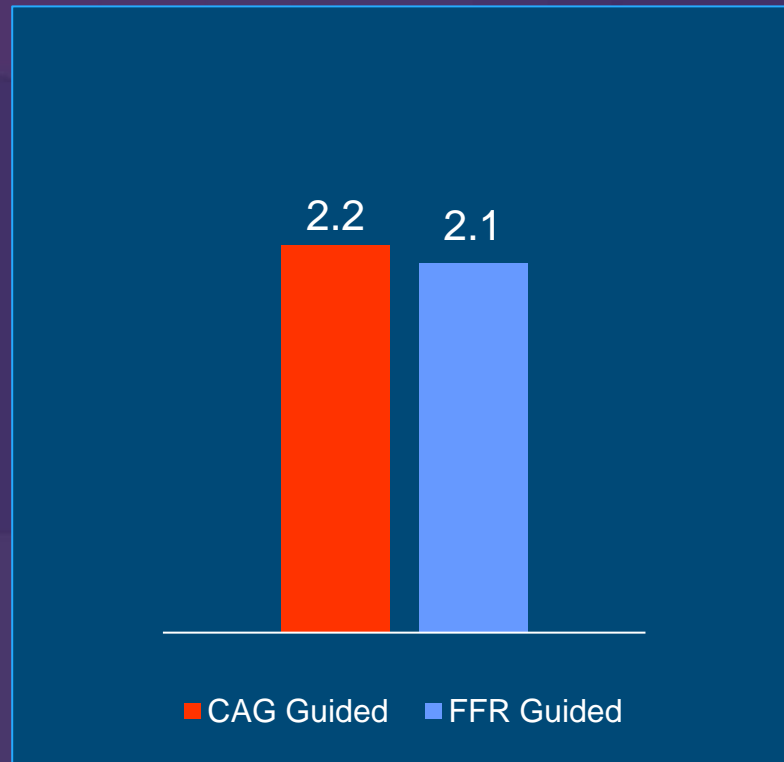
Death, nonfatal MI, stroke or unplanned hospitalization



Treatment Strategy

PCI Treatment

Number of stents per patient

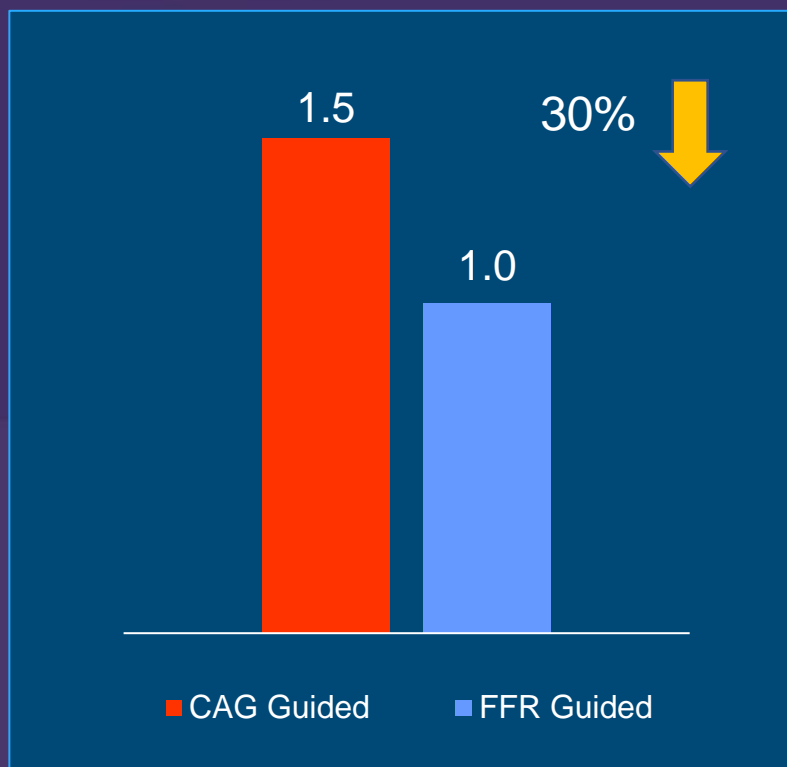


Treatment Strategy

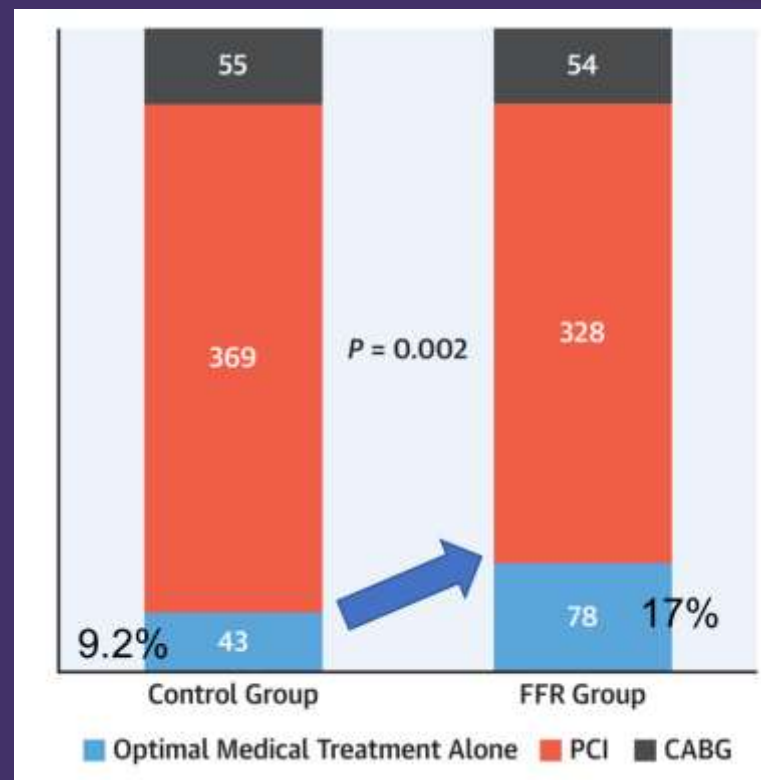
Reduced Stent Number and Increased Medical Treatment

FLOWER-MI

Number of stents per patient



FUTURE Trial



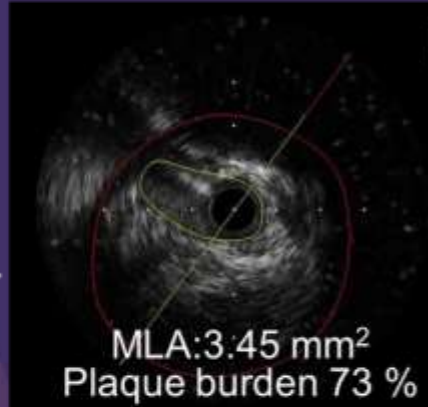
Is Deferral Safe?

Preventive PCI for $FFR > 0.80$ but vulnerable plaque

RCA, IVUS



FFR 0.89



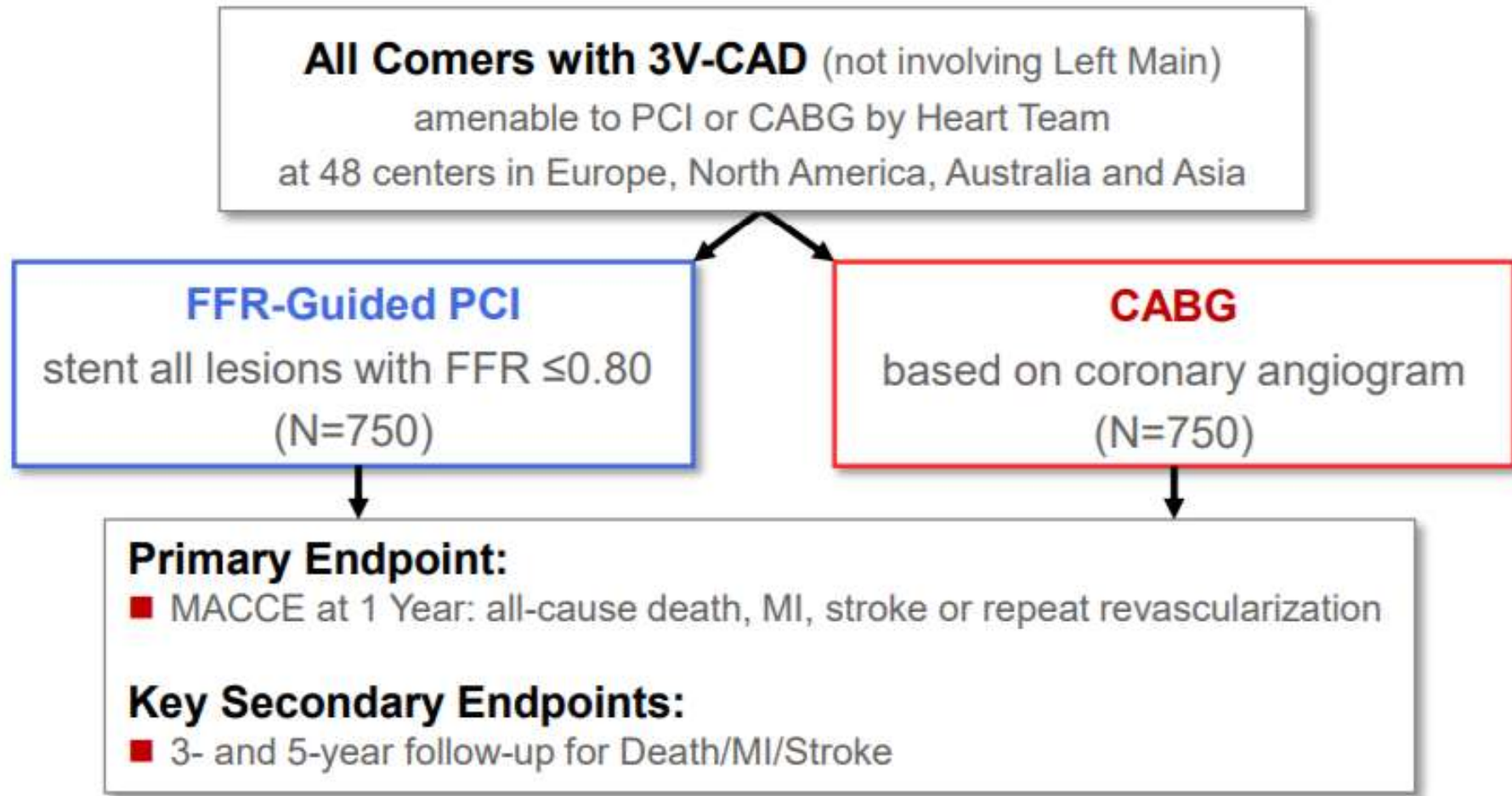
PREVENT Trial

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

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



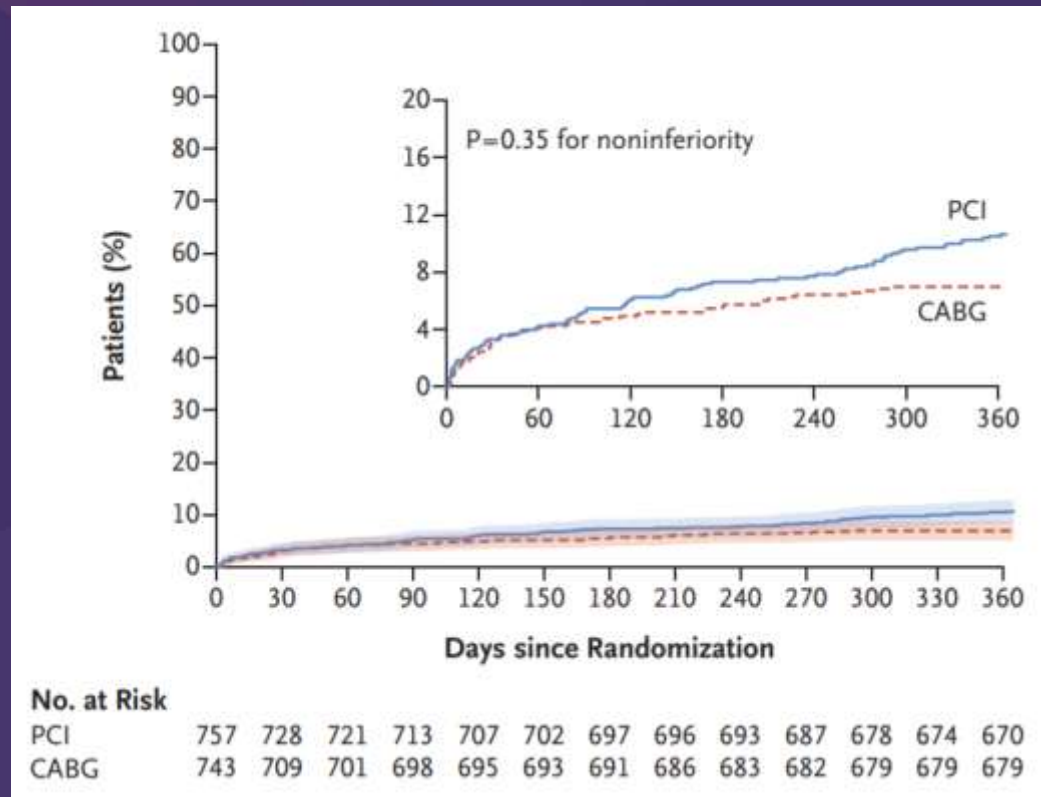
FAME3: FFR-Guided PCI vs. CABG



FAME3: FFR-Guided PCI vs. CABG

Primary Endpoint

Death, MI, stroke or Repeat revascularization

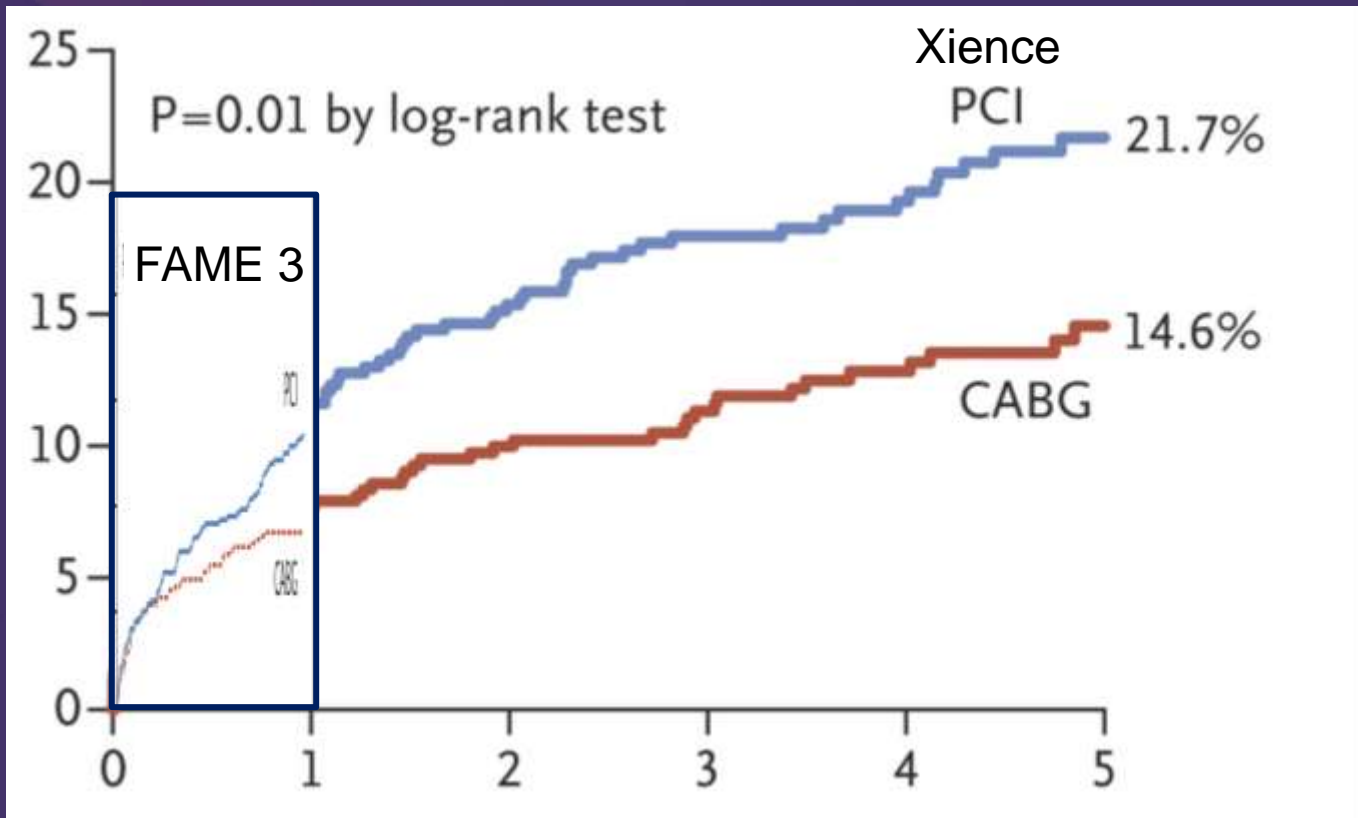


Endpoint	PCI (n=757)	CABG (n=743)	Hazard Ratio
Death	1.6%	0.9%	1.7 (0.7-4.3)
Cardiac death	0.8%	0.5%	
MI	5.2%	3.5%	1.5 (0.9-2.5)
Procedural	1.7%	1.2%	
Spontaneous	3.3%	2.3%	
Stroke	0.9%	1.1%	0.9 (0.3-2.4)
Repeat Revascularization	5.9%	3.9%	1.5 (0.9-2.3)
Death, MI or Stroke	7.3%	5.2%	1.4 (0.9-2.1)

DOI: 10.1056/NEJMoa2112299

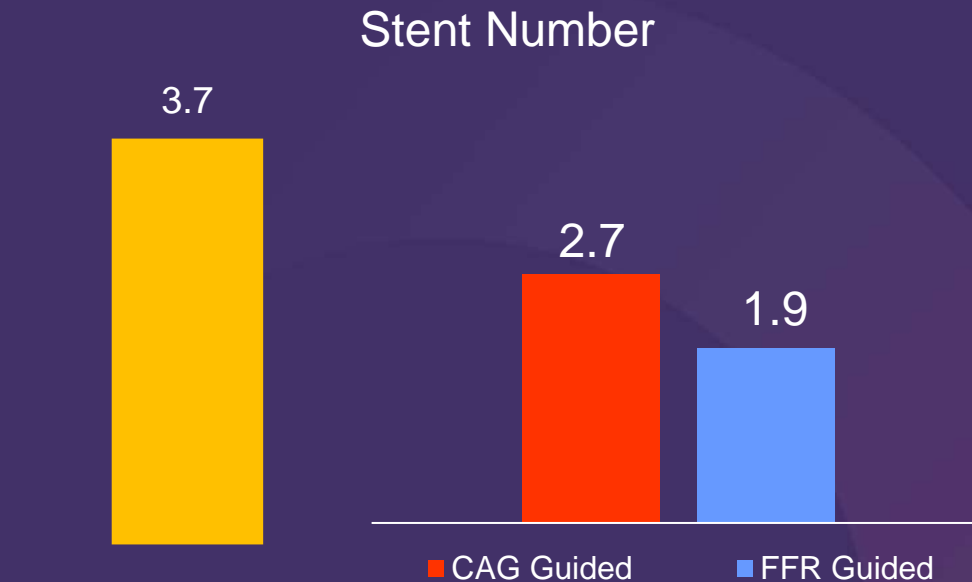
FAME3: FFR-Guided PCI vs. CABG

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) 