Imaging & Physiology Summit, FFR Workshop

VERY LONG-TERM FOLLOW-UP OF FFR – GUIDED PCI

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From a patient's point of view , the wind tunnel for any index to be used in clinical medicine, is its *influence on outcome*

For most invasive indexes in the cath lab, no outcome studies have been performed or were "negative"

FFR is the only invasive index used which systematically improved outcome in RCT's, as will be highlighted in the present session

FFR and Clinical Outcome:

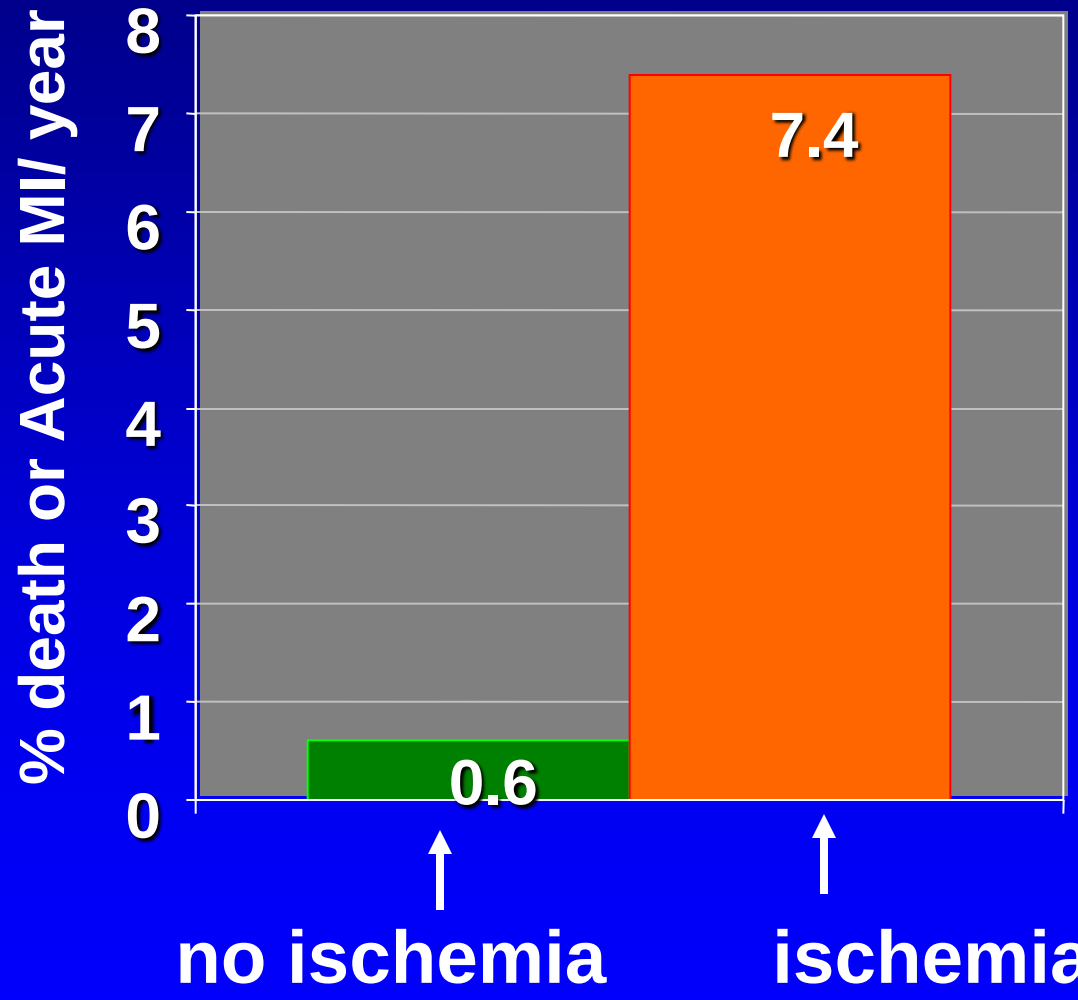
3 important questions:

- Is it safe to defer PCI if FFR is negative ?
- Is it indicated to perform PCI if FFR is positive ?
- Does systematic use of FFR improve outcome of PCI ?

Risk to die or experience myocardial infarction in the next 5 years related to a coronary stenosis:

- **non-ischemic stenosis: < *1% per year ****
  (NUCLEAR studies, PET, MRI, DEFER, FAME)
- **ischemic stenosis, if left untreated: *5-10% per year***
  (Many historical registries, nuclear studies, ACIP, CCTA, MRI, FFR)
- **stented stenosis: *2-3% per year***
  (*e.g DEFER, FAME, SYNTAX,many large studies and registries)*

The risk for death or acute myocardial infarction in the next five years is 20 times higher for an ischemic lesion compared to a non-ischemic lesion !!!



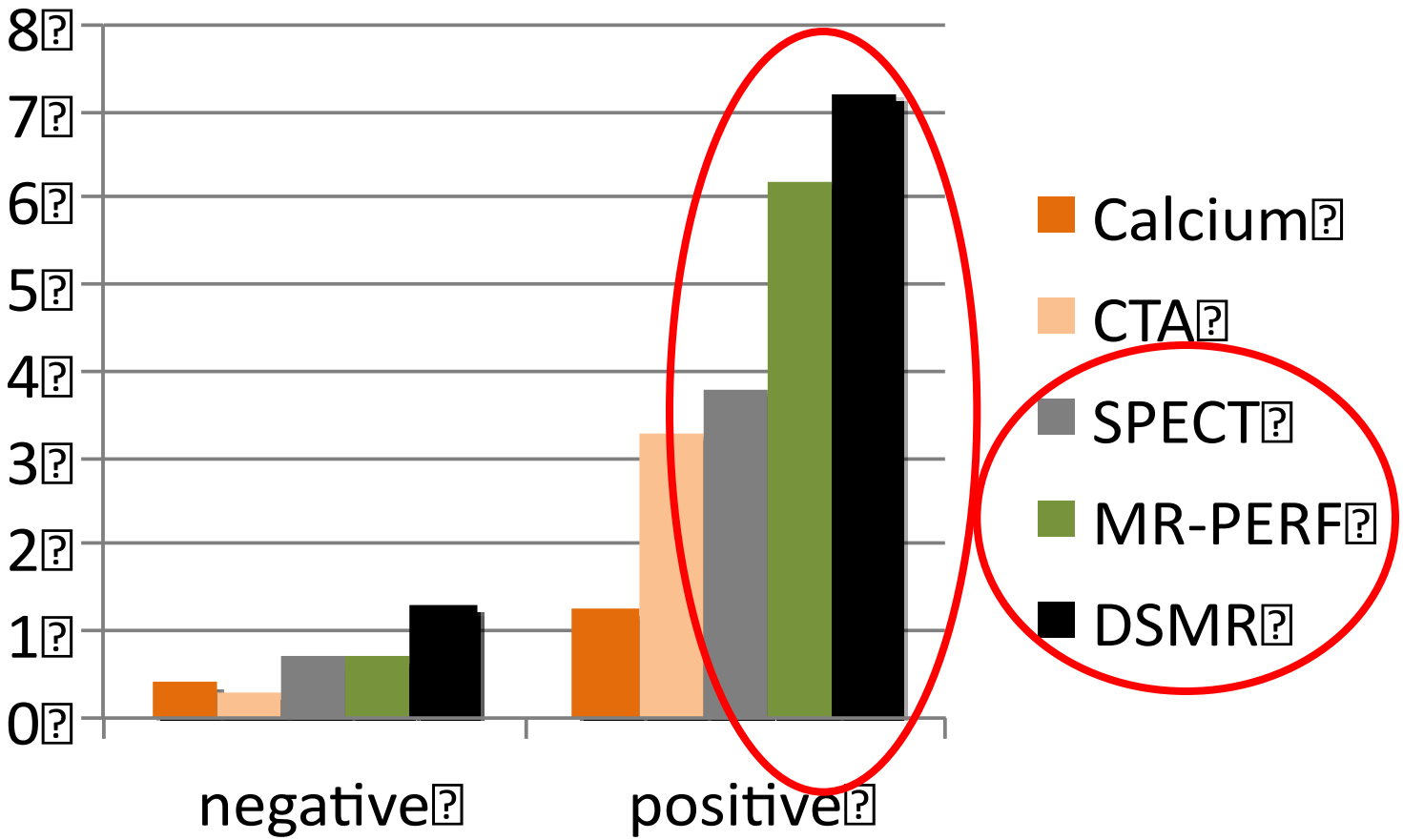
12000 Patients (2 x 6000)

similar stenosis severity by coronary angio

Iskander S, Iskandrian A E JACC 1998

Events (within 1 year)

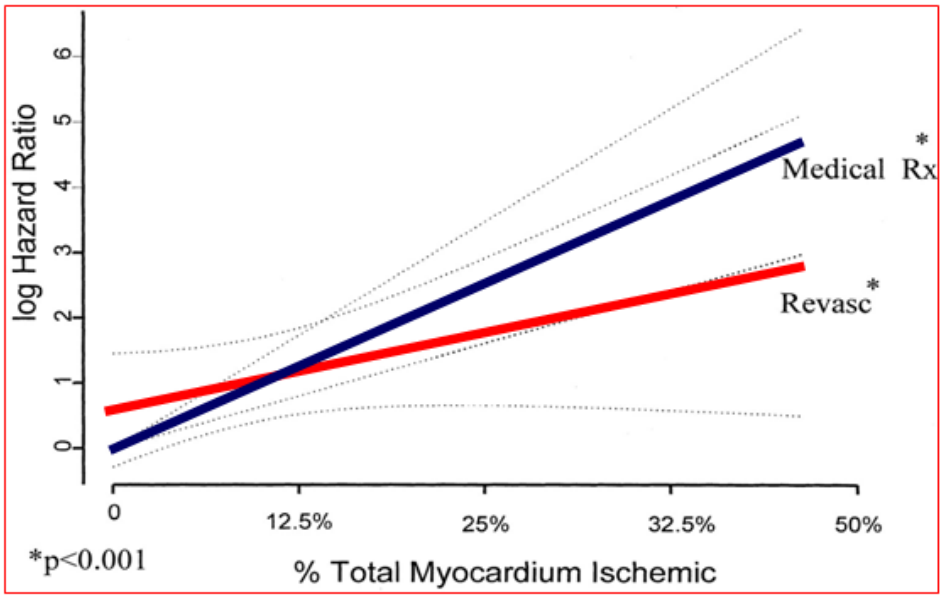
No events/1 year



Nagel; JACC Imaging 2009

Is it important to detect ischemia ?

Log hazard ratio for revascularization (Revasc) vs medical therapy (Medical Rx) as a function of % myocardium ischemic based on final Cox proportional hazards model



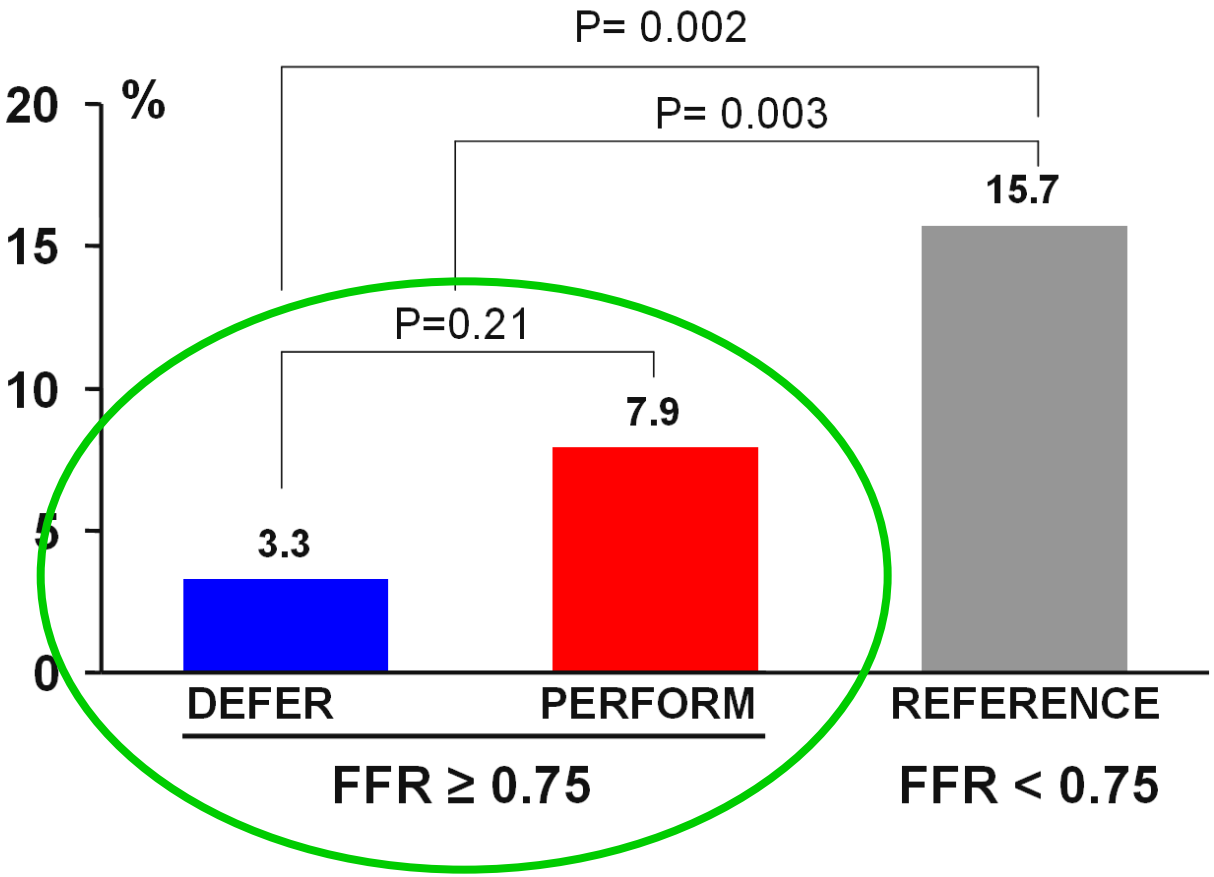
Above 10% ischemic myocardium, the survival benefit from revascularisation increases with the extent of ischemia

Hachamovitch, R. et al. Circulation 2003

Outcome is directly related to the presence and extent of (inducible or reversible) ischemia

DEFER: Cardiac Death And Acute MI After 5 Years

non-ischemic stenosis, R/x
non-ischemic stenosis, R/x + stent
ischemic stenosis, R/x + stent



DEFER-study, JACC 2007; 49 : 2105-2111

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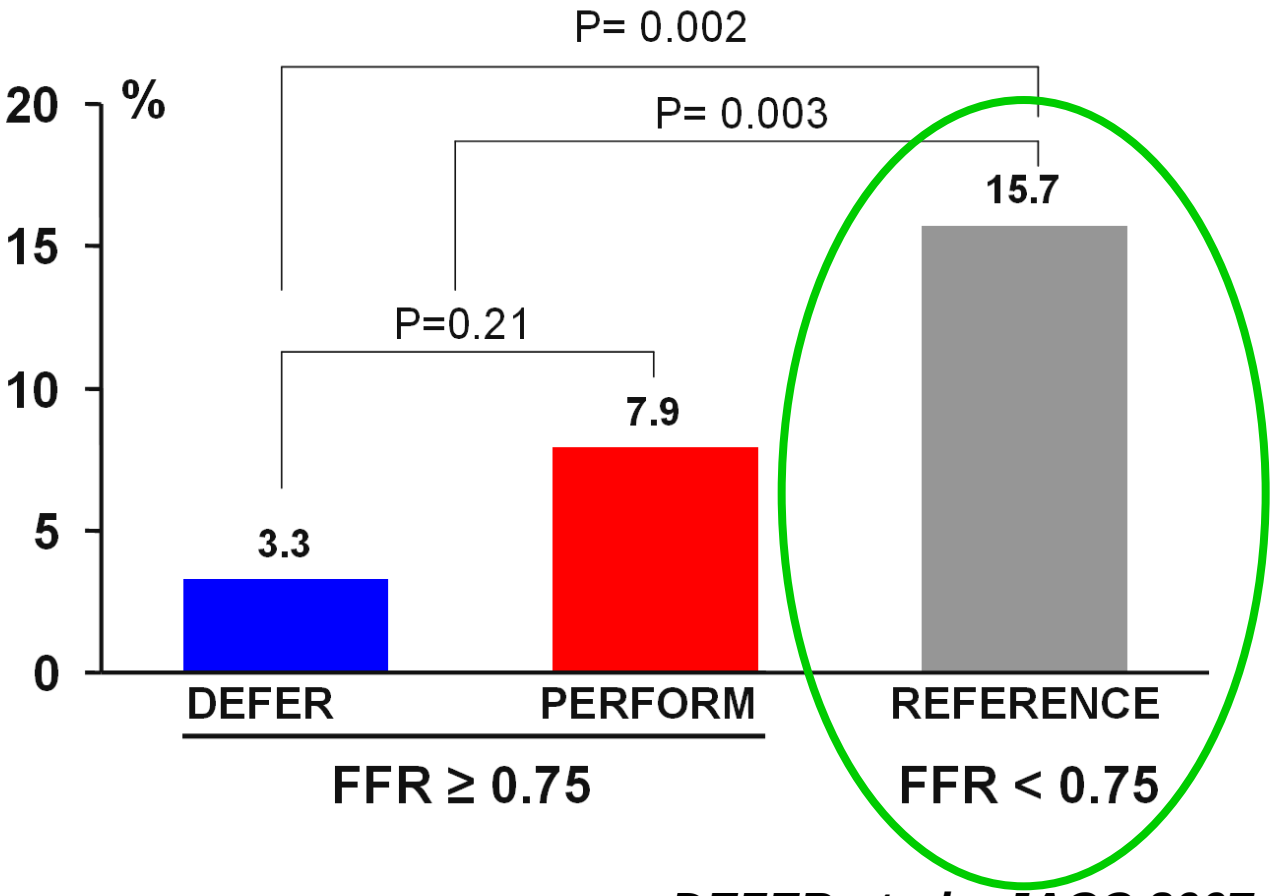

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FUNCTIONALLY *NON*-*SIGNIFICANT* STENOSIS

- **Stenting a functionally non-significant (FFR-negative) stenosis does NOT make any sense.**

  It is unnecessary, expensive, and increases the risk of death and MI without any symptomatic benefit

- **Further evidence from FAME, FAME-2 and (indirectly) from PROSPECT**

DEFER, FAME, Nuclear; Prospect

FUNCTIONALLY *SIGNIFICANT* STENOSIS

IF ischemia is present, does FFR guided PCI improve outcome ?

⟶ ***FAME STUDIES***

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

FLOW CHART

Patient with stenoses ≥ 50% in at least 2 of the 3 major epicardial vessels

Indicate all stenoses ≥ 50% considered for stenting

Randomization

Angiography-guided PCI

Stent all indicated stenoses

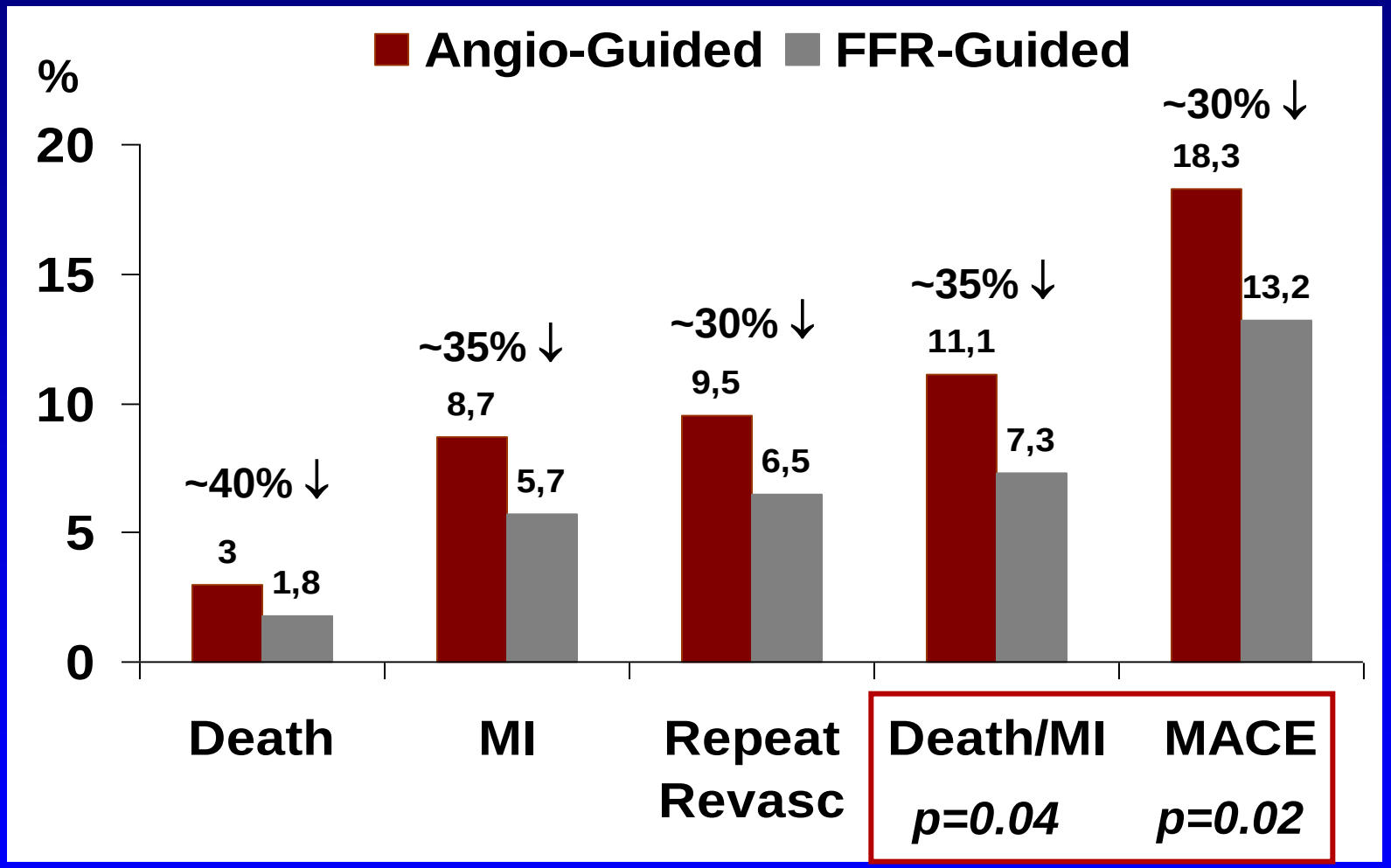
FFR-guided PCI

Measure FFR in all indicated stenoses

Stent only those stenoses with FFR ≤ 0.80

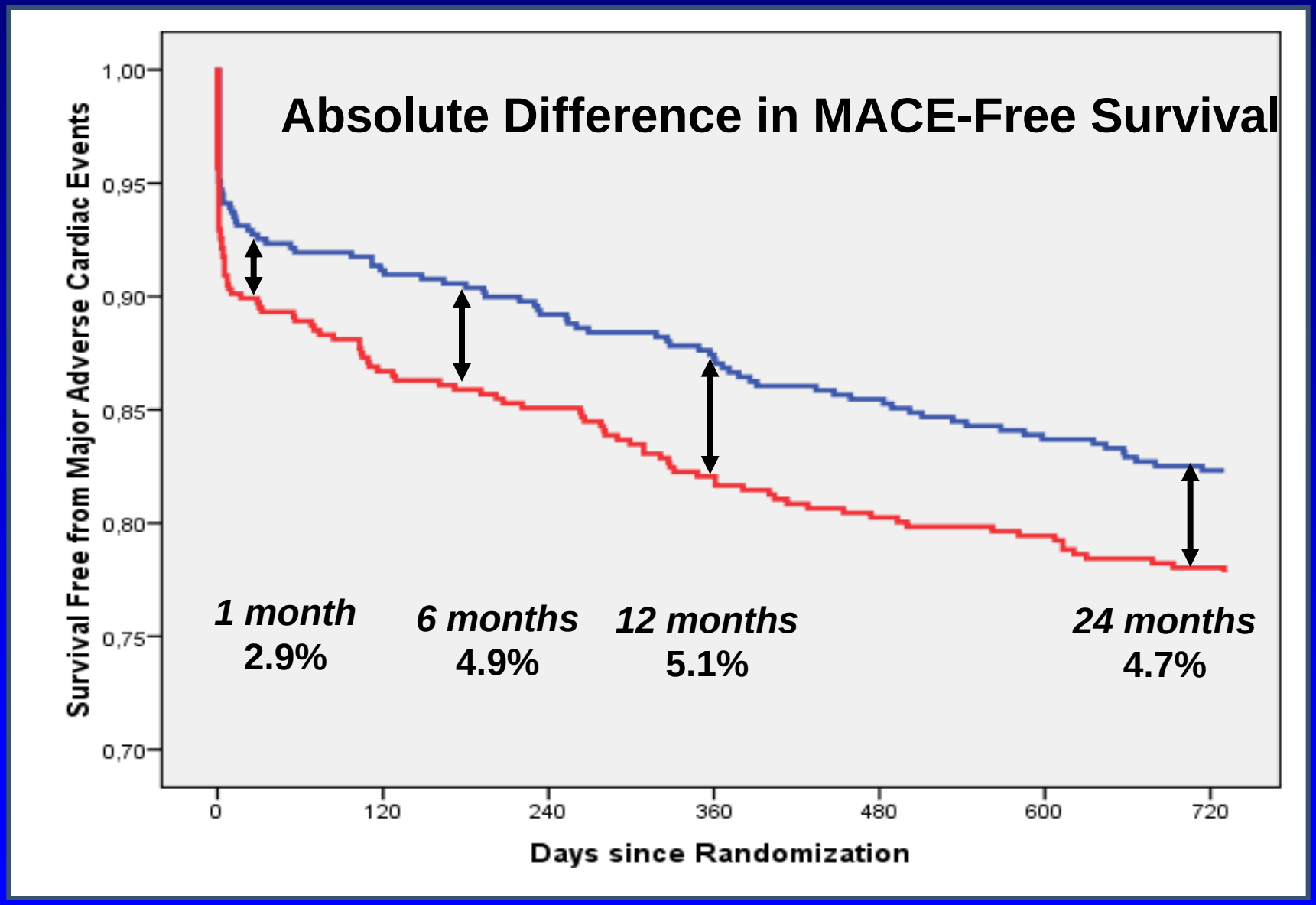
follow-up at 1,2,5 year

Measuring FFR in Multivessel Disease: FAME Study (N=1005) : One Year Outcomes

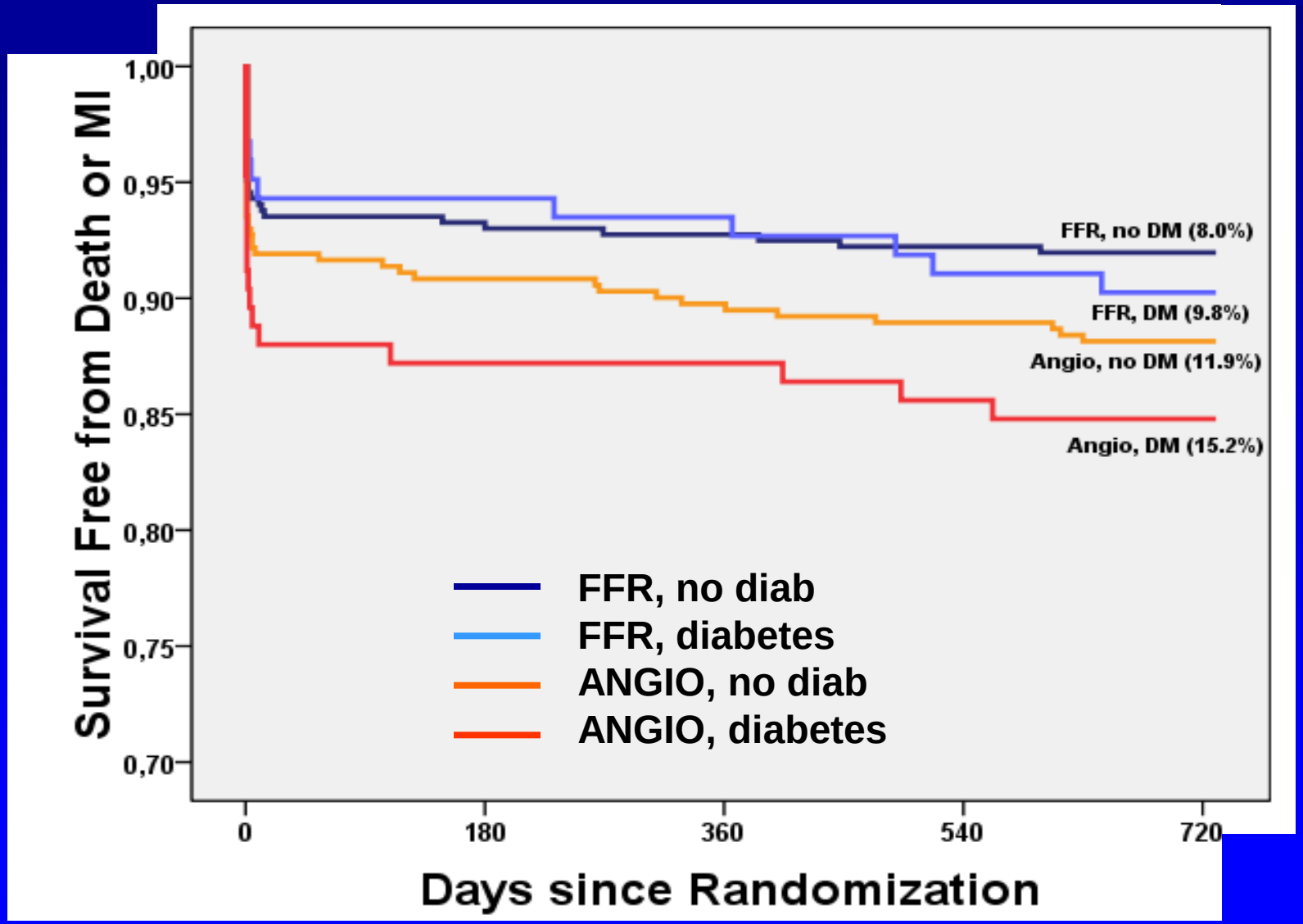


Tonino et al: New Engl J Med 2009;360:213-24.

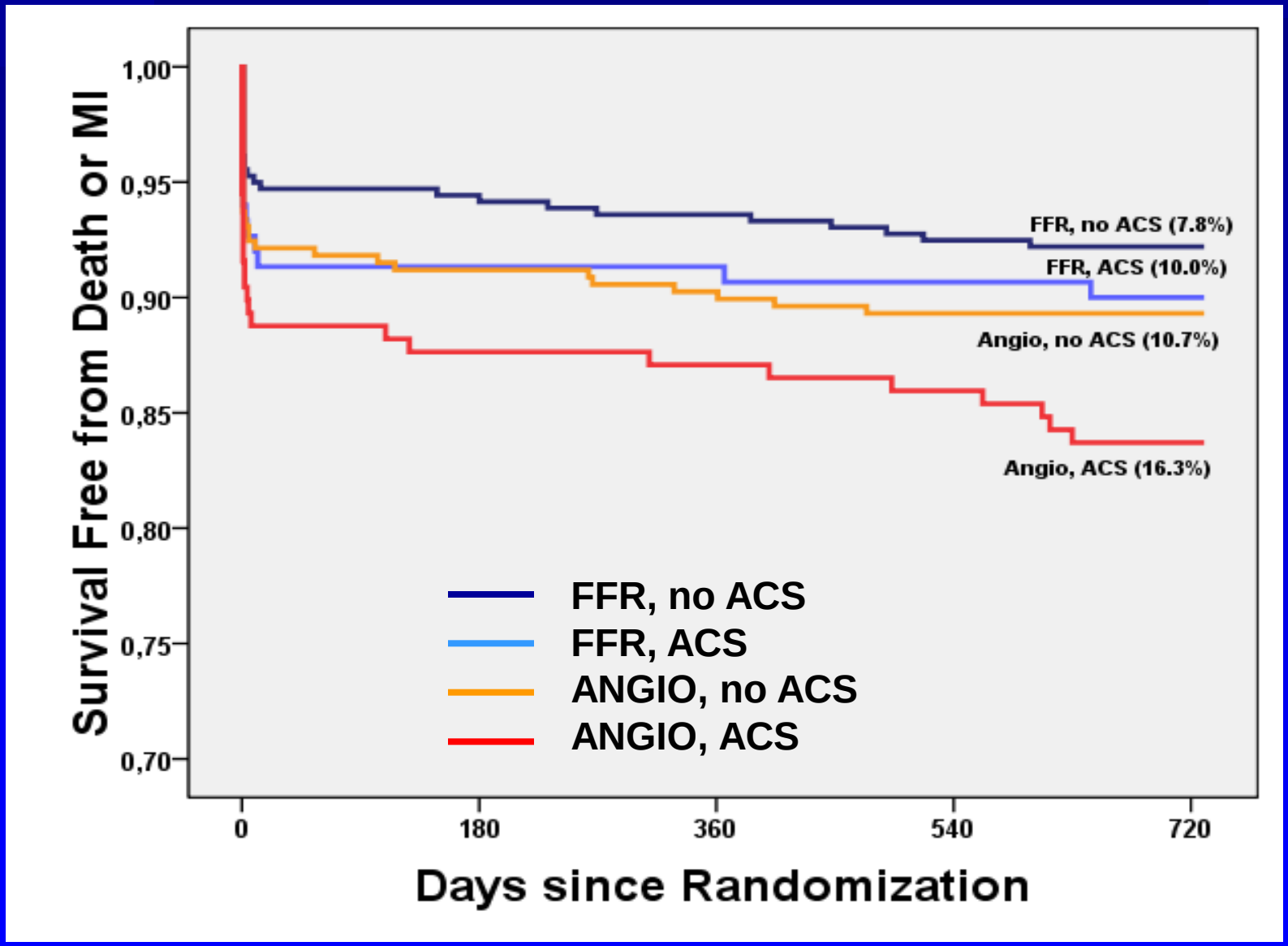
FAME study: Event-free Survival 24 months



FAME study: Diabetes vs Non-Diabetes



FAME study: Unstable Angina & Non-STEMI



Outcome of Deferred Lesions:

513 Deferred Lesions and 901 stented lesions in 509 FFR-Guided Patients

2 Years

9
Late Myocardial Infarctions

8
Due to a New Lesion or Stent Related

1
Myocardial Infarction due to an Originally Deferred Lesion

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

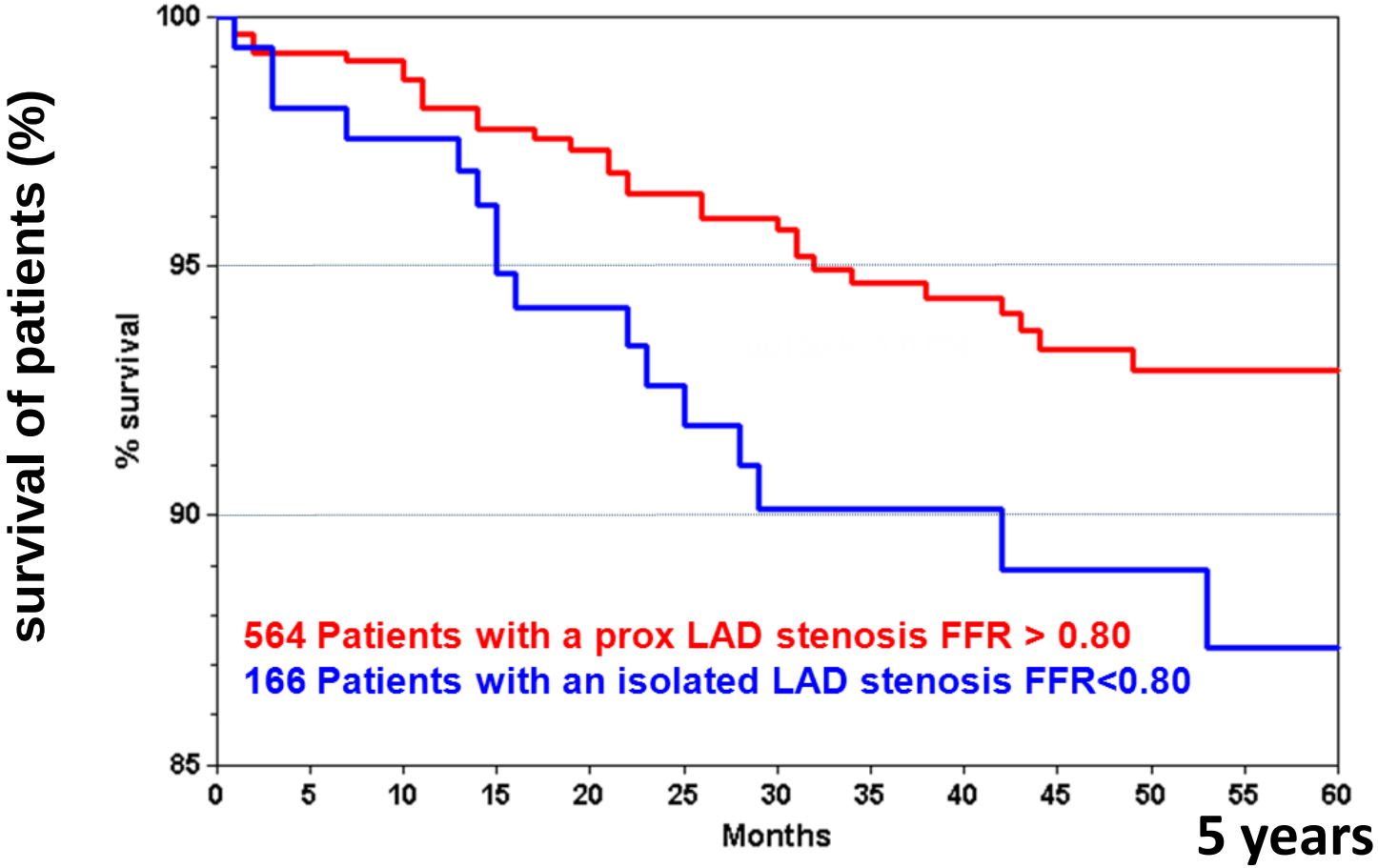
What about proximal LAD?

- FAME: in ~ 40% of patients, prox LAD was involved
  → excellent outcome

- Large registry by Muller et al (N=730)

FFR-GUIDED PCI IN PROX LAD STENOSIS

Proximal LAD Stenoses (N=730)

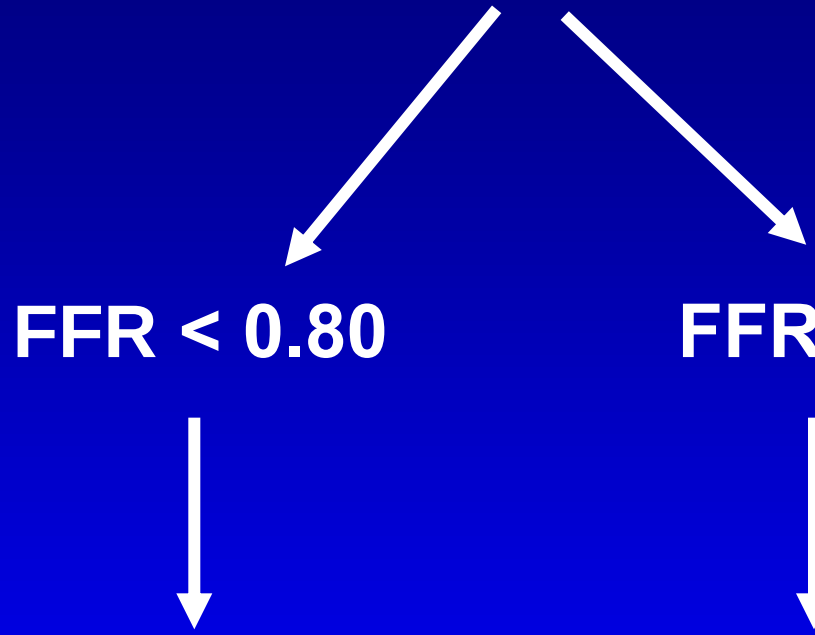


Muller O. et al. JACC Interv 2011 In Press

What about Left Main?

- 3 prospective studies and 8 registries
- together 810 patients
- not a single patient in any of these studies ever died due to a deferred LM lesion with FFR > 0.80

209 *consecutive* patients with 30% - 70% LM stenosis on the angiogram



FFR < 0.80

CABG

FFR ≥ 0.80

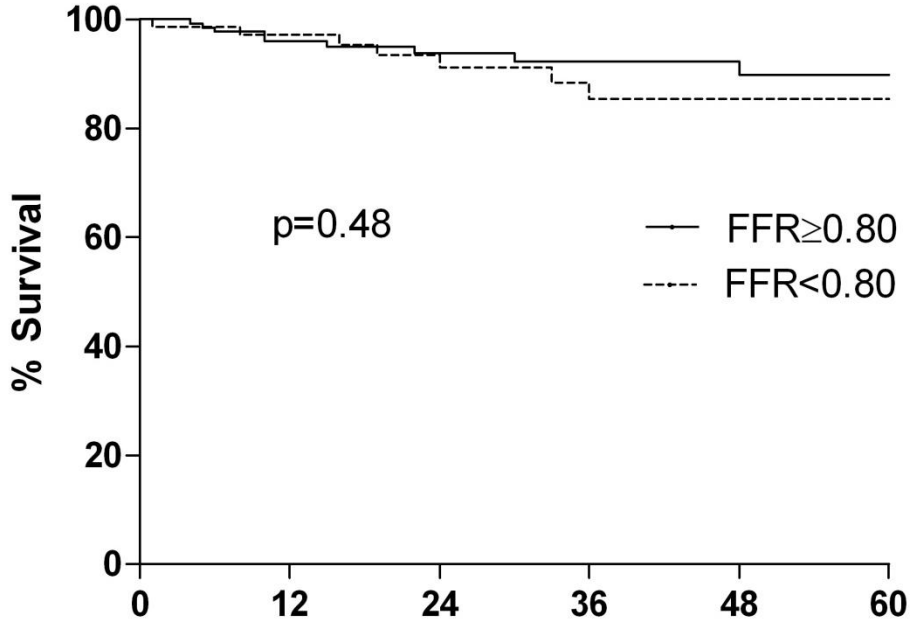
R/x (and PCI of concomittant lesions

Follow-up of 5 years

Hamilos, Circulation 2009

Clinical Outcome Data after FFR-Guided Revascularization in Patients with LM Equivocal LM Stenosis (N=209)

SURVIVAL RATE



No at risk						
FFR≥0.80	136	103	72	52	38	26
FFR<0.80	73	56	41	30	14	10

FFR ≥ 0.80 No CABG
FFR < 0.80 CABG

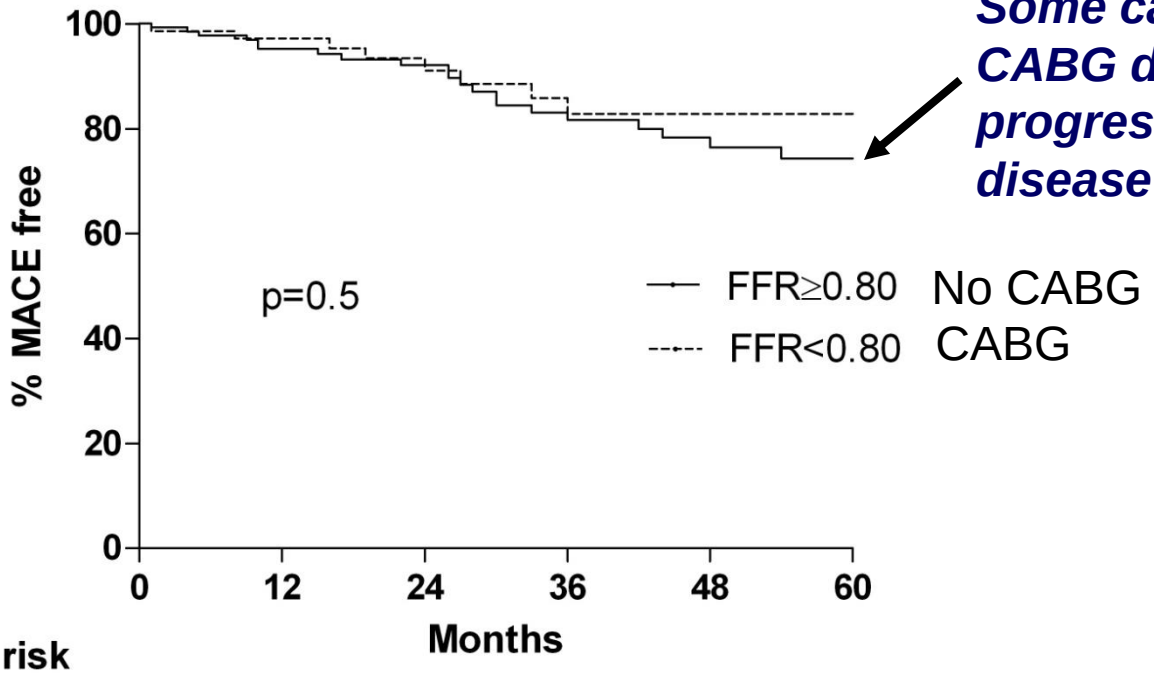
www.cardio-aalst.be

Deferring revascularization of 30-70% LM stenosis based upon FFR > 0.80, is extremely safe !!

Hamilos M, Muller O et al. Circulation 2009

Clinical Outcome Data after FFR-Guided Revascularization in Patients with LM Equivocal LM Stenosis (N = 209)

MACE RATE



No at risk						
FFR≥0.80	136	106	77	57	42	30
FFR<0.80	73	56	40	29	15	10

Some catch-up of CABG due to progression of disease

Hamilos M, Muller O et al. Circulation 2009

CONCLUSIONS:

- (very) long-term follow-up available for 3 RCT's (DEFER, FAME, FAME-2) and many very long-term follow-up registries

- 10-y fu DEFER, 5-y FU FAME, 2-y FAME2 will be available next year

- Deferring PCI of non-ischemic lesions based upon FFR is very safe, as repeatedly emonstrated

- FFR-guided PCI of ischemic lesions improves outcome and quality of life compared to angio-guided PCI and medical therapy alone