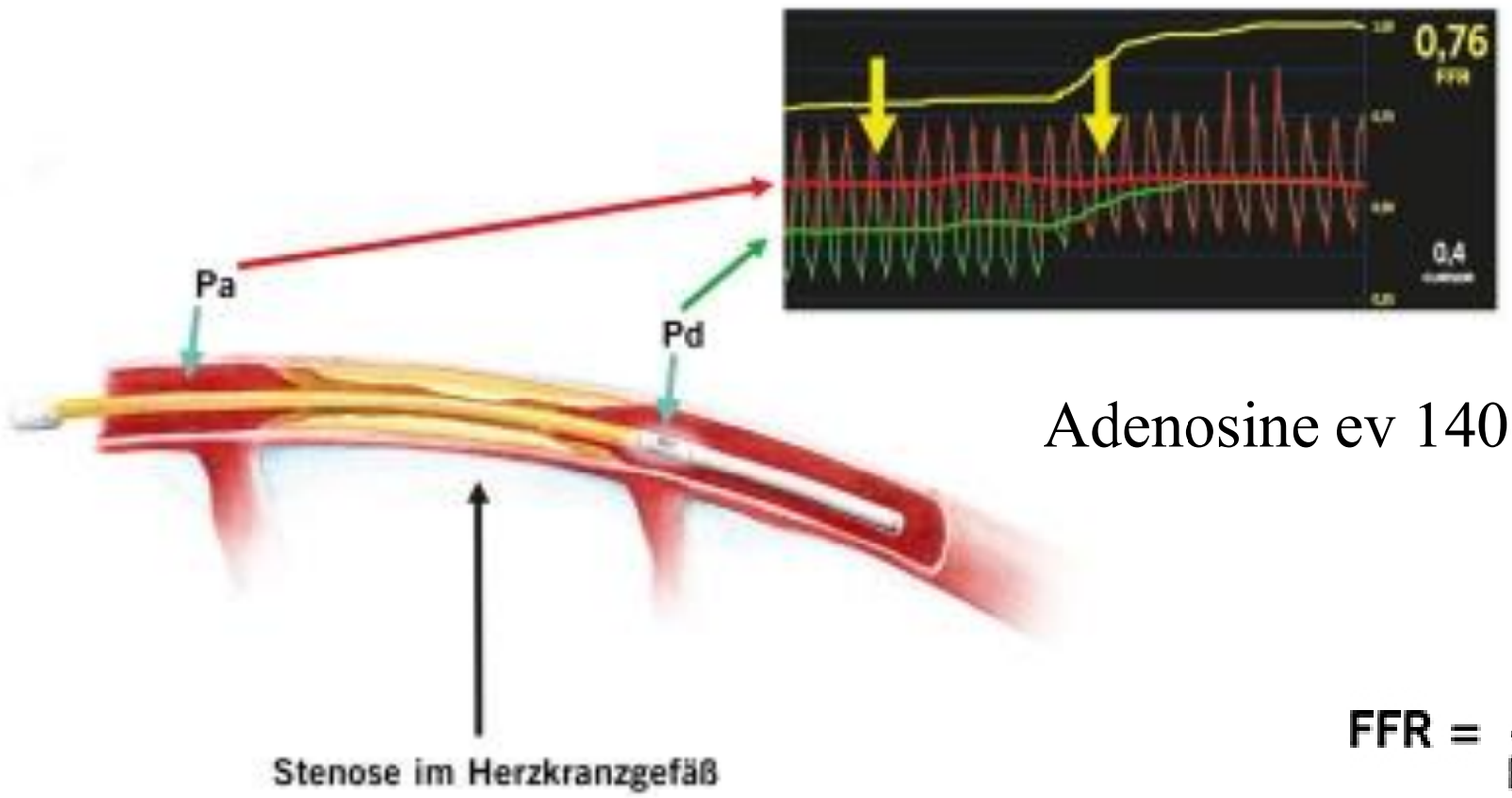
Correlation between FFR - iFR STEMI

Iris Rodríguez Costoya
Hospital del Mar
20 Abril 2018

FFR (Fractional Flow Reserve)

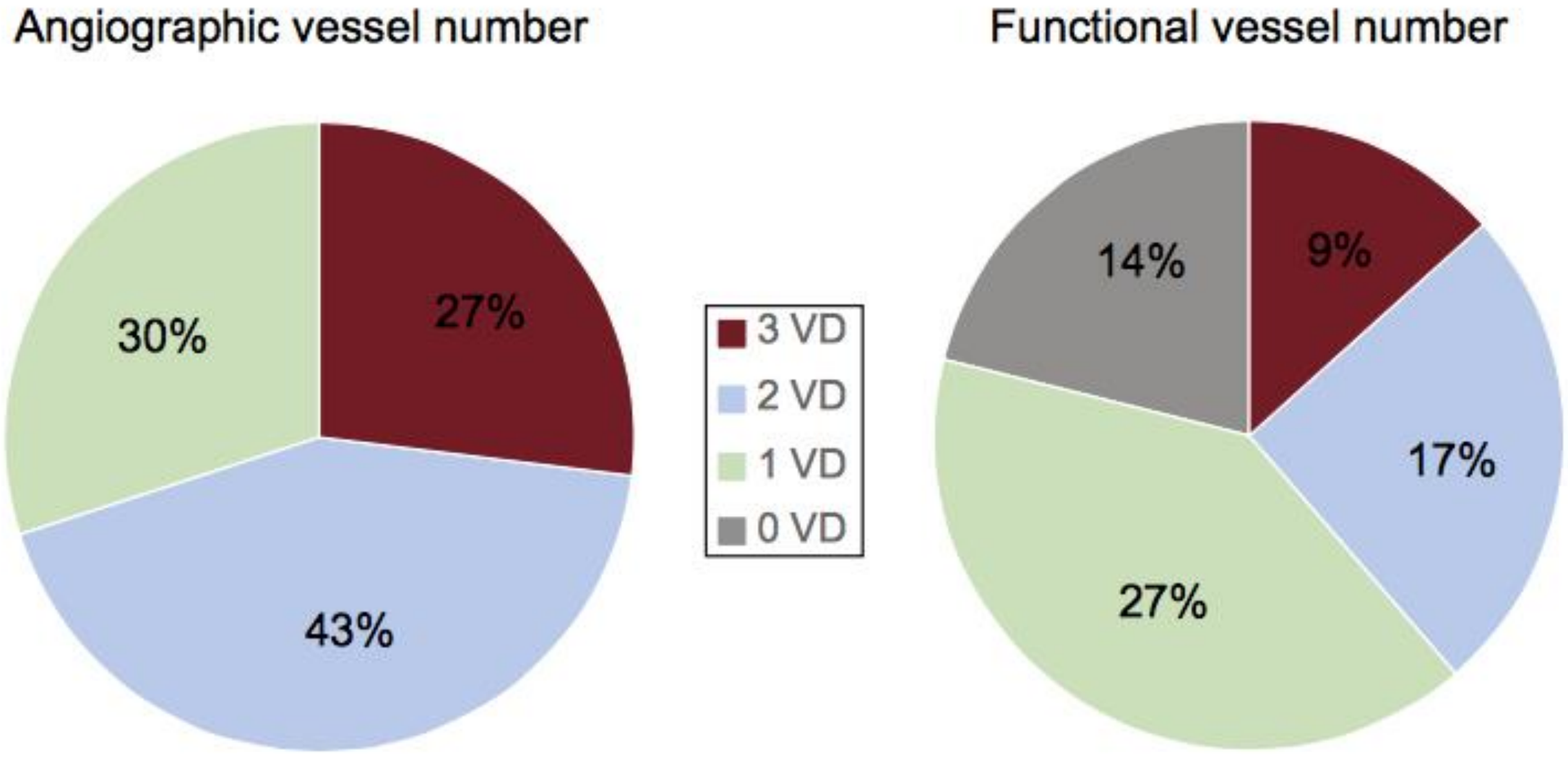


Adenosine ev 140-150 mg/kg/min

$$\text{FFR} = \frac{\text{Distal Coronary Pressure (Pd)}}{\text{Proximal Coronary Pressure (Pa)}}$$

(During Maximum Hyperemia)

Tonino PAL, et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med. 2009;360:213–224.
De Bruyne B, et al. Fractional flow reserve–guided PCI versus medical therapy in stable coronary disease. N Engl J Med. 2012;367:991–1001.



Sant'Anna FM, et al. Influence of routine assessment of fractional flow reserve on decision making during coronary interventions. Am J Cardiol. 2007;99:504–508.

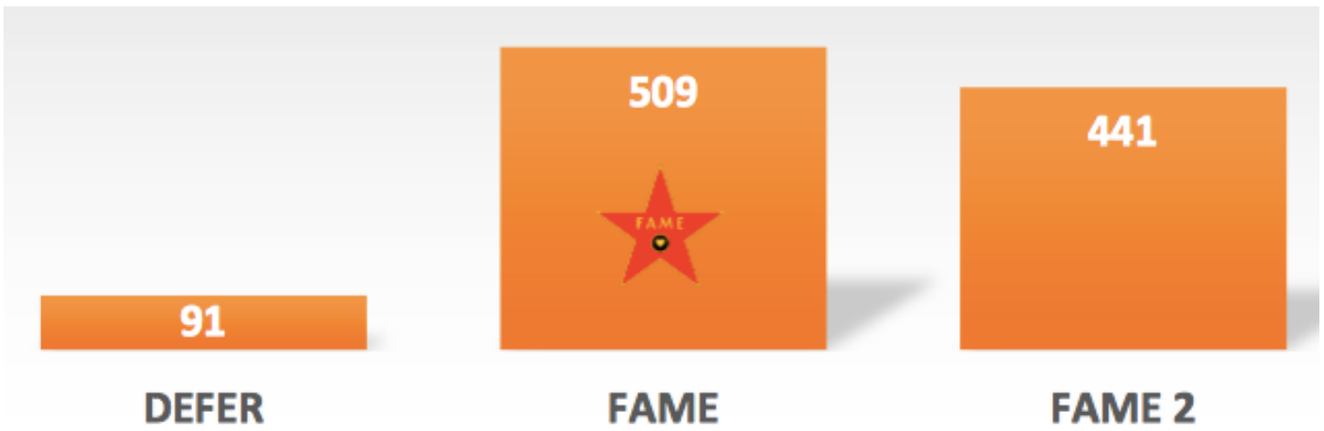
MAIN FFR RANDOMIZED STUDIES

Trial	Patients (n)	Patient population	Cut off value	Primary outcome	FFR group (%)	Control (%)	*P*
DEFER	325	AP	FFR 0.75	Event free survival	92/89	80%	<.05
FAME	1005	67% AP 33% UAP	FFR 0.80	Death, MI, repeat revascularization	13.2	18.3	.02
FAME II	888	AP	FFR 0.80	Death, MI, urgent revascularization	4.3	12.7	<.001

AP, Angina pectoris; UAP, unstable angina pectoris.

FFR >>> angiography

↓ mortality - IAM



Improve clinical outputs
Cost reduction

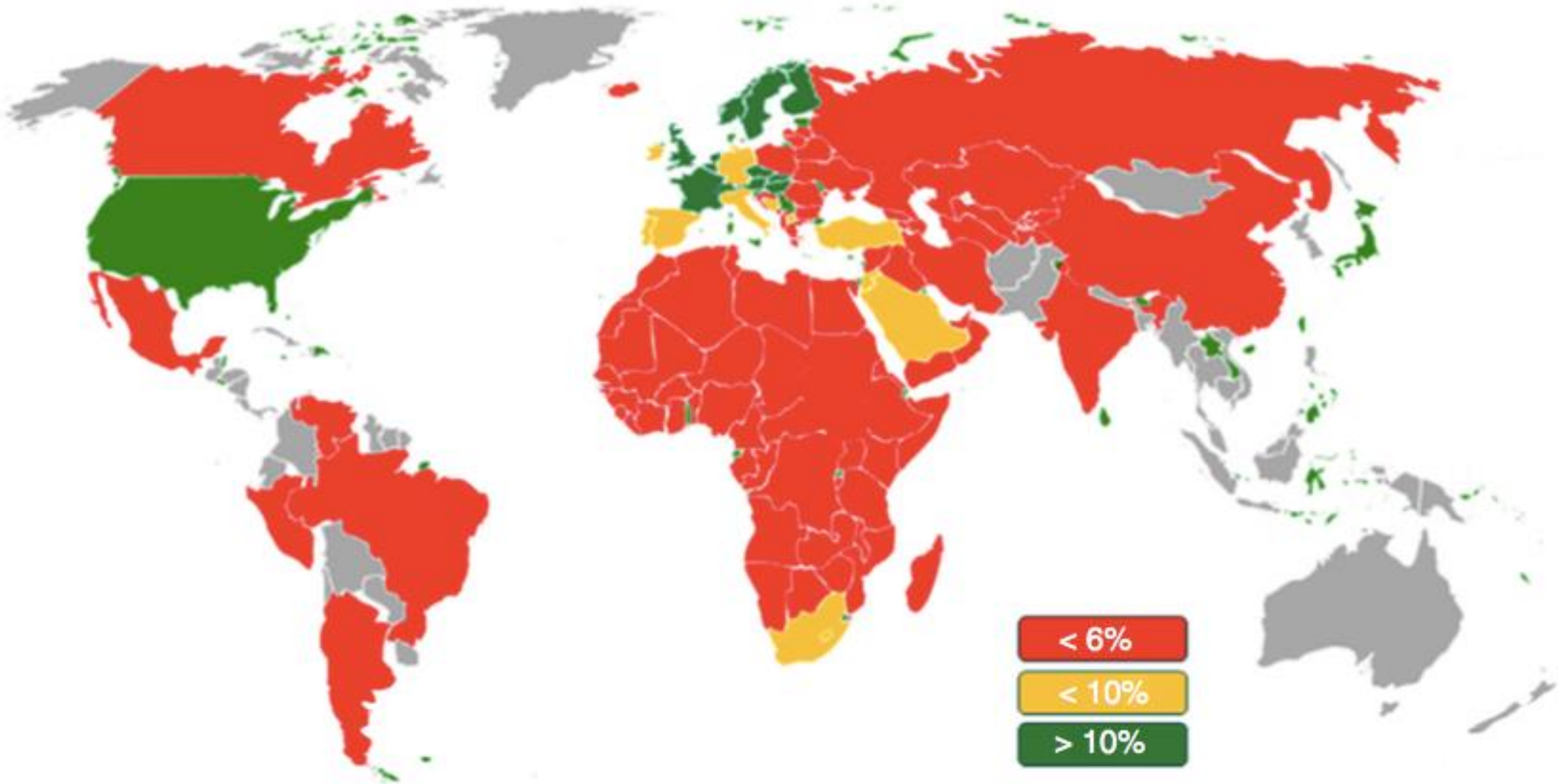
2014 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Recommendations for the clinical value of intracoronary diagnostic techniques

Recommendations	Class[a]	Level[b]	Ref.[c]
FFR to identify haemodynamically relevant coronary lesion(s) in stable patients when evidence of ischaemia is not available.	I	A	50,51,713
FFR-guided PCI in patients with multivessel disease.	IIa	B	54
IVUS in selected patients to optimize stent implantation.	IIa	B	702,703,706
IVUS to assess severity and optimize treatment of unprotected left main lesions.	IIa	B	705
IVUS or OCT to assess mechanisms of stent failure.	IIa	C	
OCT in selected patients to optimize stent implantation.	IIb	C	

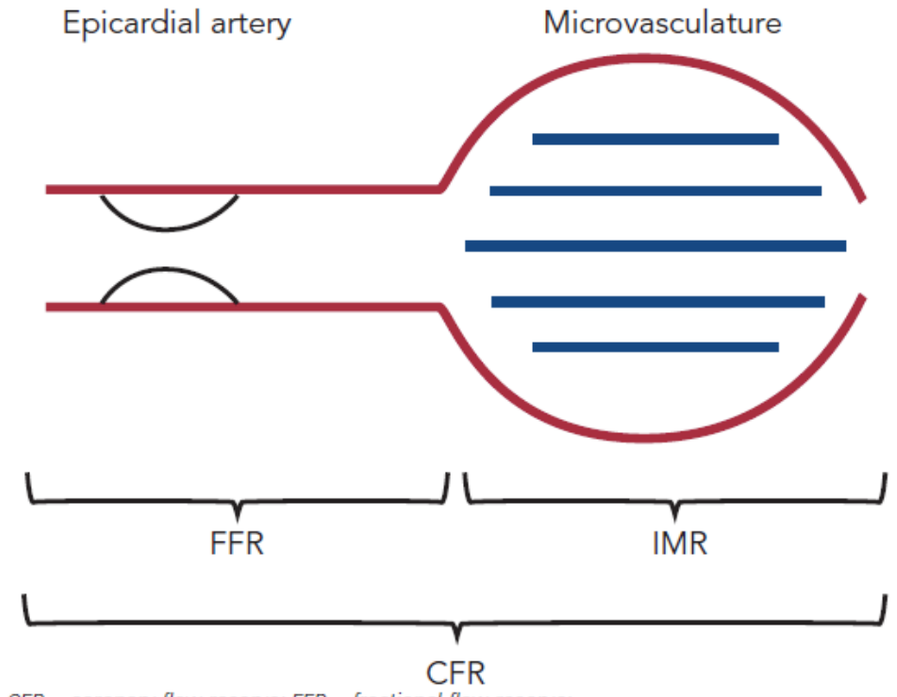
FFR 2016



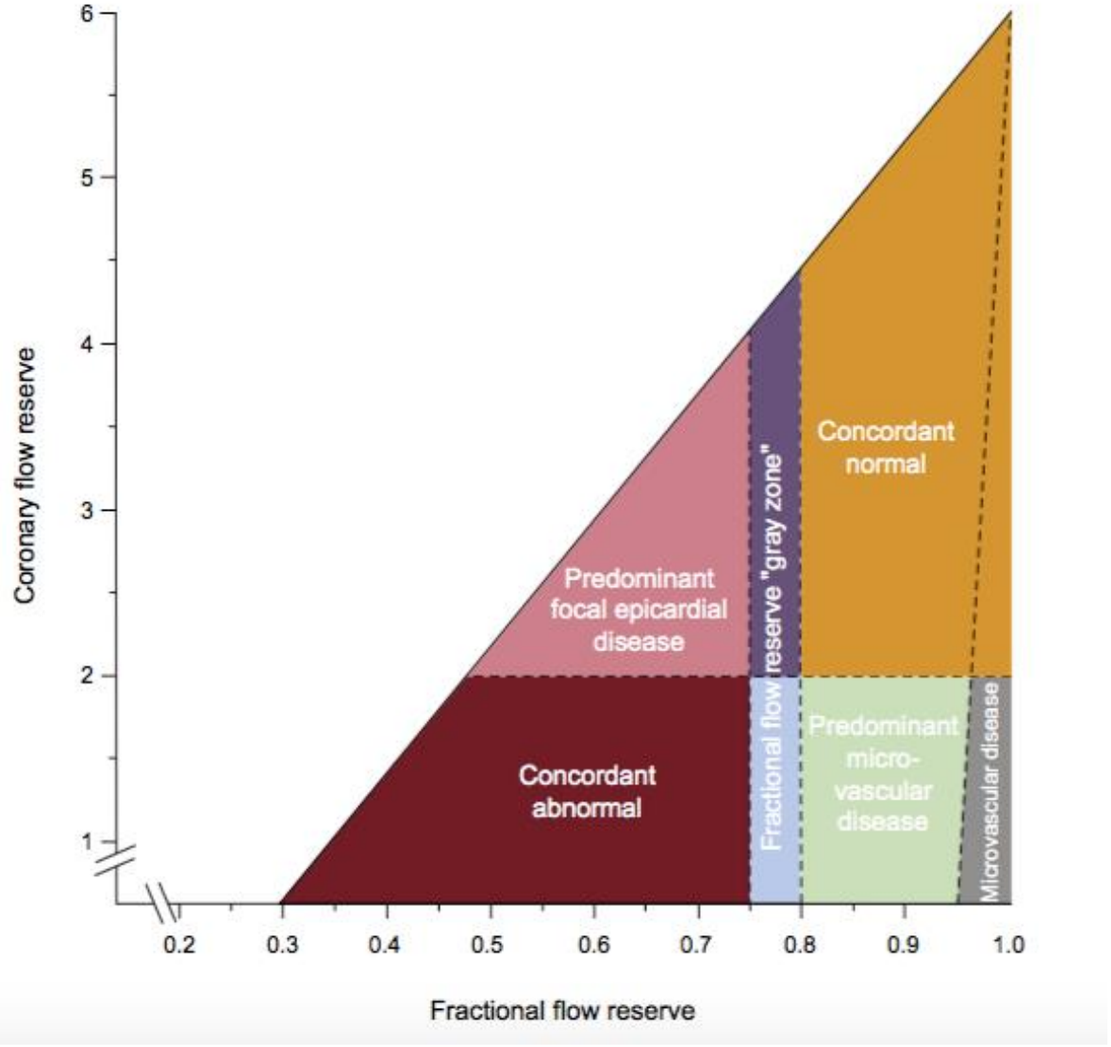
T. Warisawa et al./Rev Esp Cardiol. 2018

OTHER LIMITATIONS

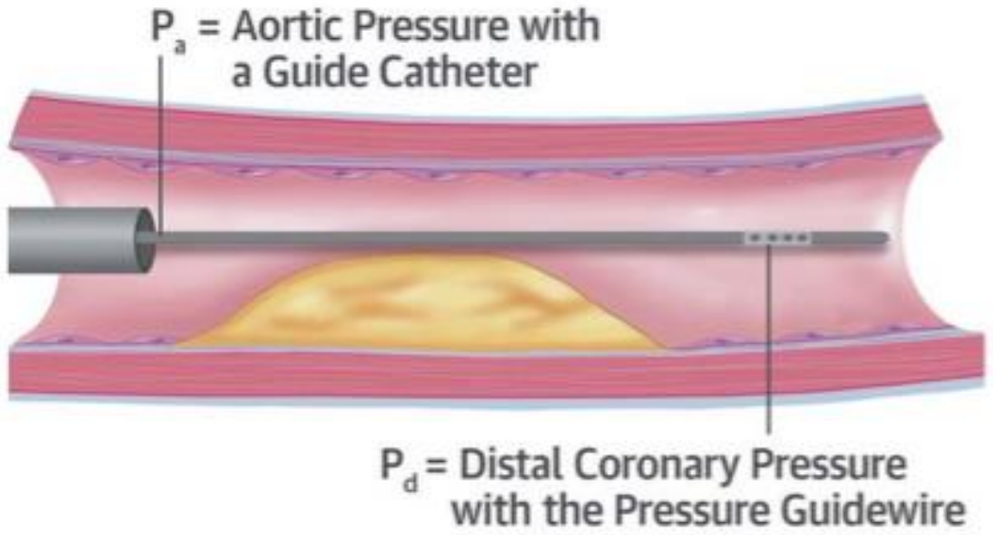
- Different adenosine response. No response.
- Tándem lesions.
- FFR vs CFR (30-40% discordance).
- Grey zone (FFR 0,75-0,80).

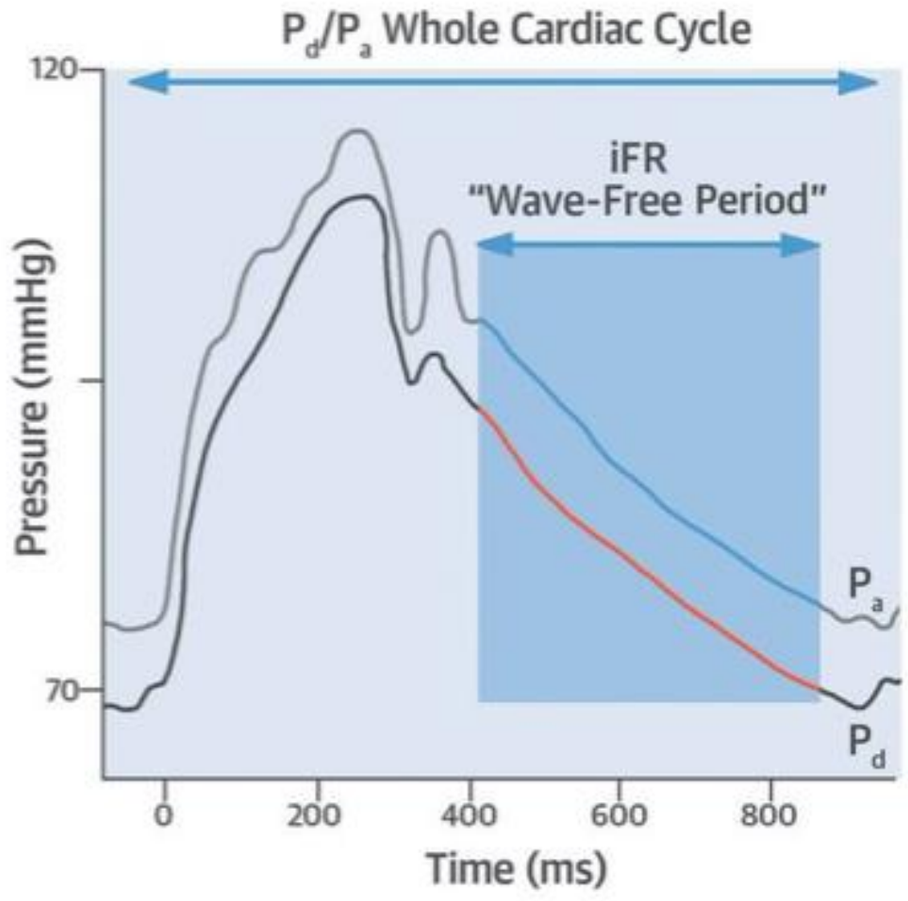


CFR = coronary flow reserve; FFR = fractional flow reserve; IMR = index of microvascular resistance.



2012 iFR (Instantaneus Wave-Free Ratio)



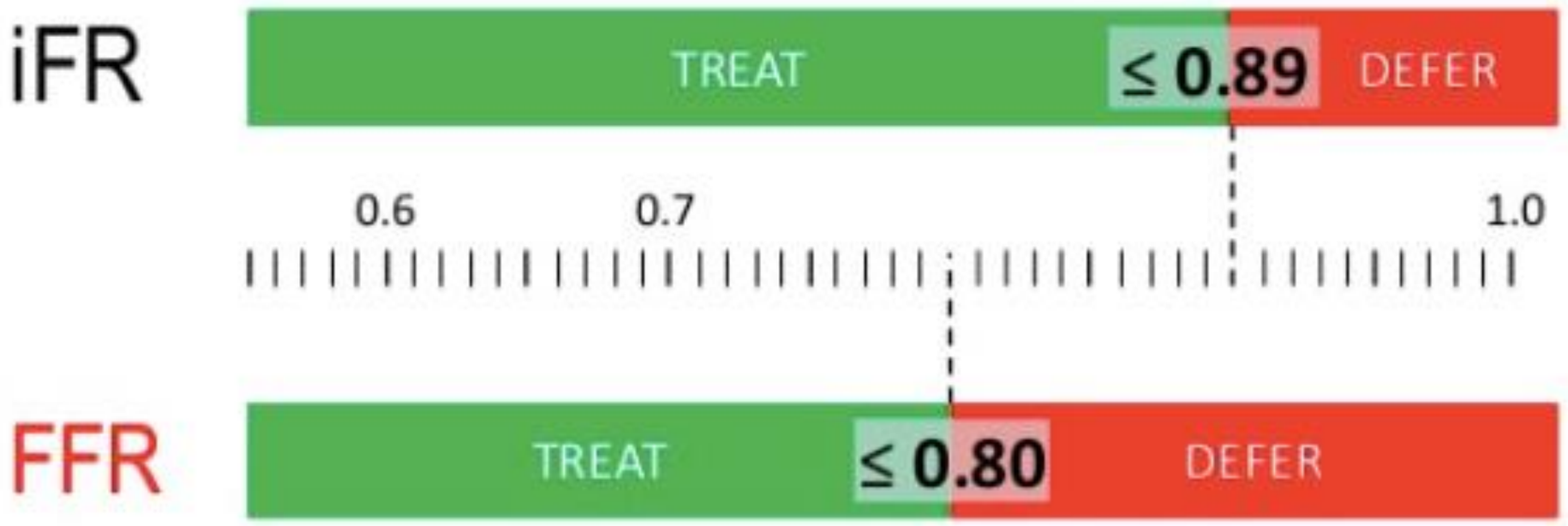


$$iFR = \frac{Pd}{Pa} \text{ (at rest in the wave-free period)}$$

Adenosine FREE

ADVISE (ADenosine Vasodilator Independent Stenosis Evaluation) study. Sen S, Escaned J, et al. J Am Coll Cardiol. 2012 Apr 10;59(15):1392-402.

Clinical iFR and FFR Cut-points



80 - 85% concordance between iFR and FFR when iFR = 0.89

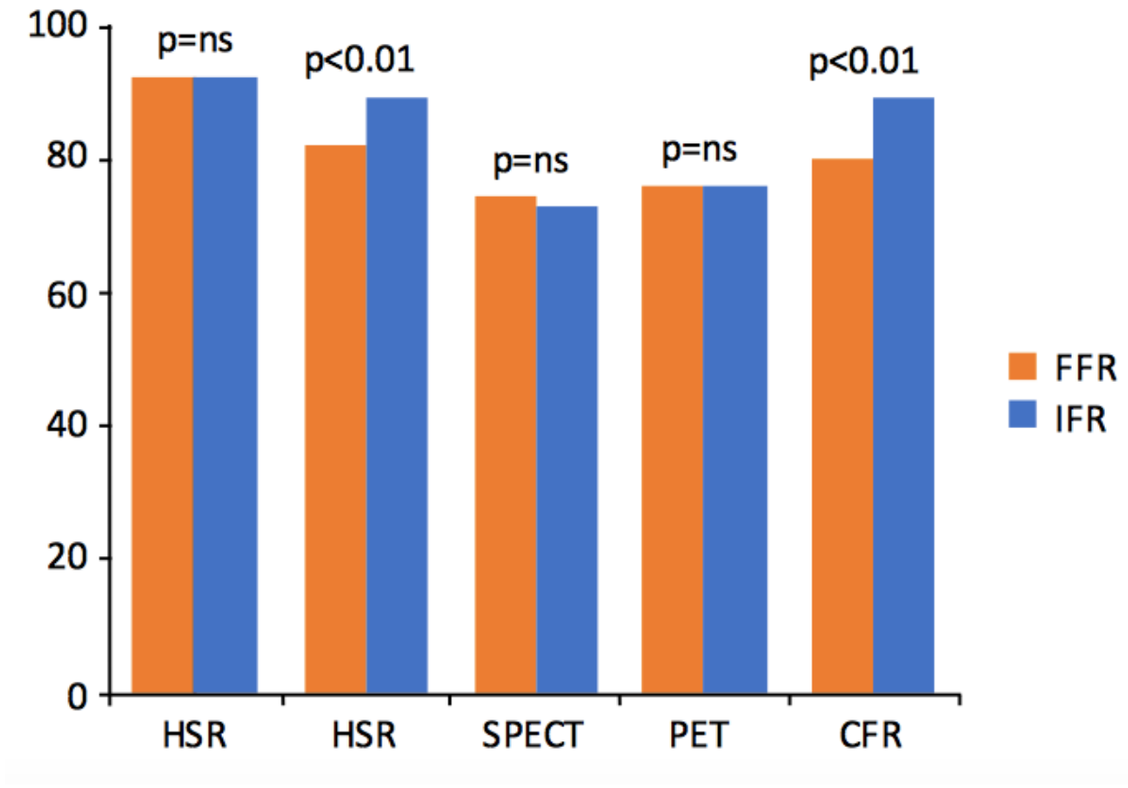
ADVISE 2 Study, JACC Cardiovasc Interv 2015;8(6):824–33.
RESOLVE Study, JACC 2014 Apr 8;63(13):1253-61

iFR and FFR

Comparison Between Instantaneous Wave-free Ratio and Fractional Flow Reserve in Ischemia Assessment

Publication	Modality	No.	FFR diagnostic accuracy of AUC (%)	iFR diagnostic accuracy of AUC (%)	*P*
Sen et al.,[70],2013	HSR	51	92	92	NS
Sen et al.,[71] 2013	HSR	120	82	89	< .01
Petraco et al.,[72] 2014	CFR	216	67	74	< .01
Van de Hoef et al.,[73] 2015	MPS	85	63	62	NS
Hwang et al.,[74] 2017	PET	115	70	74	NS

AUC, area under the curve; CFR, coronary flow reserve; FFR, fractional flow reserve; HSR, hyperemic stenosis resistance; iFR, instantaneous wave-free ratio; MPS, myocardial perfusion scintigraphy; NS, not significant; PET, positron emission tomography.



- Equivalent diagnostic performance.
- Higher correlation between iFR and microvascular function.

CFR, Coronary Flow Reserve; HSR, Hyperaemic Stenosis Resistance; ROC, receiver-operating characteristic; PET, positron emission tomography; SPECT, single-photon emission computed tomography

1. Van de Hoef TP et al. Circ Cardiovasc Interv. 2012;5:508-14; 2. Sen S et al. J Am Coll Cardiol. 2013;61:1409-20; 3. Van de Hoef TP et al. EuroIntervention. 2015;11:914-25;
4. Sen S et al. J Am Coll Cardiol. 2013;62:566; 5. Petraco R et al. Circ. Int. 2014;7:492-502; 6. de Waard G et al. J Am Coll Cardiol. 2014;63:A1692.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 11, 2017 VOL. 376 NO. 19

Instantaneous Wave-free Ratio versus Fractional Flow Reserve to Guide PCI

M. Götberg, E.H. Christiansen, I.J. Gudmundsdottir, L. Sandhall, M. Danielewicz, L. Jakobsen, S.-E. Olsson, P. Öhagen, H. Olsson, E. Omerovic, F. Calais, P. Lindroos, M. Maeng, T. Tödt, D. Venetsanos, S.K. James, A. Kåregren, M. Nilsson, J. Carlsson, D. Hauer, J. Jensen, A.-C. Karlsson, G. Panayi, D. Erlinge, and O. Fröbert, for the iFR-SWEDEHEART Investigators*

ORIGINAL ARTICLE

Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI

J.E. Davies, S. Sen, H.-M. Dehbi, R. Al-Lamee, R. Petraco, S.S. Nijjer, R. Bhindi, S.J. Lehman, D. Walters, J. Sapontis, L. Janssens, C.J. Vrints, A. Khashaba, M. Laine, E. Van Belle, F. Krackhardt, W. Bojara, O. Going, T. Härle, C. Indolfi, G. Niccoli, F. Ribichini, N. Tanaka, H. Yokoi, H. Takashima, Y. Kikuta, A. Erglis, H. Vinhas, P. Canas Silva, S.B. Baptista, A. Alghamdi, F. Hellig, B.-K. Koo, C.-W. Nam, E.-S. Shin, J.-H. Doh, S. Brugaletta, E. Alegria-Barrero, M. Meuwissen, J.J. Piek, N. van Royen, M. Sezer, C. Di Mario, R.T. Gerber, I.S. Malik, A.S.P. Sharp, S. Talwar, K. Tang, H. Samady, J. Altman, A.H. Seto, J. Singh, A. Jeremias, H. Matsuo, R.K. Kharbanda, M.R. Patel, P. Serruys, and J. Escaned

iFR®

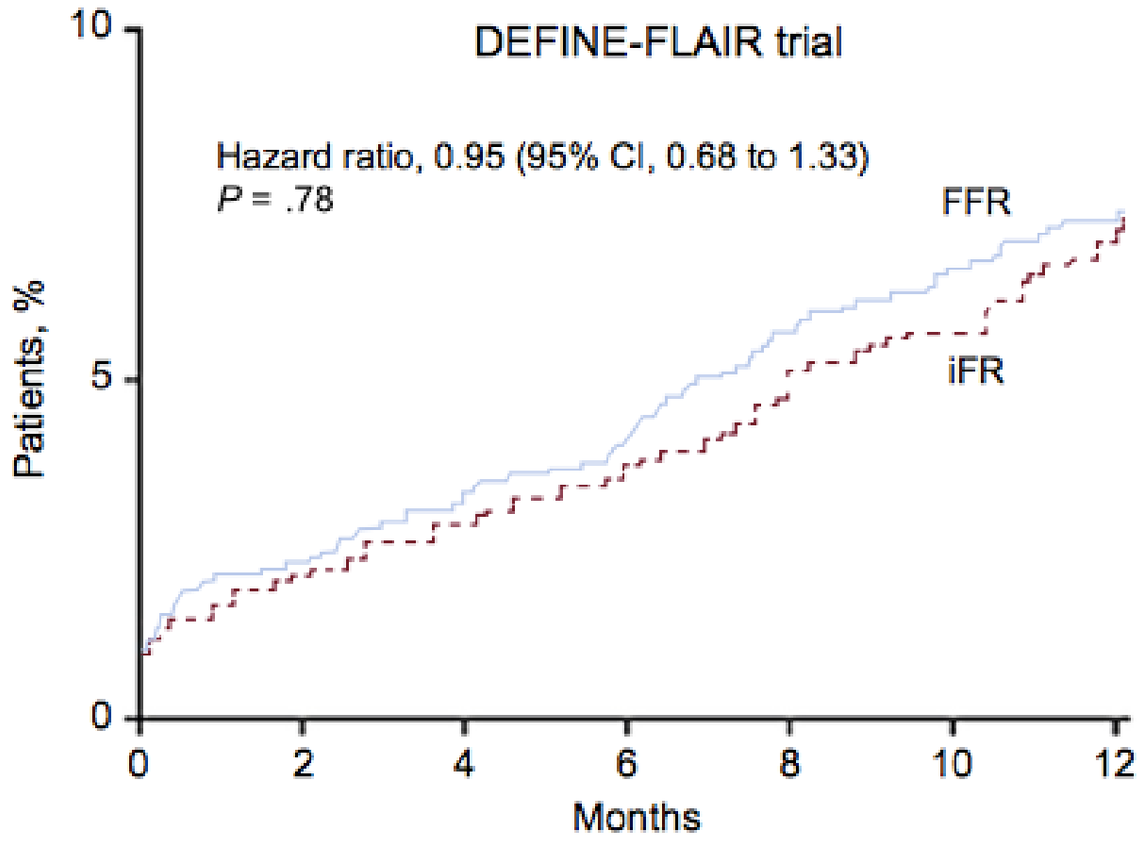
SWEDEHEART

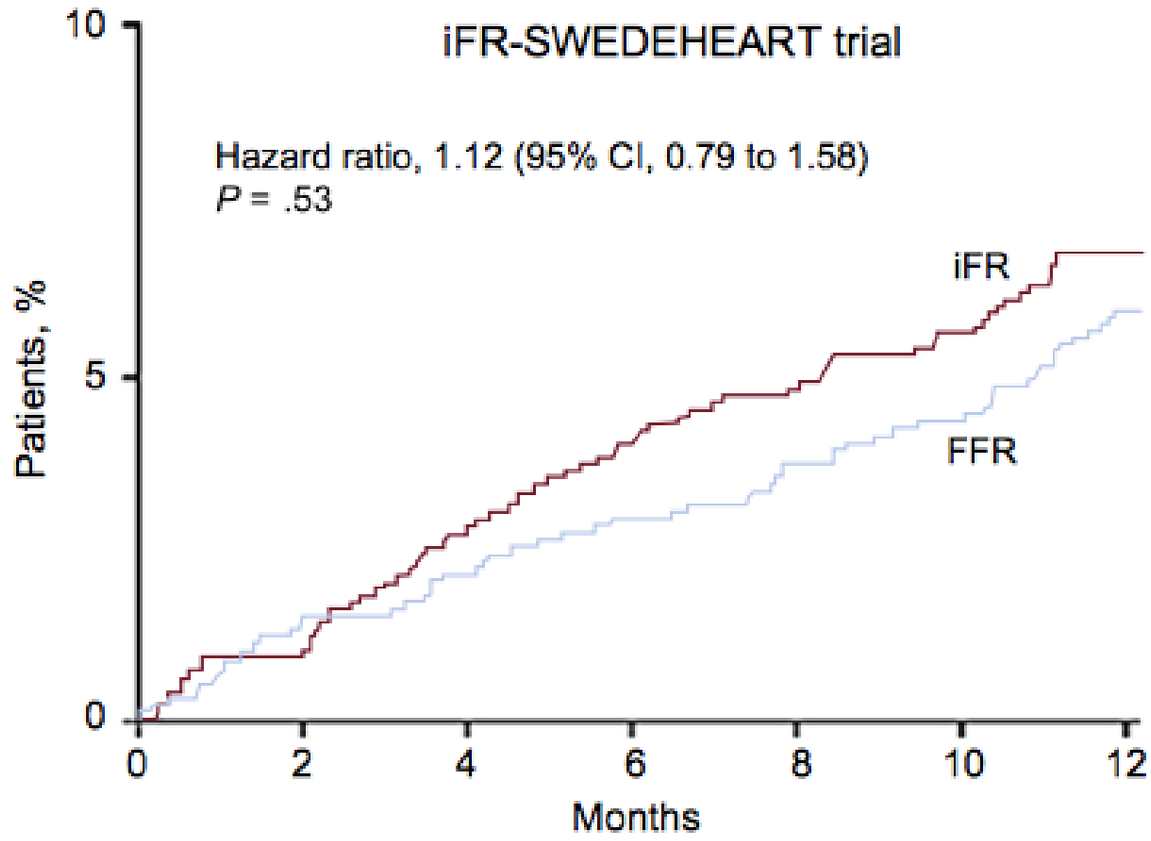
DEFINE FLAIR

4529 patients

Noninferior
iFR - FFR

MACE composite endpoint of:
- Death
- Non-fatal myocardial infarction
- Unplanned revascularization





iFR was non inferior to FFR
with respect MACE at 12 months
(dead, non fatal MI, unplanned revascularization)

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iFR®

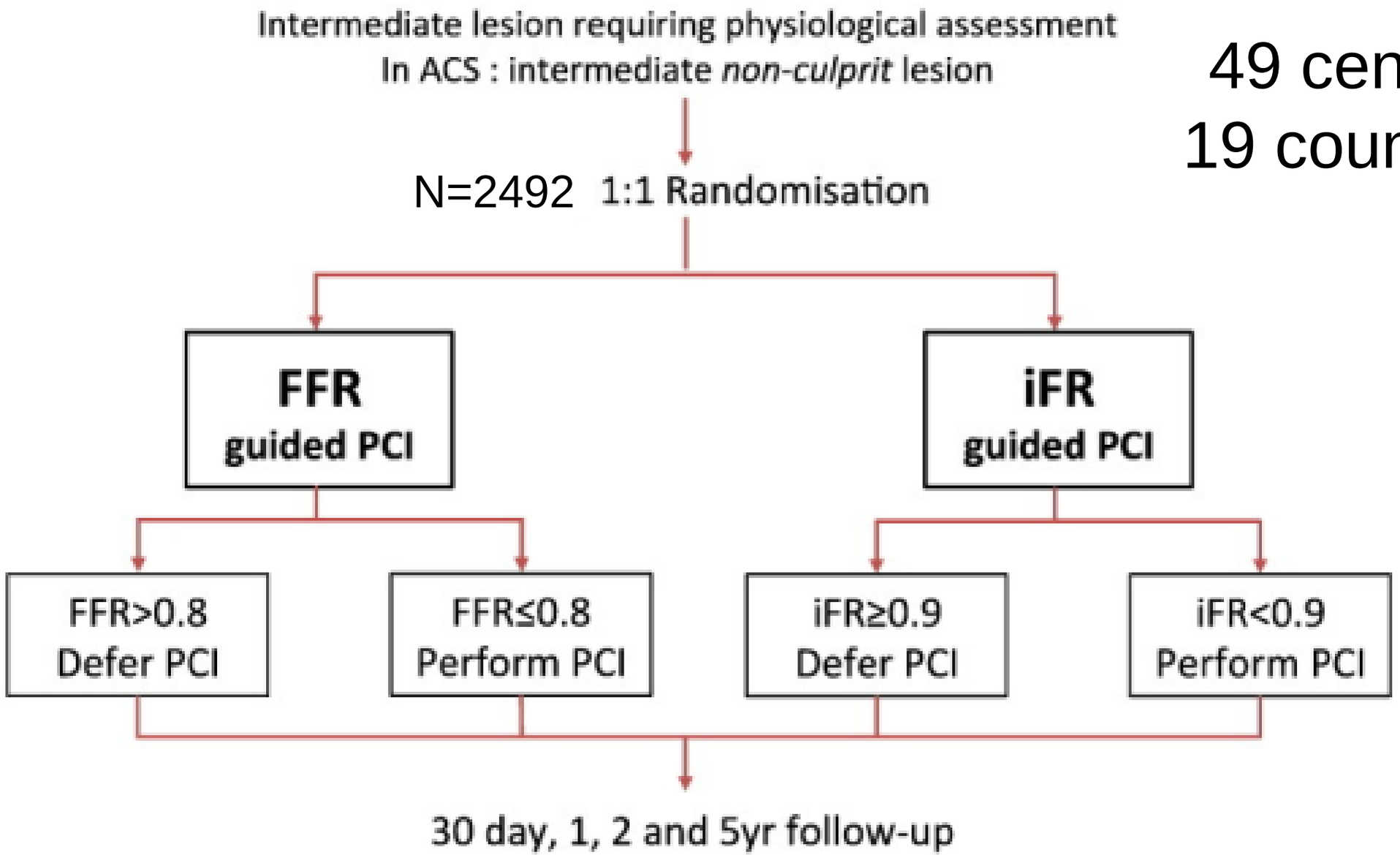
SWEDEHEART

- 15 Scandinavian centers
- 2037 randomized patients

Indication for angiography - no. (%)	iFR	FFR
Stable angina	632 (62.0)	632 (62.0)
Unstable angina	211 (20.7)	208 (20.4)
NSTEMI	176 (17.3)	178 (17.5)

DEFINE FLAIR

Functional **L**esion **A**ssessment of **I**ntermediate stenosis to guide **R**evascularisation



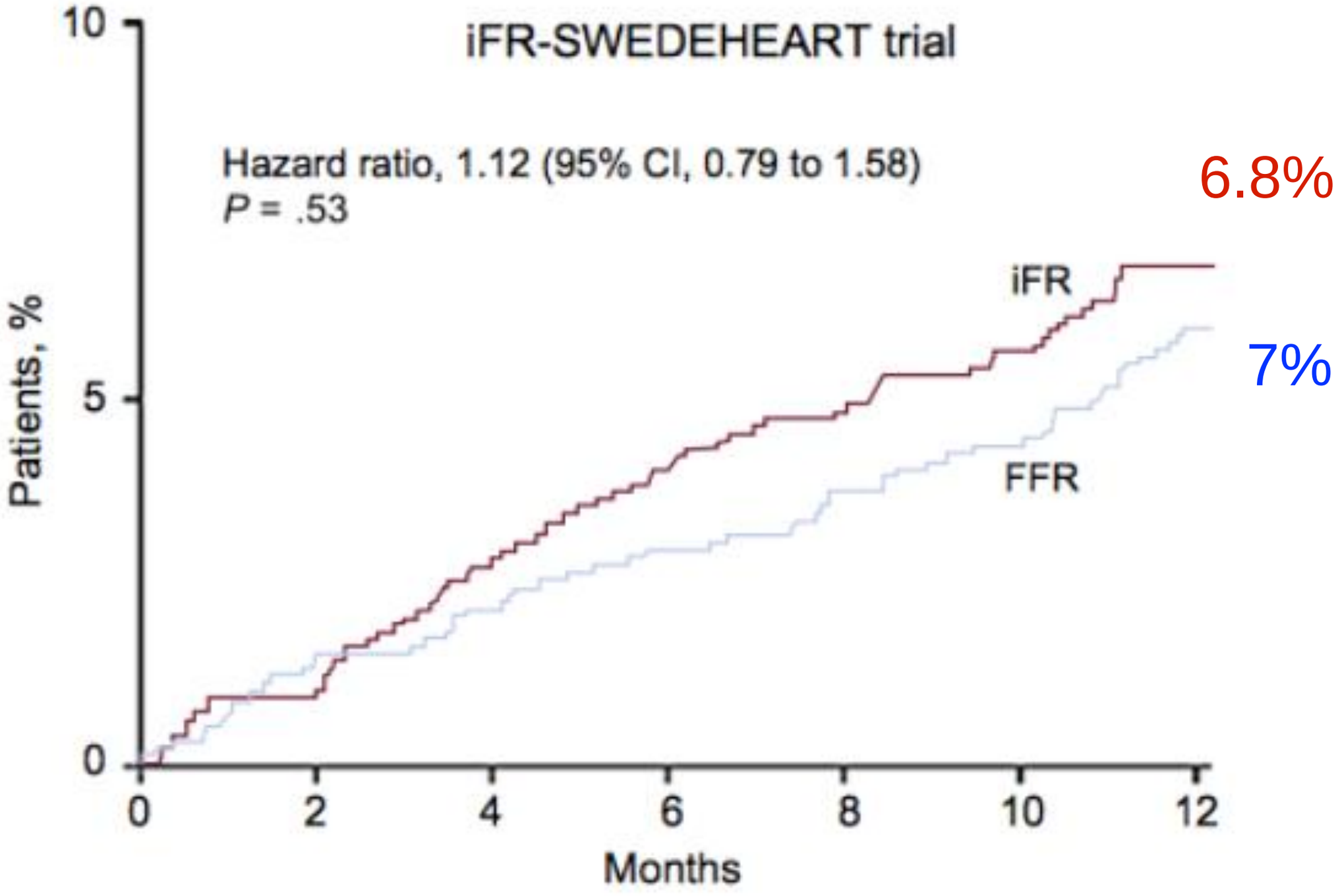
49 centers
19 countries

DEFINE FLAIR

Functional Lesion Assessment of Intermediate stenosis to guide Revascularisation

		iFR	FFR
Number of patients		1242	1250
Age, Years, mean (sd)		65.5 (10.8)	65.2 (10.6)
Gender, N (%)			
	Female	280 (22.5)	321 (25.7)
	Male	962 (77.5)	929 (74.3)
Disease type, N (%)			
	>48hr post STEMI*	49 (3.9)	42 (3.4)
	Acute coronary syndrome*	186 (15.0)	184 (14.7)
	Stable disease	986 (79.4)	1012 (81.0)

* Non-culprit lesions only


iFR-SWEDEHEART trial
Hazard ratio, 1.12 (95% CI, 0.79 to 1.58)
P = .53
6.8%
7%
iFR
FFR
Patients, %
10
5
0
0
2
4
6
8
10
12
Months

DEFINE FLAIR

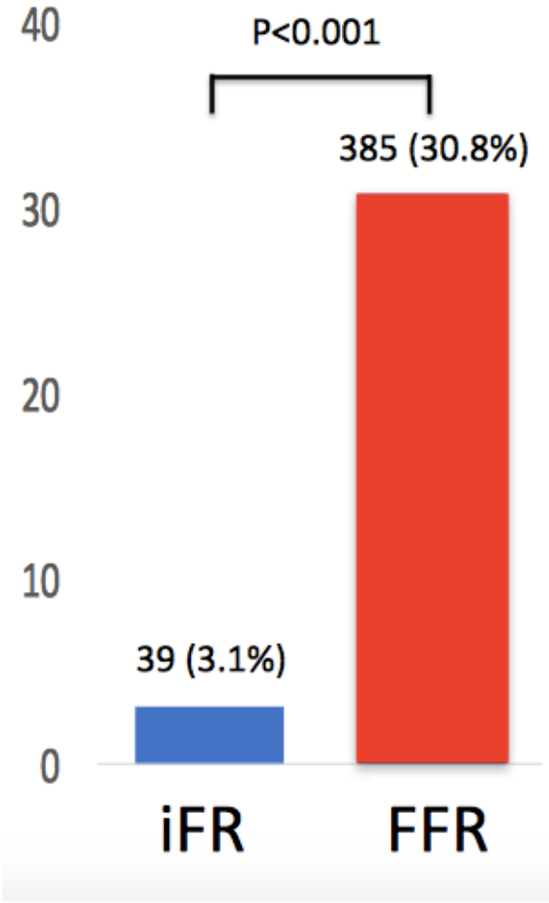
Functional Lesion Assessment of Intermediate stenosis to guide Revascularisation

	iFR n=1242	FFR n=1250	Hazard Ratio (95% CI)	Hazard Ratio (99% CI)	P value
	number, %				
Primary Endpoint	**78 (6.28)**	**83 (6.64)**	**0.95 (0.68 to 1.33)**	**0.95 (0.62 to 1.48)**	**0.78**
Components of Primary Endpoint					
Unplanned Revascularization	46 (3.70)	63 (5.04)	0.81 (0.55 to 1.19)	0.81 (0.49 to 1.35)	0.29
Myocardial Infarction	31 (2.50)	28 (2.24)	1.03 (0.56 to 1.92)	1.03 (0.46 to 2.33)	0.92
All Cause Mortality	22 (1.77)	13 (1.04)	1.74 (0.88 to 3.46)	1.74 (0.71 to 4.30)	0.11

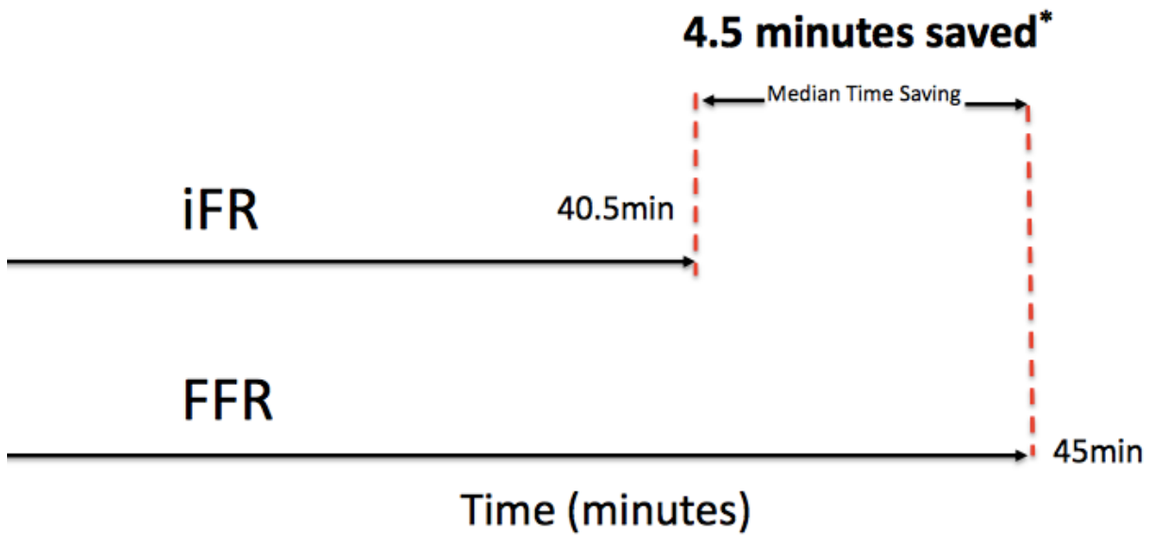
Non-inferiority was also confirmed in per-protocol analysis

The risks of each individual component of the primary end point and of the death from cardiovascular or non cardiovascular causes did not differ significantly between 2 groups.

Outcome	iFR Group N=2240 no.(%)	FFR Group N=2246 no. (%)	Hazard Ratio (95% CI)	P value
Primary outcome: death from any cause, nonfatal myocardial infarction, or unplanned revascularisation	145 (6.47)	144 (6.41)	1.03 (0.81-1.31)	0.81
Death from cardiovascular causes	15 (0.67)	10 (0.45)	1.52 (0.68-3.39)	0.3
Death from noncardiovascular causes	21 (0.94)	15 (0.67)	1.42 (0.73-2.76)	0.3
Nonfatal myocardial infarction	53 (2.37)	45 (2.00)	1.19 (0.76-1.85)	0.45
Unplanned revascularisation	93 (4.15)	109 (4.85)	0.91 (0.69-1.21)	0.53



	iFR	FFR
Dyspnea	13 (1.0%)	250 (20.0%)
Chest pain	19 (1.5%)	90 (7.2%)
Rhythm disturbance	2 (0.2%)	60 (4.8%)
Hypotension	4 (0.3%)	13 (1.0%)
Vomiting / Nausea	1 (0.1%)	11 (0.9%)
Bronchospasm/VT	1 (0.1%)	8 (0.6%)
Other	4 (0.3%)	38 (3.0%)



↓ Complications.
↓ Time.
↓ Symptoms.

* Threshold for reduction in median time (p=0.001)

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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

iFR = FFR

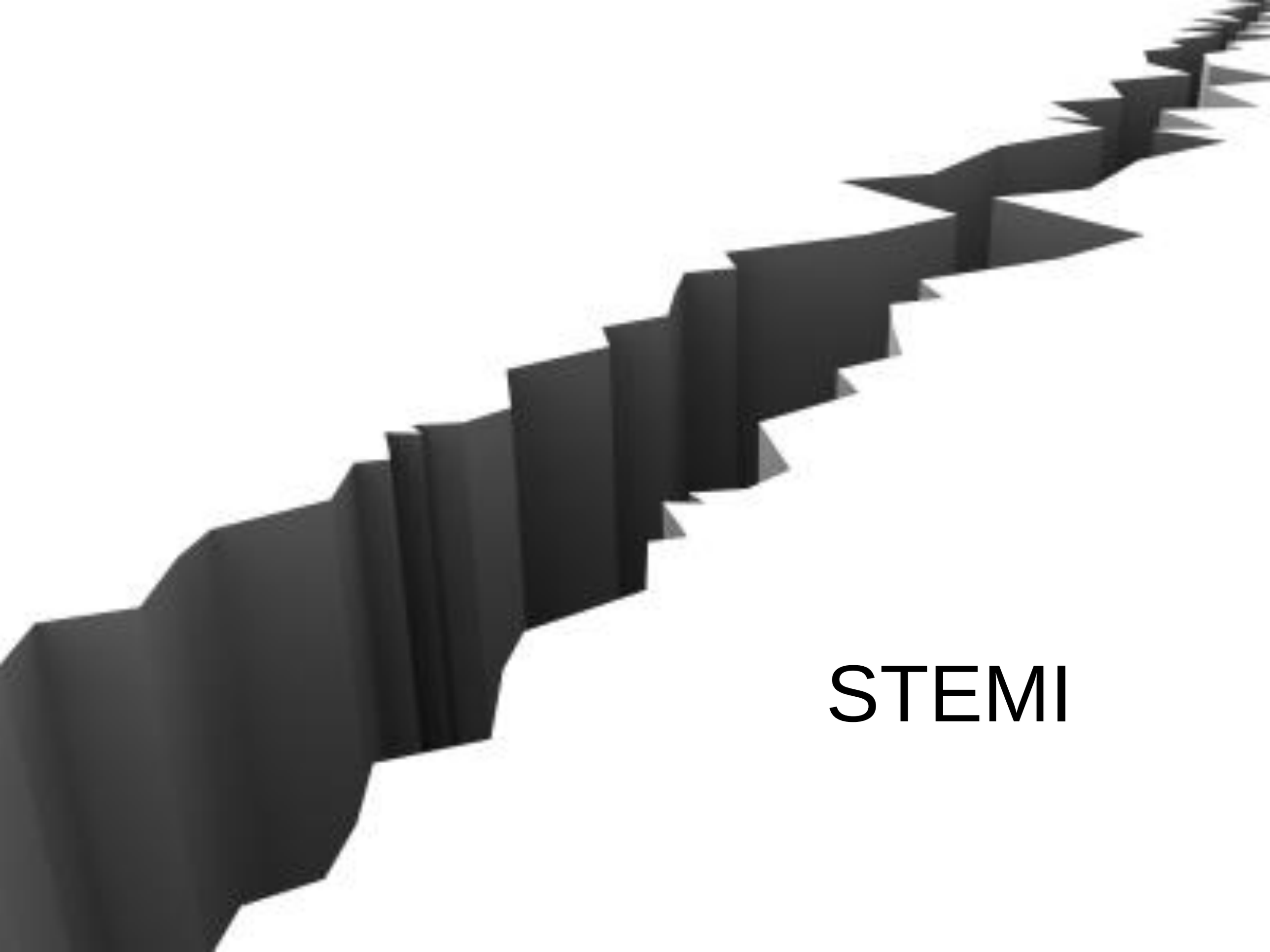
67th Annual Scientific Session & Expo

SUBANALYSIS

iFR More Cost-Effective Than FFR in PCI Guidance

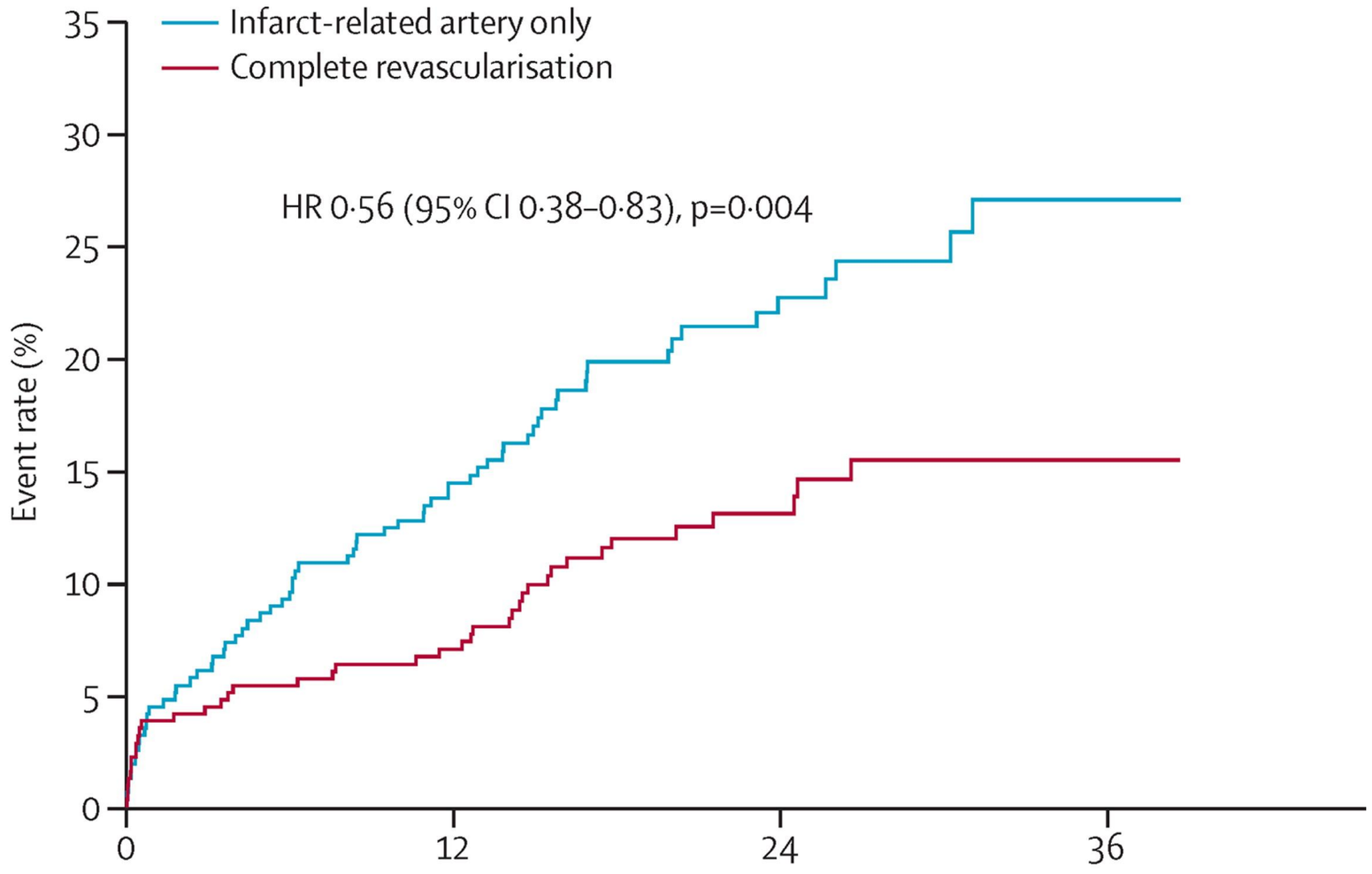
Health economic data from DEFINE FLAIR trial demonstrates iFR-guided strategy reduces costs and improves patient comfort compared to FFR-guided strategy

procedures. With an average saving of nearly $900 per patient per year, the study found that iFR offers a total procedure cost saving of approximately 10 percent per patient over FFR. Additionally, patients treated with the use of an iFR-guided revascularization strategy had fewer coronary artery bypass graft procedures and fewer subsequent revascularizations. Previous data from DEFINE FLAIR released in 2017 found that iFR-guided treatments reduced procedure time by 10 percent versus FFR-guided treatments, while reducing patient discomfort by 90 percent[2].



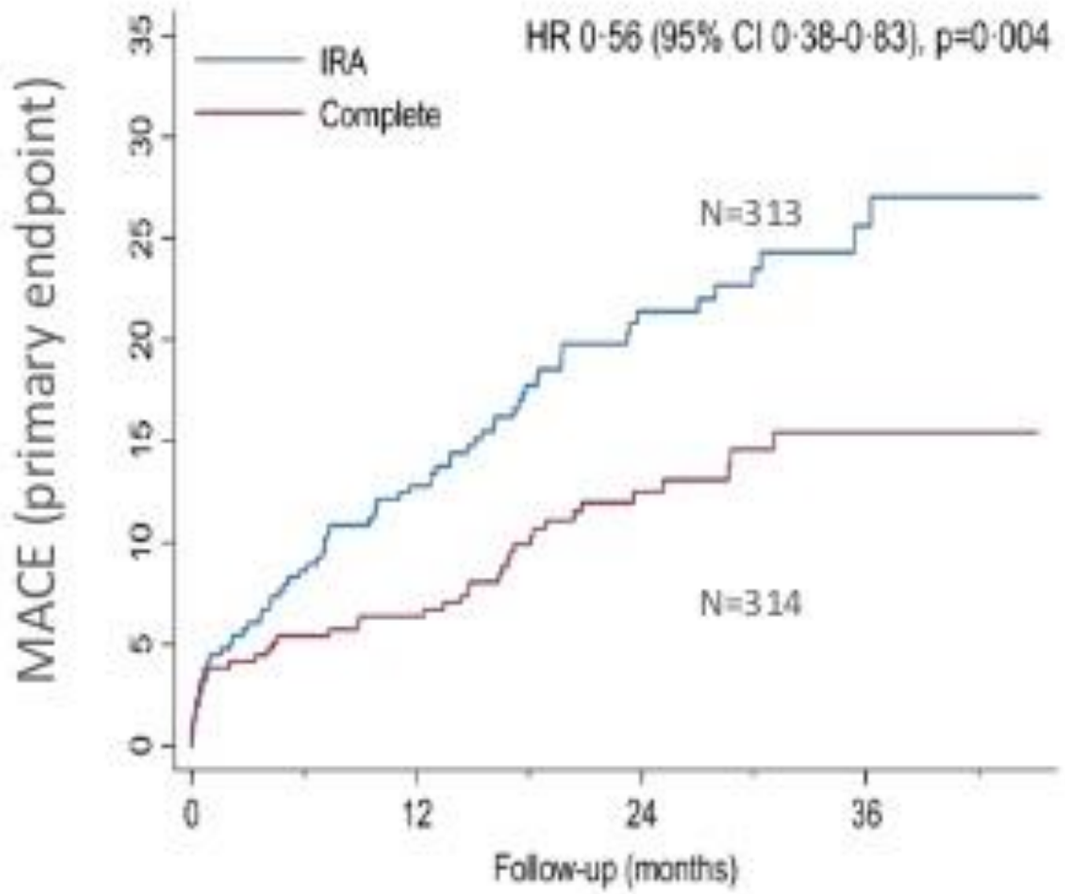
STEMI

CULPRIT-SHOCK: A Randomized Trial of Multivessel PCI in Cardiogenic Shock



Number at risk				
Infarct-related artery only	313	271	142	53
Complete revascularisation	314	291	159	55

DANAMI 3-PRIMULTI: staged FFR-guided management of non-culprit stenoses



Complete FFR guided revascularisation of MVD STEMI patients, staged within the index admission, reduced the primary endpoint. This reduction was driven by repeat revascularisations and not by hard endpoints

Engstrøm T et al ACC 2015

CHANGE IN RECOMMENDATIONS

2012		2017
Radial access[a]	MATRIX[143]	
DES over BMS	EXAMINATION[150,151] COMFORTABLE-AMI[149], NORSTENT[152]	
Complete Revascularization[b]	PRAMI[168], DANAMI-3-PRIMULTI[170], CVLPRIT[169], Compare-Acute[171]	
Thrombus Aspiration[c]	TOTAL[159], TASTE[157]	
Bivalirudin	MATRIX[209], HEAT-PPCI[205]	
Enoxaparin	ATOLL[200,201], Meta-analysis[202]	
Early Hospital Discharge[d]	Small trials & observational data[259–262]	
Oxygen when SaO2 <95%	AVOID[64], DETO2X[66]	Oxygen when SaO2 <90%
Dose i.V. TNK-tPA same in all patients	STREAM[121]	Dose i.V. TNK-tPA half in Pts ≥75 years

2017 NEW RECOMMENDATIONS

- **Additional lipid lowering therapy if LDL >1.8 mmol/L (70 mg/dL) despite on maximum tolerated statins**
  IMPROVE-IT[376], FOURIER[382]
- **Complete revascularization during index primary PCI in STEMI patients in shock**
  Expert opinion

- **Cangrelor if $P2Y_{12}$ inhibitors have not been given**
  CHAMPION[193]
- **Switch to potent $P2Y_{12}$ inhibitors 48 hours after fibrinolysis**
  Expert opinion
- **Extend Ticagrelor up to 36 months in high-risk patients**
  PEGASUS-TIMI 54[333]
- **Use of polypill to increase adherence**
  FOCUS[323]

- **Routine use of deferred stenting**
  DANAMI 3-DEFER[155]

I **IIa** **IIb** **III**

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1. Nonculprit Stenosis Evaluation Using **Instantaneous Wave-Free Ratio** in Patients With **ST**-Segment **Elevation Myocardial Infarction**.
Thim T, Götberg M, Fröbert O, Nijveldt R, van Royen N, Baptista SB, Koul S, Kellerth T, Bøtker HE, Terkelsen CJ, Christiansen EH, Jakobsen L, Kristensen SD, Maeng M.
JACC Cardiovasc Interv. 2017 Dec 26;10(24):2528-2535. doi: 10.1016/j.jcin.2017.07.021. Epub 2017 Nov 29.
PMID: 29198461
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2. **Instantaneous wave-free ratio** and fractional flow reserve for the assessment of nonculprit lesions during the index procedure in patients with **ST**-segment **elevation myocardial infarction**: The WAVE study.
Musto C, De Felice F, Rigattieri S, Chin D, Marra A, Nazzaro MS, Cifarelli A, Violini R.
Am Heart J. 2017 Nov;193:63-69. doi: 10.1016/j.ahj.2017.07.017. Epub 2017 Aug 3.
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Nonculprit Stenosis Evaluation Using Instantaneous Wave-Free Ratio in Patients With ST-Segment Elevation Myocardial Infarction

Troels Thim, MD, PhD,[a] Matthias Götberg, MD, PhD,[b] Ole Fröbert, MD, PhD,[c] Robin Nijveldt, MD, PhD,[d] Niels van Royen, MD, PhD,[d] Sergio Bravo Baptista, MD,[e] Sasha Koul, MD, PhD,[b] Thomas Kellerth, MD, DMSc,[c] Hans Erik Bøtker, MD, DMSc,[a] Christian Juhl Terkelsen, MD, PhD, DMSc,[a] Evald Høj Christiansen, MD, PhD,[a] Lars Jakobsen, MD, PhD,[a] Steen Dalby Kristensen, MD, DMSc,[a] Michael Maeng, MD, PhD[a]

Observational, prospective, multicenter.

Denmark, Sweden Amsterdam, Netherland, Portugal

(June 2015 - Nov 2016)

ment IFR-FFR in across nonculprit stenoses on acute CAG in ST

120 patients
157 nonculprit

1 Asthma

119 patients
156 nonculprit

1 died intra-H
3 died out-of-H
2 declined followup

113 patients
147 nonculprit

5 day **> 16 day**

Acute CAG STEMI with successful PCI
>=1 nonculprit stenoses
>=18 years

IC

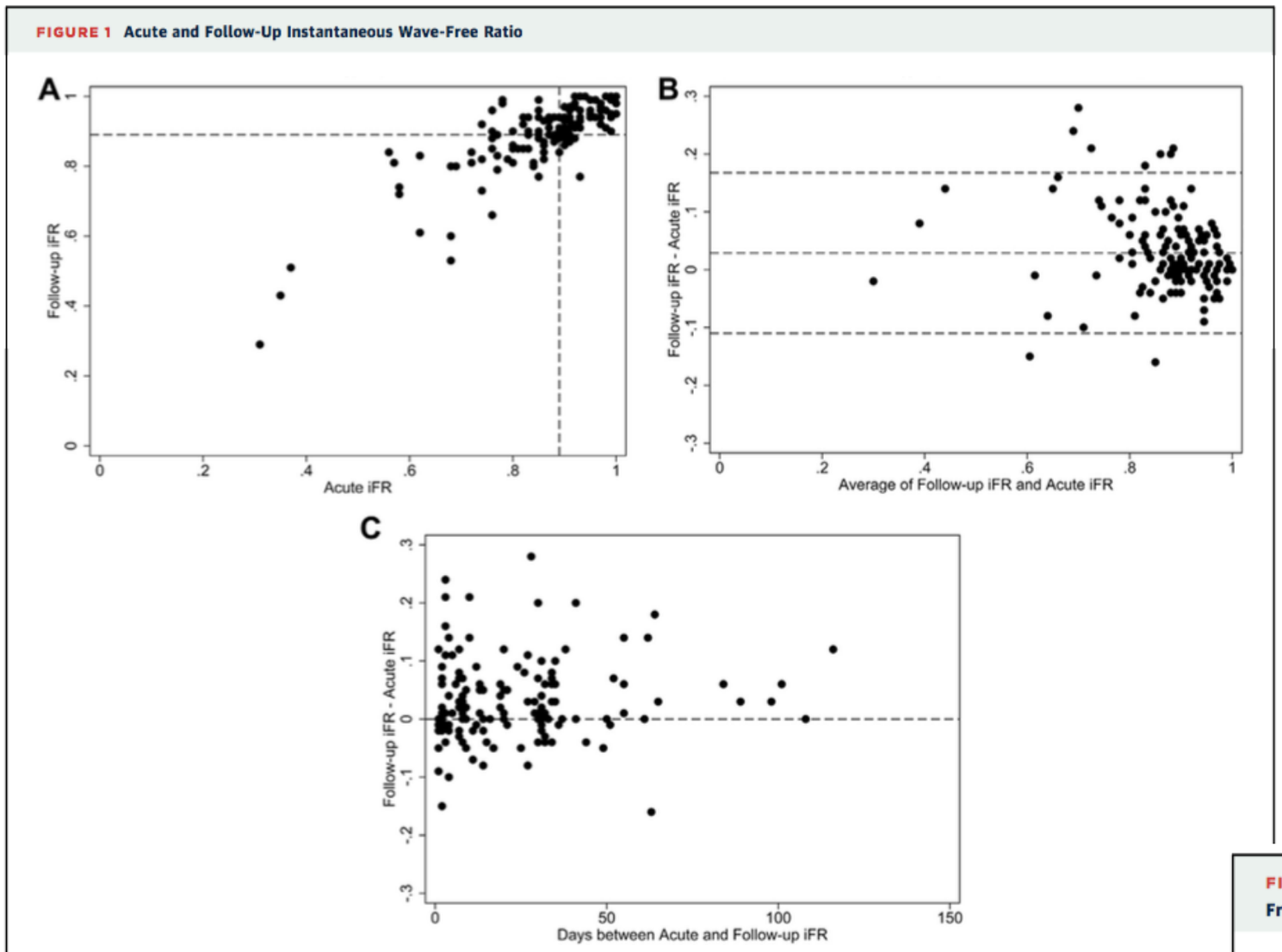
Inability to provide

Cardiogenic shock

TABLE 1 Baseline Patient Characteristics (n = 120)

Age, yrs	66 ± 11
Male	88 (73)
Body mass index, kg/m^2	27 ± 5
Family history of ischemic heart disease	41 (34)
Current smoking	39 (33)
Hypertension*	48 (40)
Hypercholesterolemia†	30 (25)
Diabetes‡	11 (9)
Previous acute myocardial infarction	11 (9)
Previous percutaneous coronary intervention	15 (13)
Previous coronary artery bypass grafting	1 (1)

Values are mean ± SD or n (%). *Treatment with blood pressure–lowering agents. †Treatment with lipid-lowering agents. ‡Treatment with antidiabetic drugs or diet.



Acute iFR <0.9 (52%)

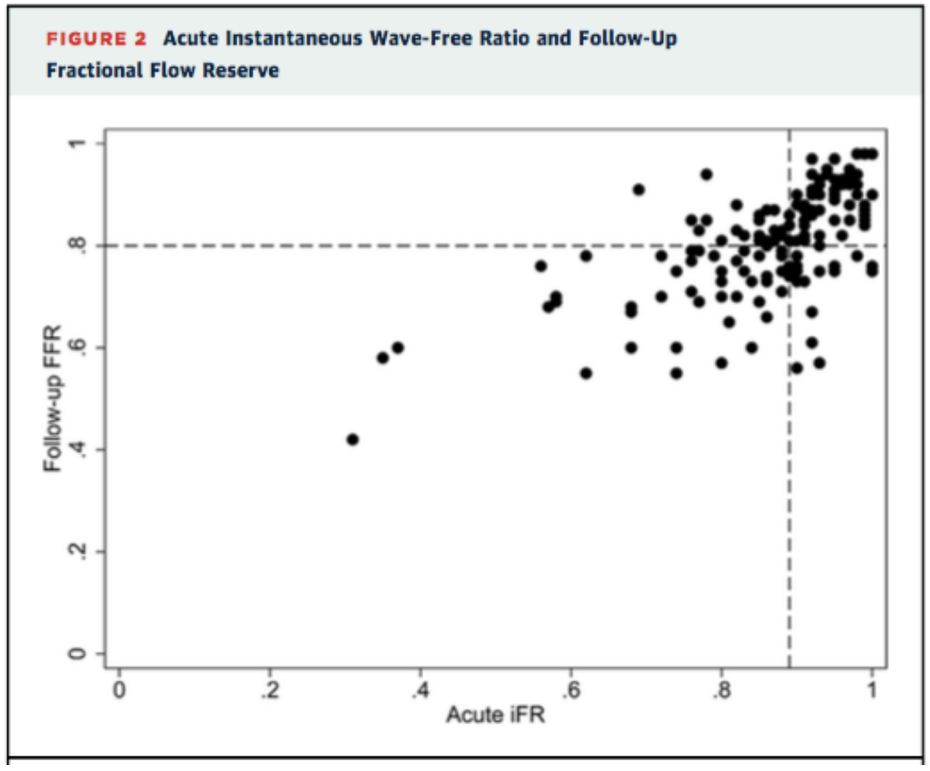
Acute iFR correctly classified 87% of stenoses with follow-up iFR <0.9

Classification agreement (sig. vs. non-sig.) between acute and follow-up iFR 78%, but was high when acute iFR was >=0.90 but only moderate when acute iFR was <0.90.

Acute iFR was lower than follow-up iFR. With shorter time intervals between acute and follow-up iFR, the differences between were minor.

<u>Reproductibility iFR after STEMI</u>

Day 5	89%
Day >=16	70%



CONCLUSION

- In STEMI, iFR of nonculprit lesions immediately after treatment of the culprit was feasible.

- iFR seems to have acceptable reproductility. Physiological STEMI conditions, may explain some of the observed disagreements.

- iFR may be a tool to guide acute full revascularization.

- Acute iFR can be used to defer revascularization or staged follow-up evaluation (reduce risk, costs?).

Instantaneous Wave-Free Ratio and Fractional Flow Reserve for the Assessment of Non-Culprit Lesions during the Index Procedure in Patients with ST-Segment Elevation Myocardial Infarction: The WAVE study

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Observational, prospective, single-center. (Rome, Sept 2015 - Dec 2016)

AIM: **Evaluate diagnostic performance IFR vs. FFR**

56 patients

6 excluded

3 no IC
1 Hemodynamic instability
2 Several bradichardia post-ATP

50 patients
66 nonculprit

Acute

Day 5

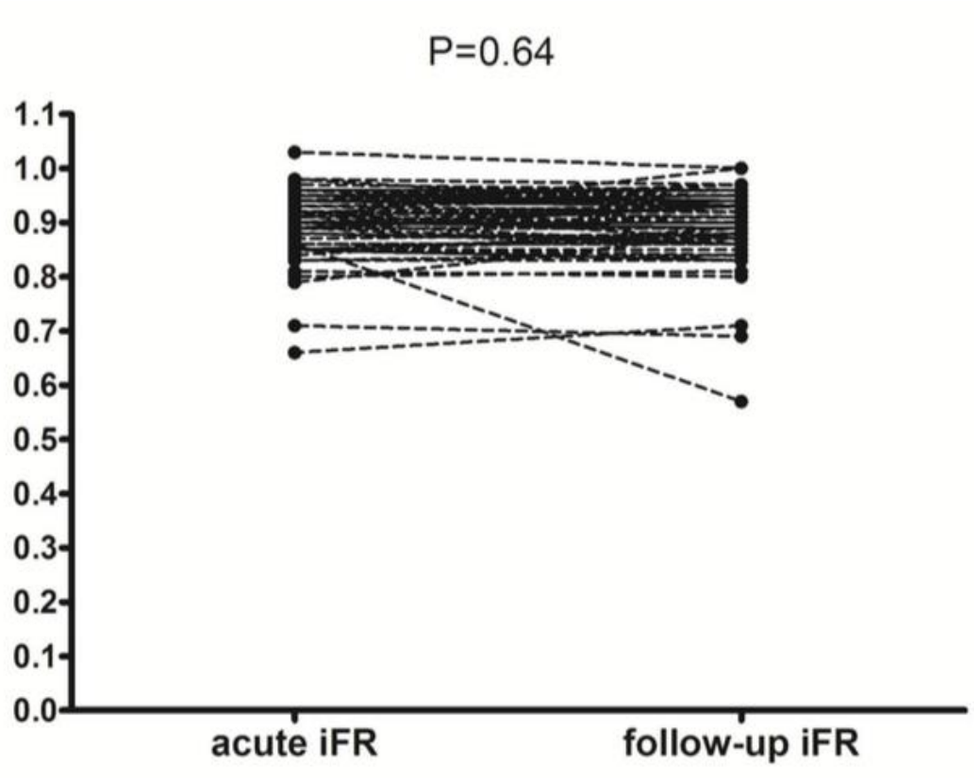
STEMI criterial (clinic-ECG)
At least 1 nonculprit lesion
(Esten. 50-95% o QCA >= 2.5mm)

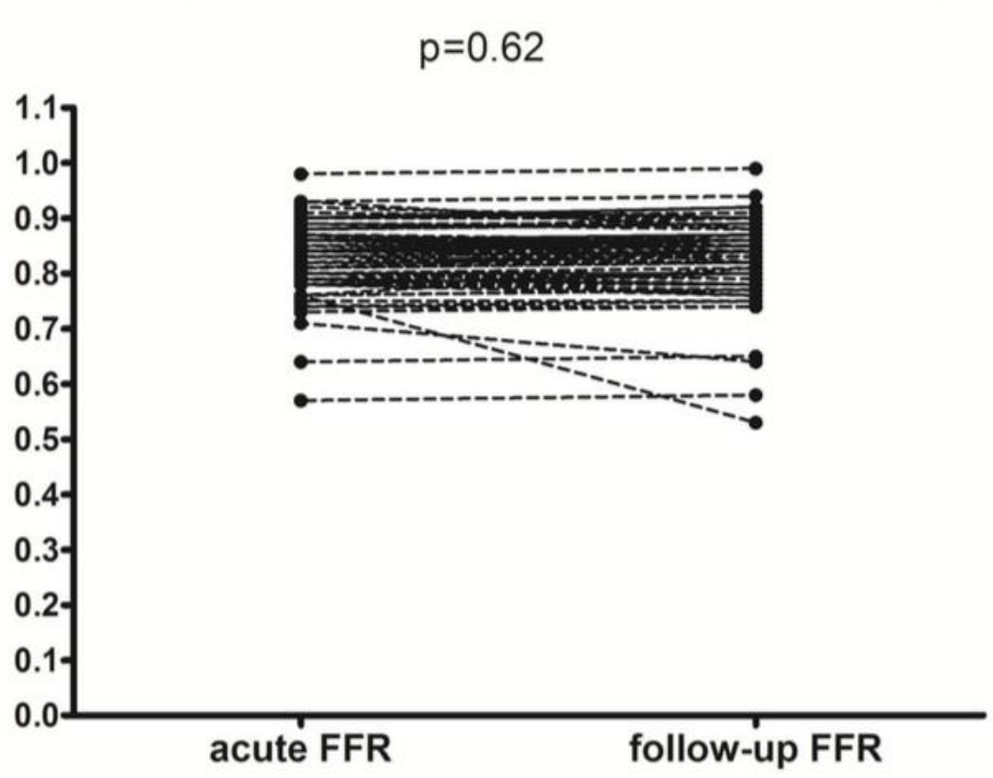
HD instability **FEVI<=30%**
Arrythmias **TIMI 1-2**
Previous STEMI **CI Adenosine**

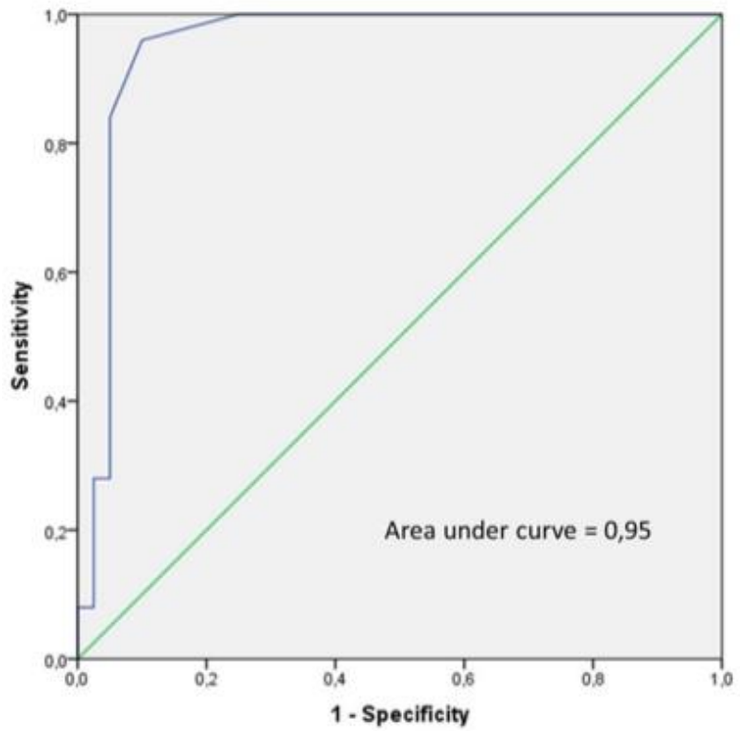
Baseline characteristics	All patients N.50
Female, n. (%)	13(26)
Age, years (mean±SD)	68±11
Arterial Hypertension, n. (%)	31(62)
Smoker, n. (%)	19(38)
Diabetes, n. (%)	13(26)
Hyperlipidemia, n. (%)	24(48)
Familiry history of CAD	14(28)
Anterior MI, n. (%)	20(40%)
Thrombus aspiration, n. (%)	15(30)
GP IIb/IIIa inhibitors, n. (%)	2(4)
Culprit: LAD/RCA/LCX/others, n.	20/16/9/5
Non-IRA n.	66
Nonculprit:LAD/RCA/LCX/others, n.	33/15/13/5
Symptoms duration, min (mean±SD)	246±198
Time from index to staged procedure Days (range; mean±SD; median)	5-8; 5.9±1.5 6

Angiographic and functional measurements of non-culprit lesions

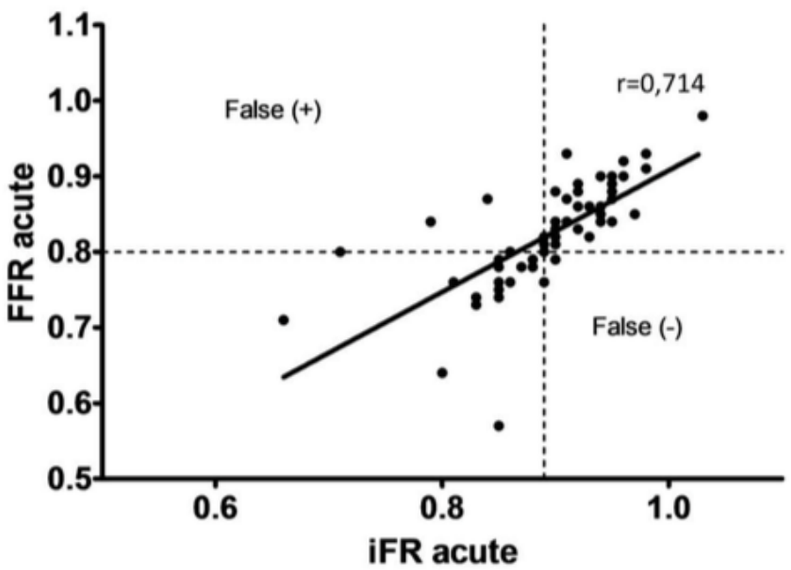
	Index procedure	Staged procedure	p value
LVEF (mean±SD)	52±12	53±10	NS
iFR non-culprit (mean±SD)	0.90±0.06	0.89±0.07	0.64
FFR non-culprit (mean±SD)	0.82±0.07	0.82±0.08	0.62
DS non-culprit (%) (mean±SD)	58±12	58± 9	NS
RD non-culprit (mm) (mean±SD)	2.91±1.48	2.90±1.33	NS
MLD nonculprit (mm) (mean±SD)	1.43±0.51	1.44±1.09	NS
TIMI flow non-culprit (mean±SD)	2.98±0.17	2.98± 0.19	NS
cTFC non-culprit (mean±SD)	15±7	16±3	NS



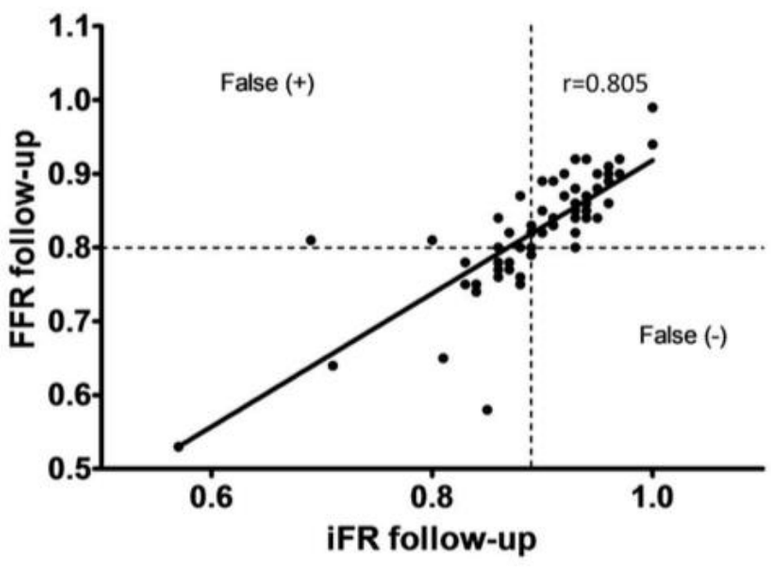




High precision iFR to identify
a positive (<= 0.80) FFR in acute



Diagnostic accuracy 92%
(+) predictive value 86%
(-) predictive value 97%
Sensitivity 96%
Specificity 90%



Diagnostic accuracy 86%
(+) predictive value 73%
(-) predictive value 97%
Sensitivity 96%
Specificity 81%

CONCLUSION

- iFR valúes in non-IRA lesiones are reproducible when measured during the acute setting of STEMI and some days later. They significantly correlate with the FFR measurements.

- iFR is an accurate method to identify a positive FFR (≤0.80) during the index procedure following the treatment of IRA lesions.

- The best cut-off of iFR to identify functionally significant stenosis during the index procedure is ≤ 0,89.

Take Home Messages

- Coronary physiology is becoming increasingly important to current interventional cardiologists with abundant evidence and an evolving future.

- iFR was non-inferior to FFR regarding death, MI and unplanned revascularization in 1 year. iFR was superior to FFR regarding procedural disconfort.

- iFR more comfortable, faster, cheaper.

- Evidence amases to date would have to say *"Use FFR / iFR for better PCI"*.

- The current evidence of FFR/iFR on the treatment of multivessel coronary artery disease in patients with STEMI is limited.

- Future studies are needed.

Gracias