

ROLE OF CORONARY PRESSURE & FFR IN MULTIVESSEL DISEASE

*Angioplasty Summit TCT ASIA
Seoul, Korea, april 24th, 2008*

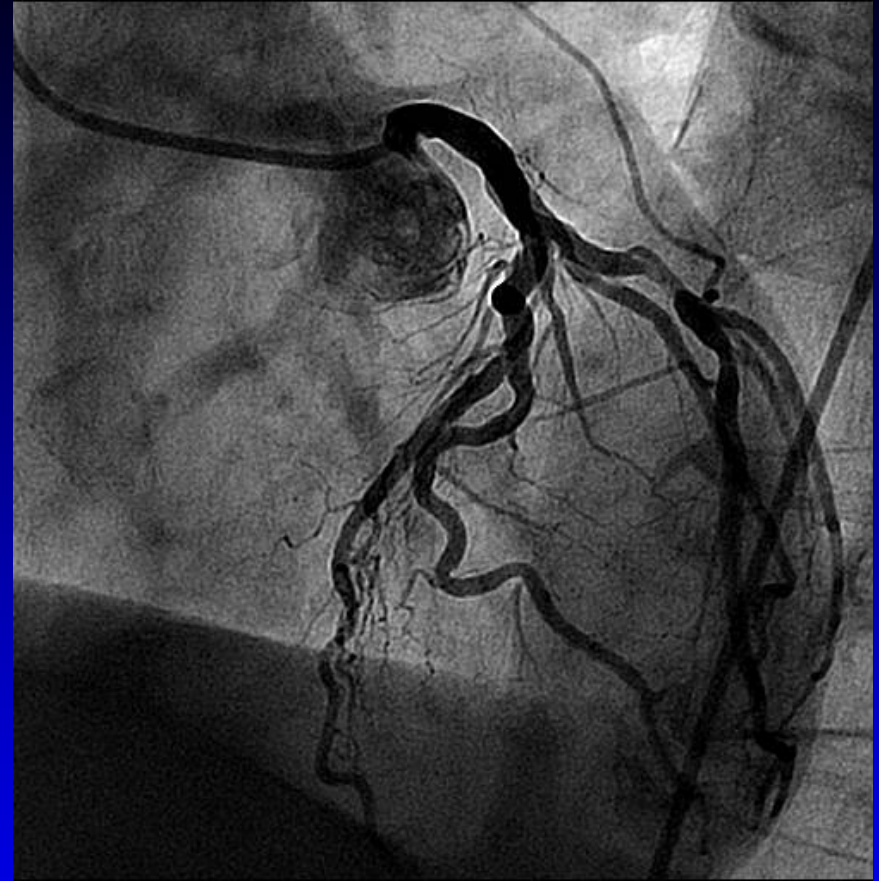
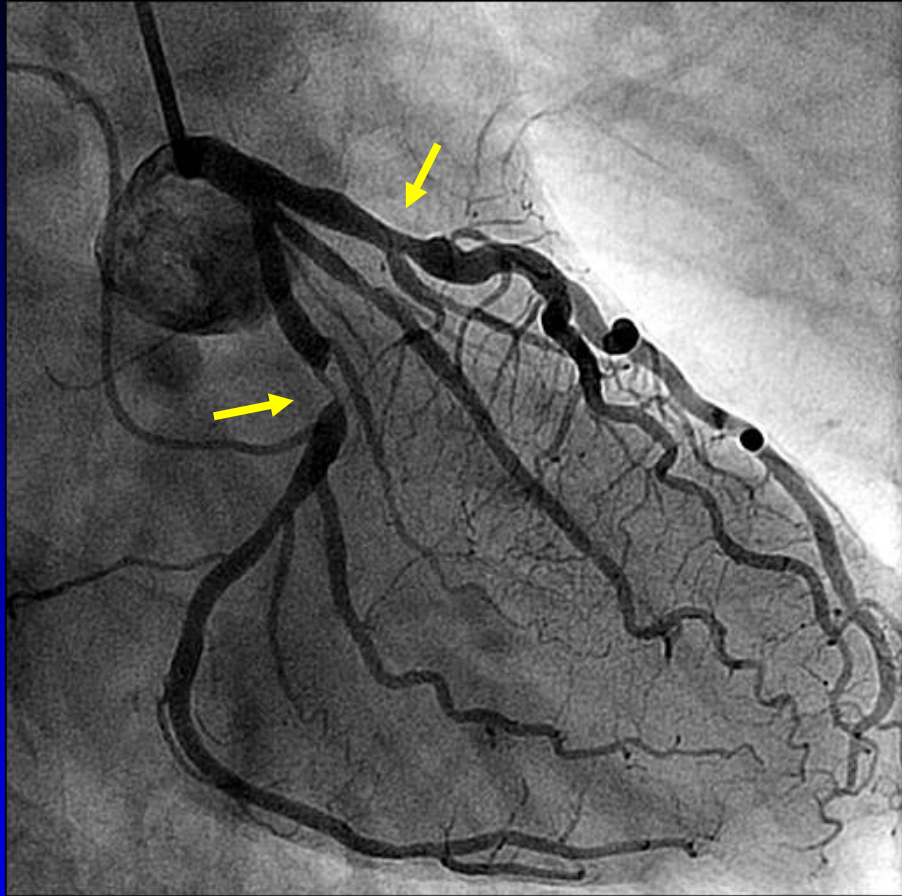


Nico H. J. Pijls, MD, PhD
Catharina Hospital,
Eindhoven, The Netherlands

A rather common patient in our cath lab today.....

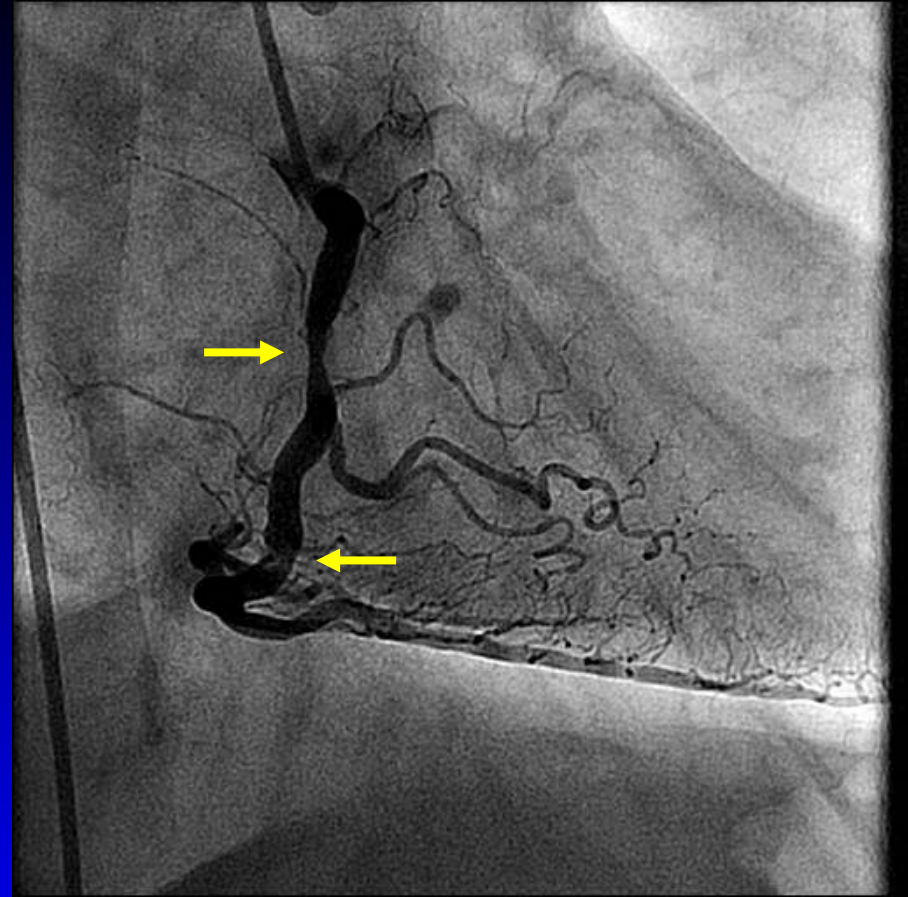
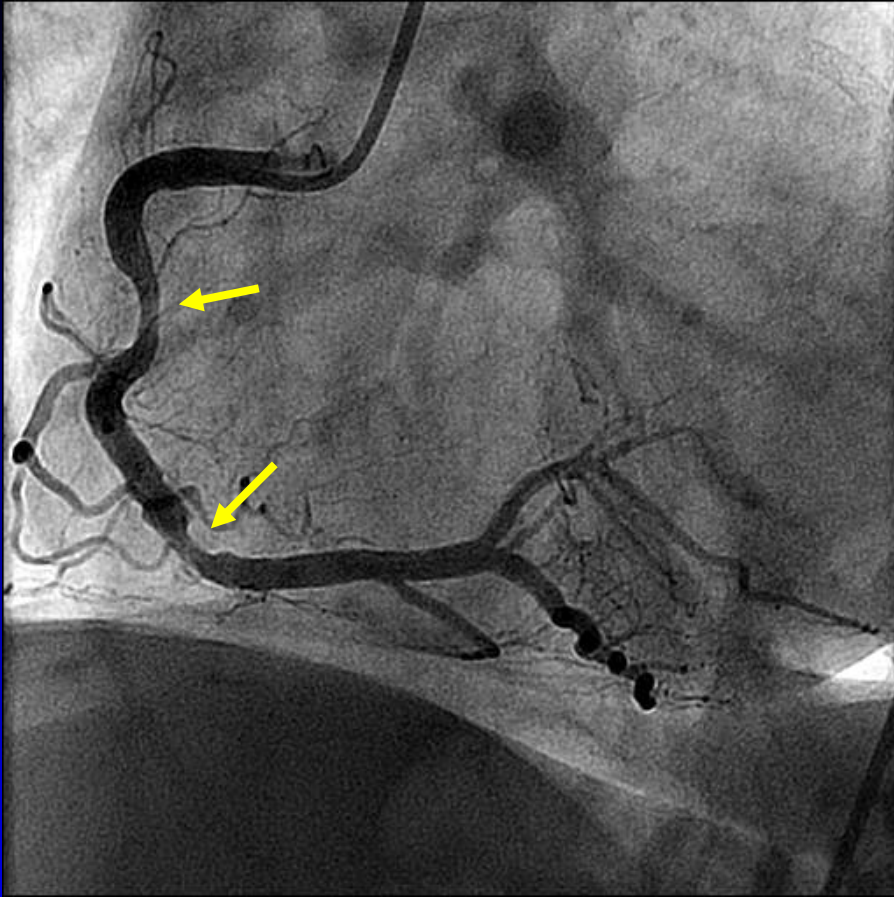
- 72-year-old male, stable angina class 3
- small non-STEMI 3 weeks earlier,
no diagnostic Δ -ECG
- residual angina class 2-3
- positive exercise stress test

————→ **Coronary angiography**



LCA

FAME STUDY patient # 1249
June 25th, 2007



RCA

FAME STUDY patient # 1249
June 25th, 2007

A rather common patient in our cath lab today.....

- 72-year-old male, stable angina class 3
- small non-STEMI 3 weeks earlier, no diagnostic Δ -ECG
- residual angina class 2-3
- positive exercise stress test

————→ **Coronary angiography**

- 50% LAD artery
- 50% Intermediate branch
- 90% LCX artery
- 70 % RCA proximal
- 50% RCA mid

A rather common patient in our cath lab today.....

BUT HOW TO PROCEED.....???

It is not the question ***IF*** stenting is indicated,
but ***WHERE*** and ***HOW MANY***

Several scenario's

- If you are a very practical dedicated interventionalist:
 - *“stent the LCX and see what happens afterwards”*
- If you are a more aggressive interventionalist and believe that every lesion should be treated:
 - *“nice lesions to fix, let's place 3 or 4 stents”*
 - (expensive, maybe unnecessary or even increasing risk, but neither the doctor, nor the patient will ever know)*
- If you are strictly following guidelines (and not too familiar with FFR) :
 - *“let's do a MIBI-SPECT first”*
 - (expensive, time consuming, not very practical)*

Which lesions should be stented ?

IMPORTANT ISSUE TO KEEP IN MIND

In patients with coronary artery disease, the most important factor with respect to *both*

- *functional class (symptoms)*
- *and prognosis (outcome)*

Is the *presence and extent of inducible ischemia*

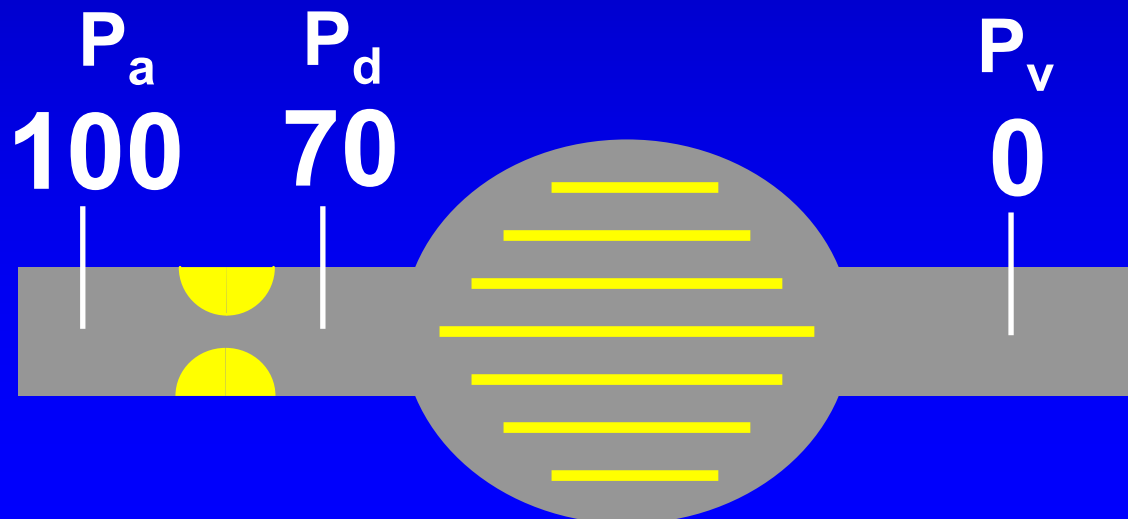
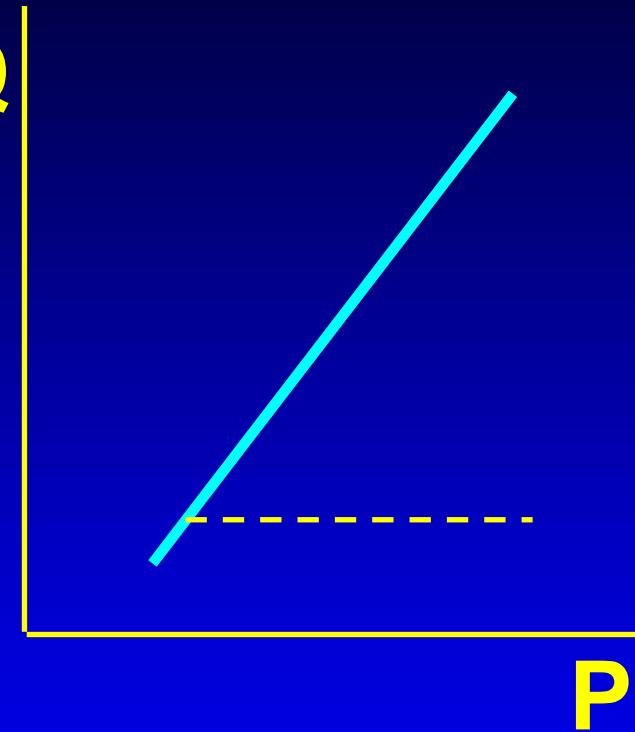
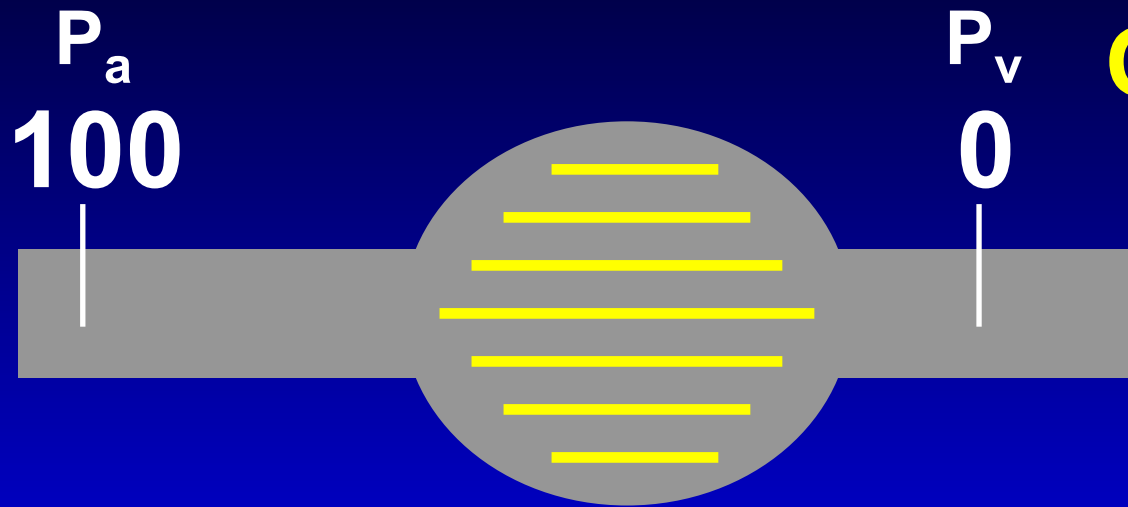
EVIDENCE-BASED MEDICINE:

- PCI of “culprit” lesions (**associated with reversible ischemia**) makes sense and improves symptoms and sometimes also outcome
- PCI of non-ischemic lesions has no benefit, is not superior to medical treatment, potentially harmful, and unnecessary expensive
- FFR is the **gold standard** for assessment of ischemia in the catheterization lab

→ **Let's measure FFR**

DEFER study; JACC 2007
ACIP study; Circulation 1997
Courage trial; NEJM 2007

During Maximal Vasodilatation



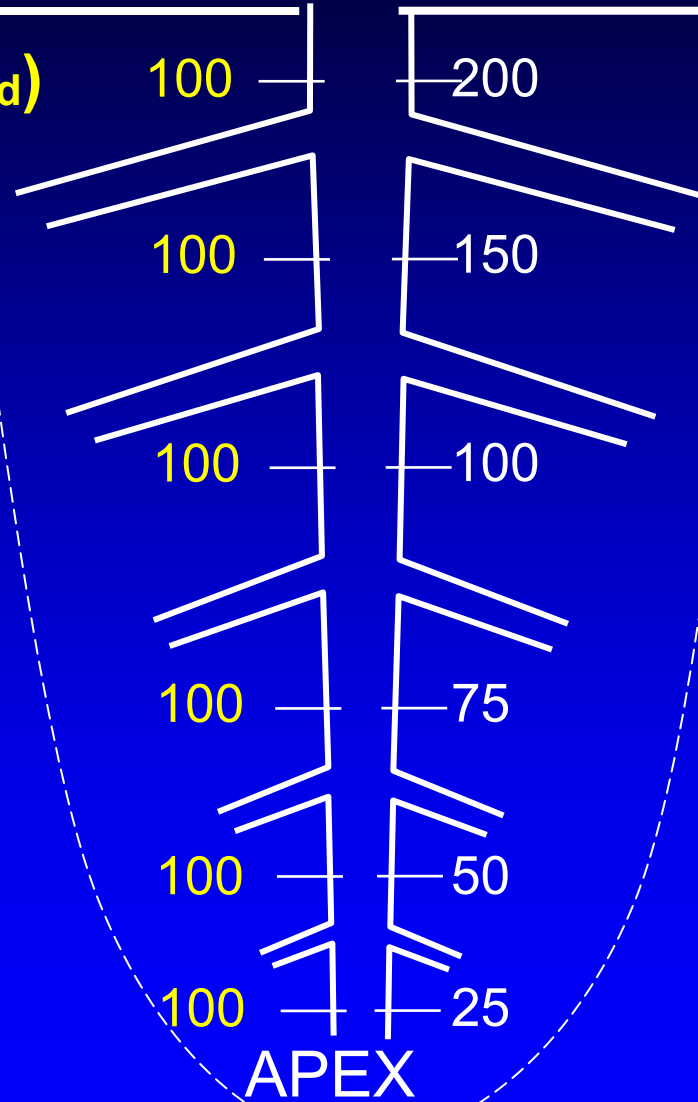
$$\text{FFR}_{\text{myo}} = \frac{P_d}{P_a} = 0.70$$

AORTA
100 mmHg

IVUS-CSA

pressure (P_d)
(mm Hg)

flow (Q)
(ml/min)



9 mm²

7 mm²

5 mm²

3 mm²

Threshold value of FFR to detect significant stenosis

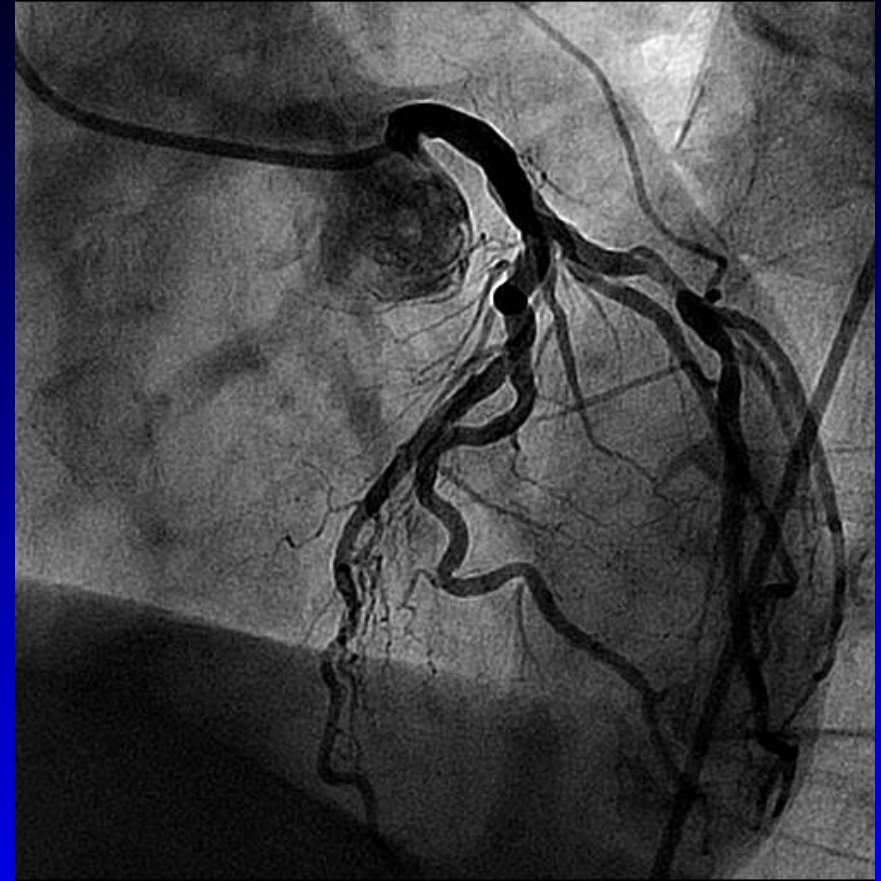
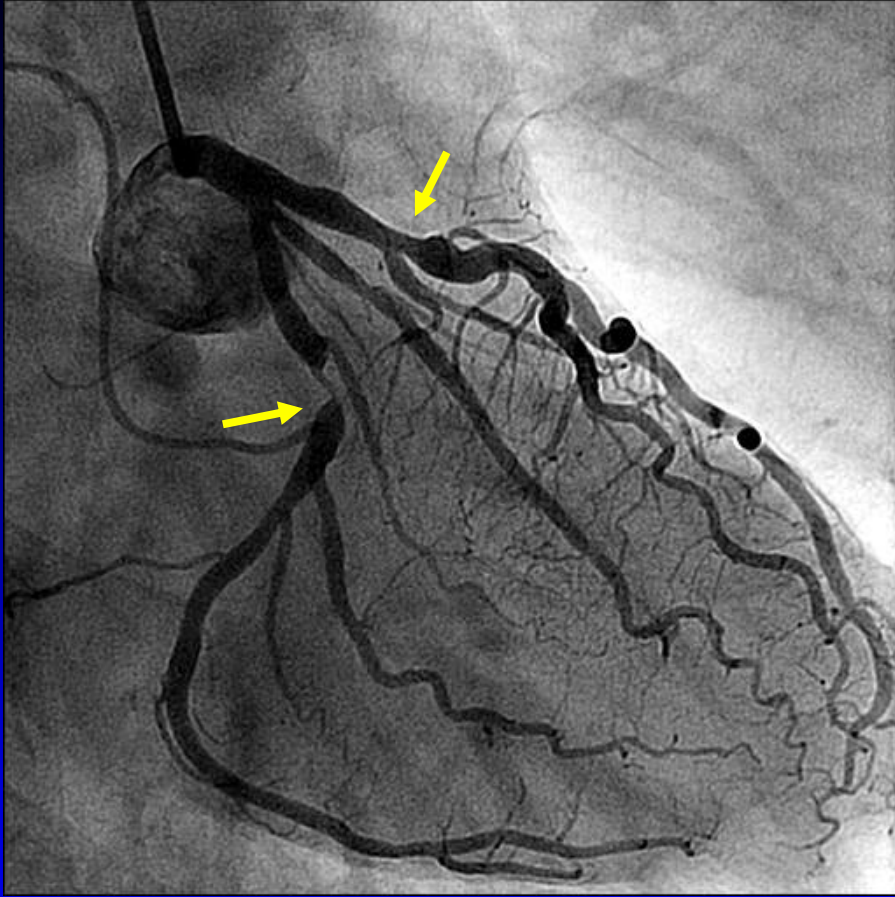


FFR is the **only** functional index which has ever been validated versus a **true gold standard**.
(Prospective multi-testing Bayesian methodology)

ALL studies ever performed in a wide variety of clinical & angiographic conditions, found threshold between 0.75 and 0.80

Sensitivity : 90%

Specificity : 100%



LCA RAO 30/20 view

ARCHIVE CUSTOM

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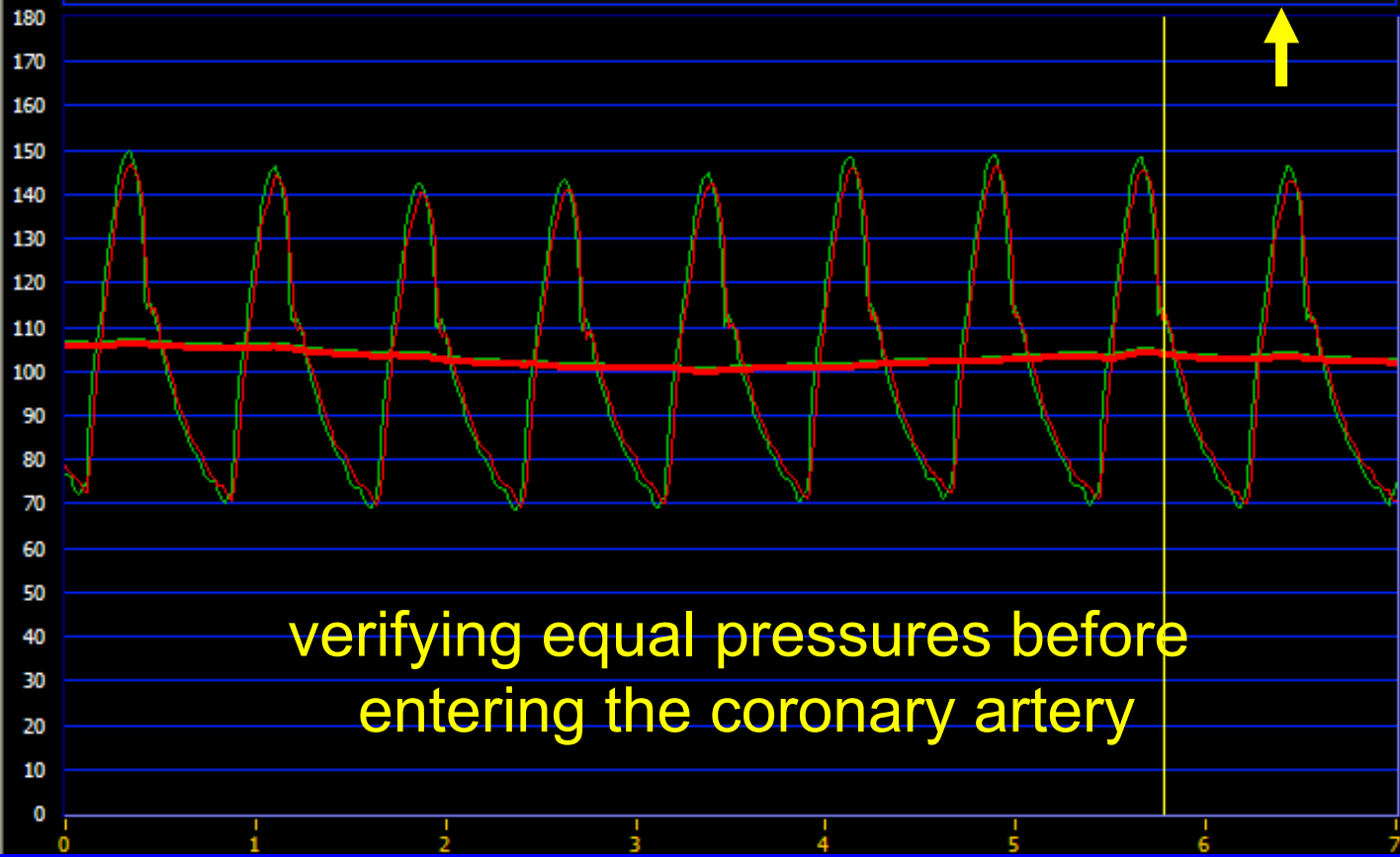
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SmDo dd 280805	FAME1249	2007-06-25	12:54:59				FFR	71Kb
Simons	FAME1249	2007-06-25	12:50:40				FFR	7Kb
salmans	FAME1249	2007-06-25	12:49:42				FFR	353Kb



PRINT EDIT RENAME EXPORT ERASE SETUP

FAME1249 2007-06-25 12:50:40



104
Pa mean

104
Pd mean

1,00
FFR

5,8
CURSOR



RESET

verifying equal pressures before entering the coronary artery



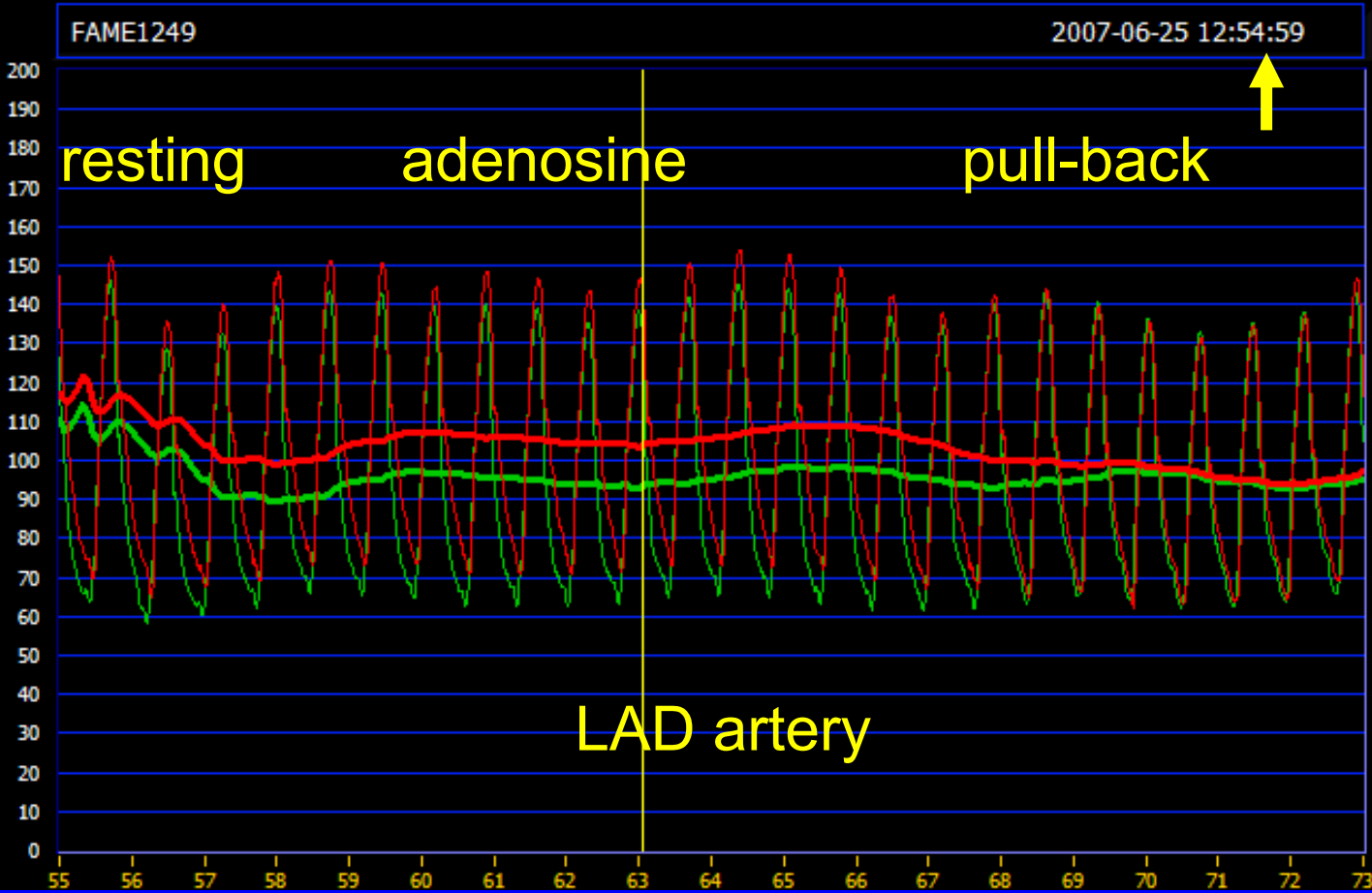
PW in LAD artery



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FAME1249	2007-06-25	12:50:40				FFR	7Kb
FAME1249	2007-06-25	12:49:42				FFR	353Kb

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104
Pa mean

93
Pd mean

0,90
FFR

63,1
CURSOR

+ [magnifying glass] [crosshair]
RESET

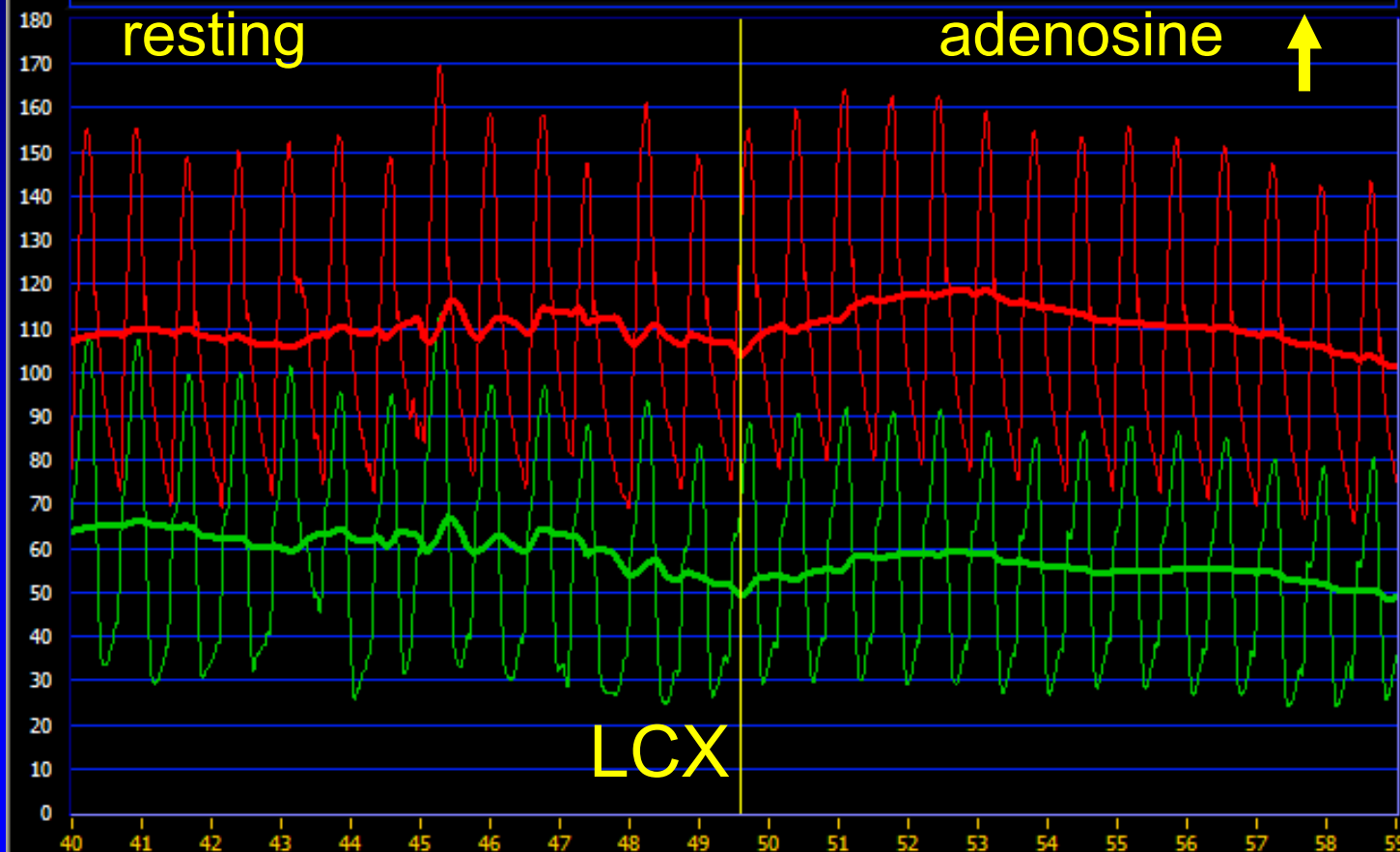


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FAME1249	2007-06-25	12:58:31				FFR	58Kb
FAME1249	2007-06-25	12:56:47				FFR	6Kb

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104
Pa mean

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Pd mean

0,48
FFR

49,6
CURSOR

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RESET



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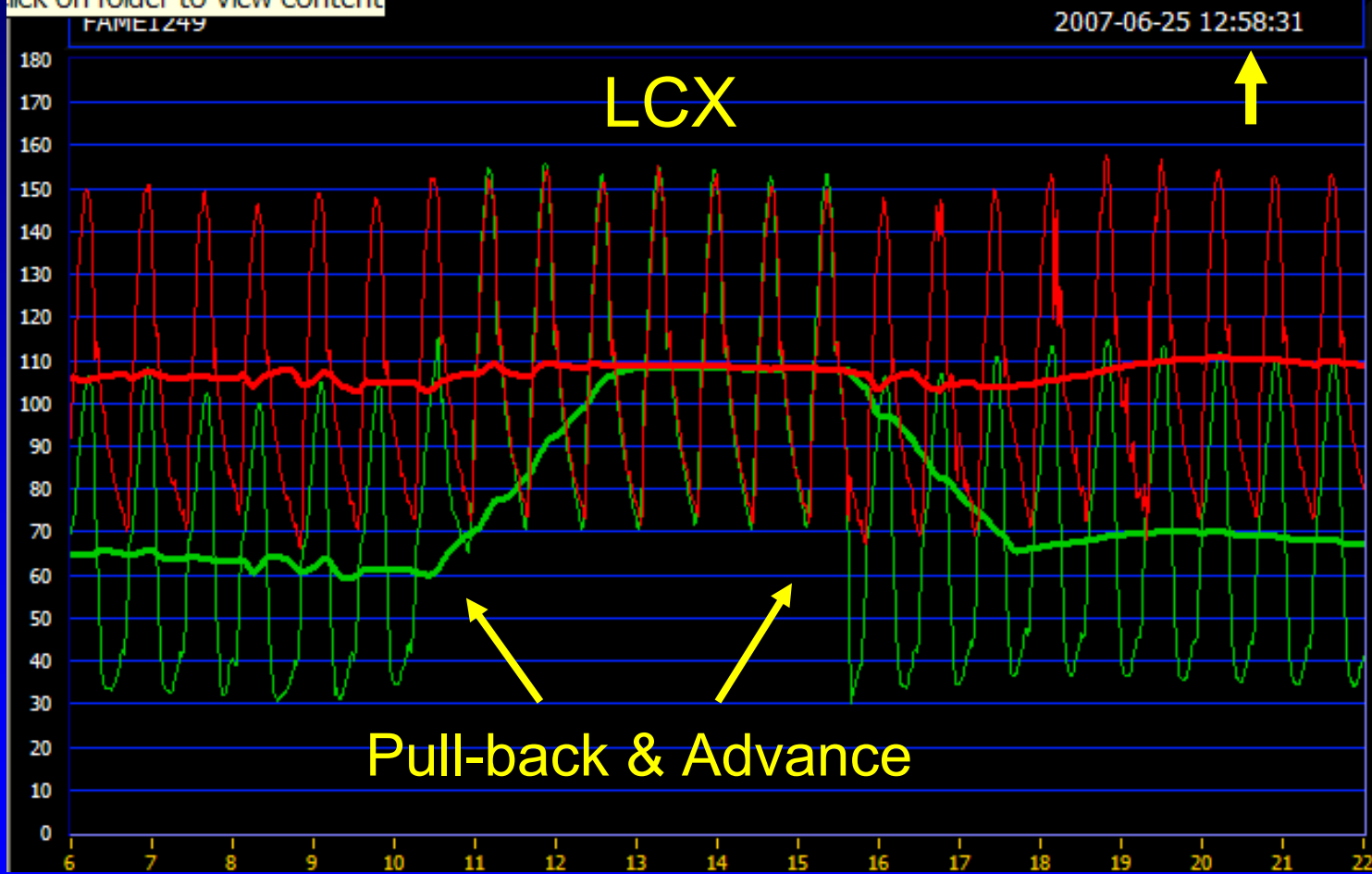
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FAME1249	2007-06-25	13:05:11				FFR	95Kb
FAME1249	2007-06-25	12:58:31				FFR	58Kb
FAME1249	2007-06-25	12:56:47				FFR	6Kb

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click on folder to view content



104
Pa mean

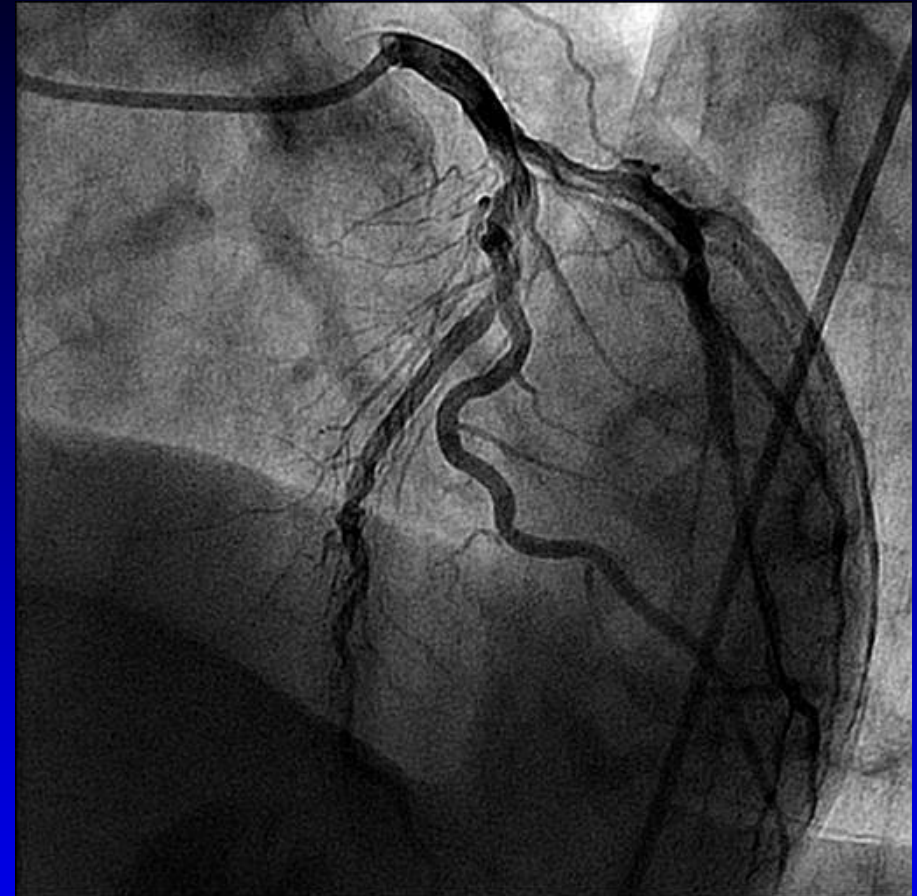
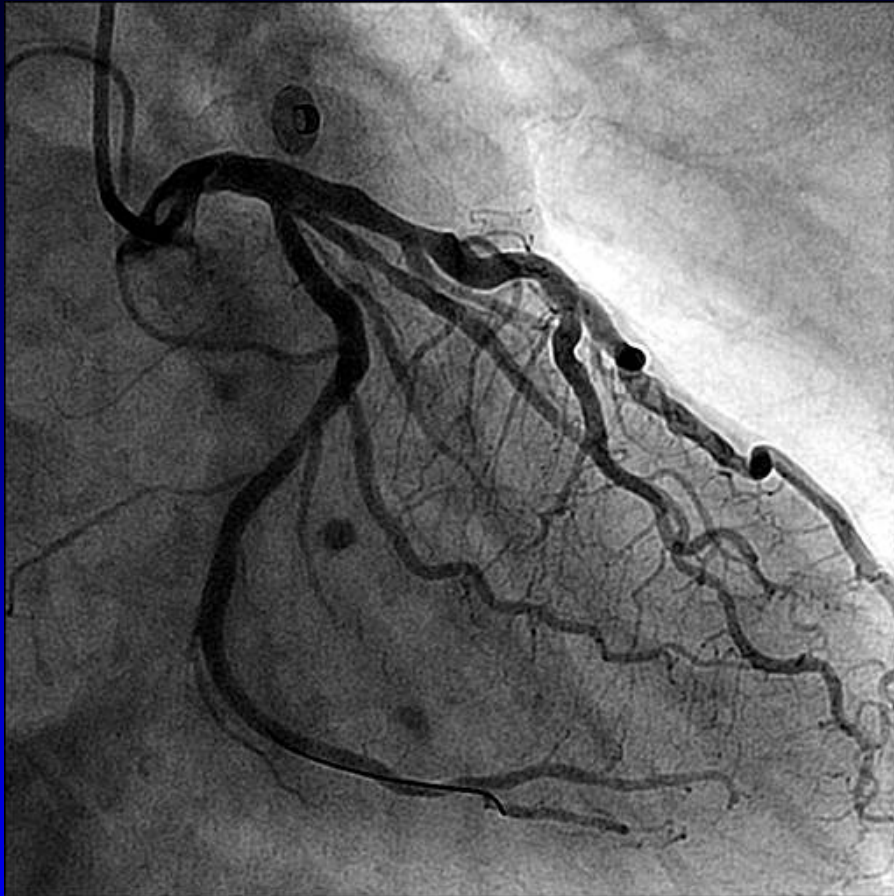
50
Pd mean

0,48
FFR

49,6
CURSOR



RESET



LCX after stenting (Endeavour 3.5 x 12)



ARCHIVE CUSTOM

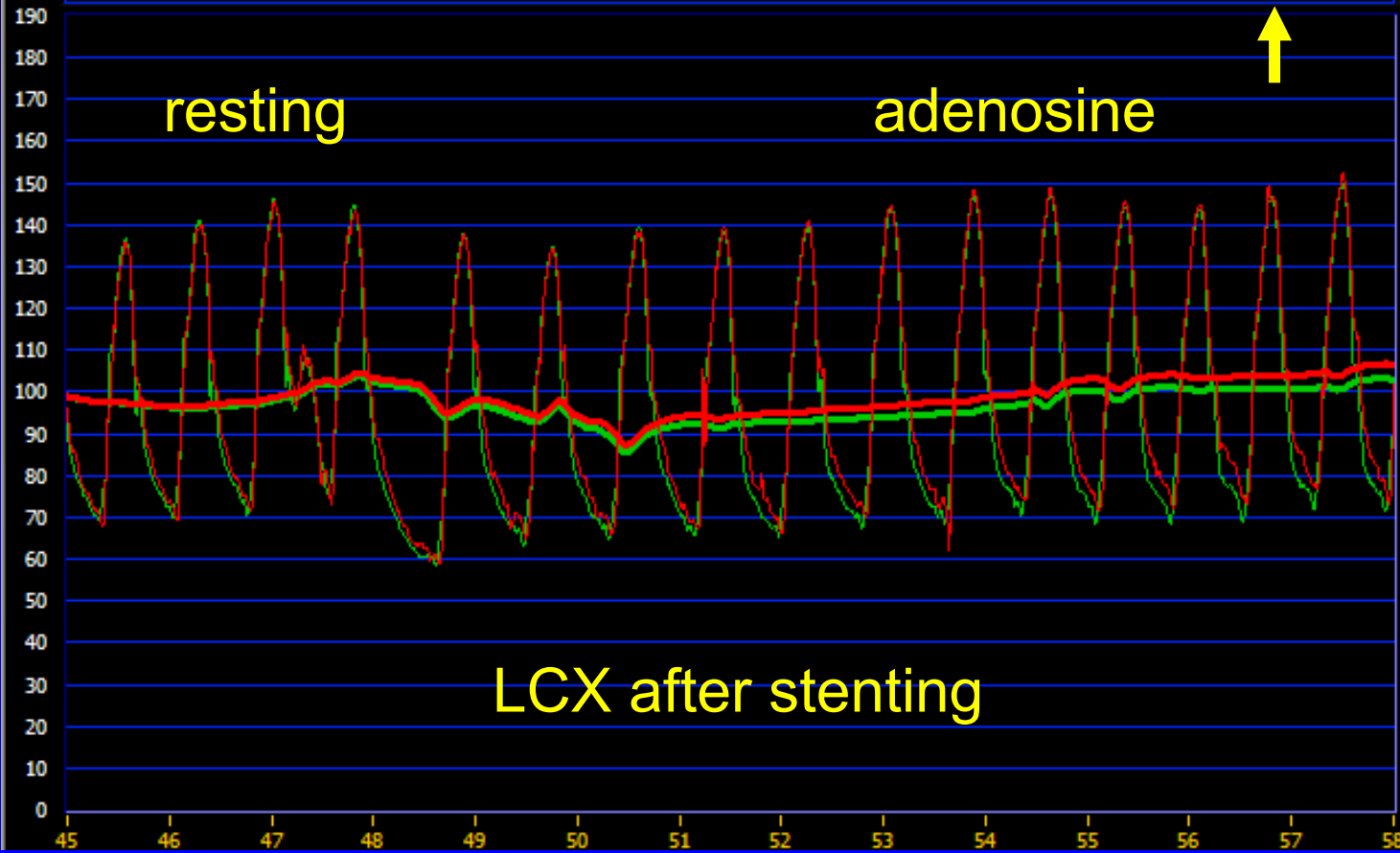
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- SmDo280805
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- Simons
- salmans
- RULO

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FAME1249	2007-06-25	13:05:11				FFR	95Kb
FAME1249	2007-06-25	12:58:31				FFR	58Kb
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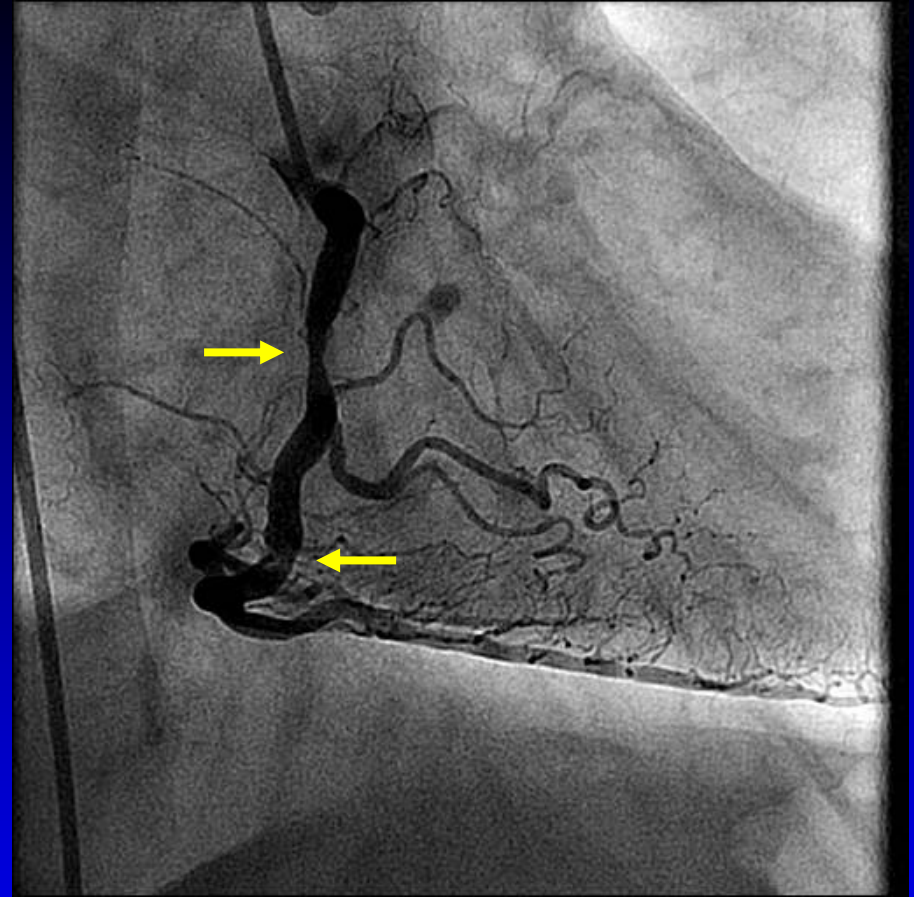
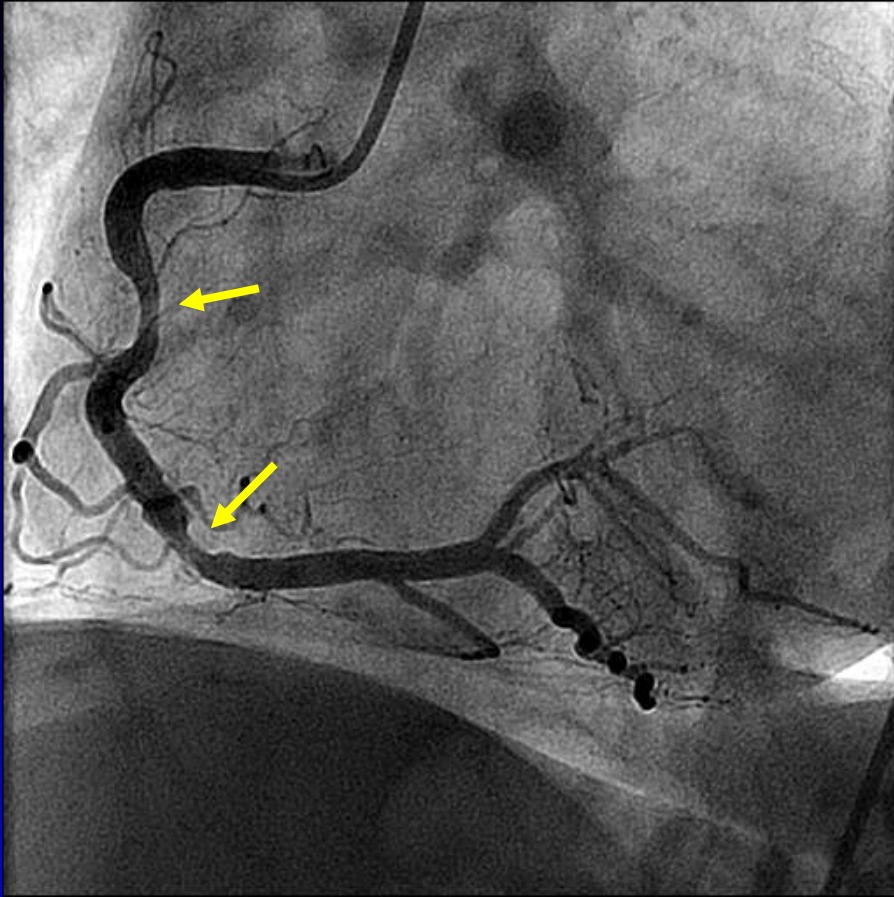


96
Pa mean
92
Pd mean
0,96
FFR

65,0
CURSOR



RESET



RCA

ARCHIVE CUSTOM

- FOLDER
- SmDo280805
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- Simons
- salmans
- RULO

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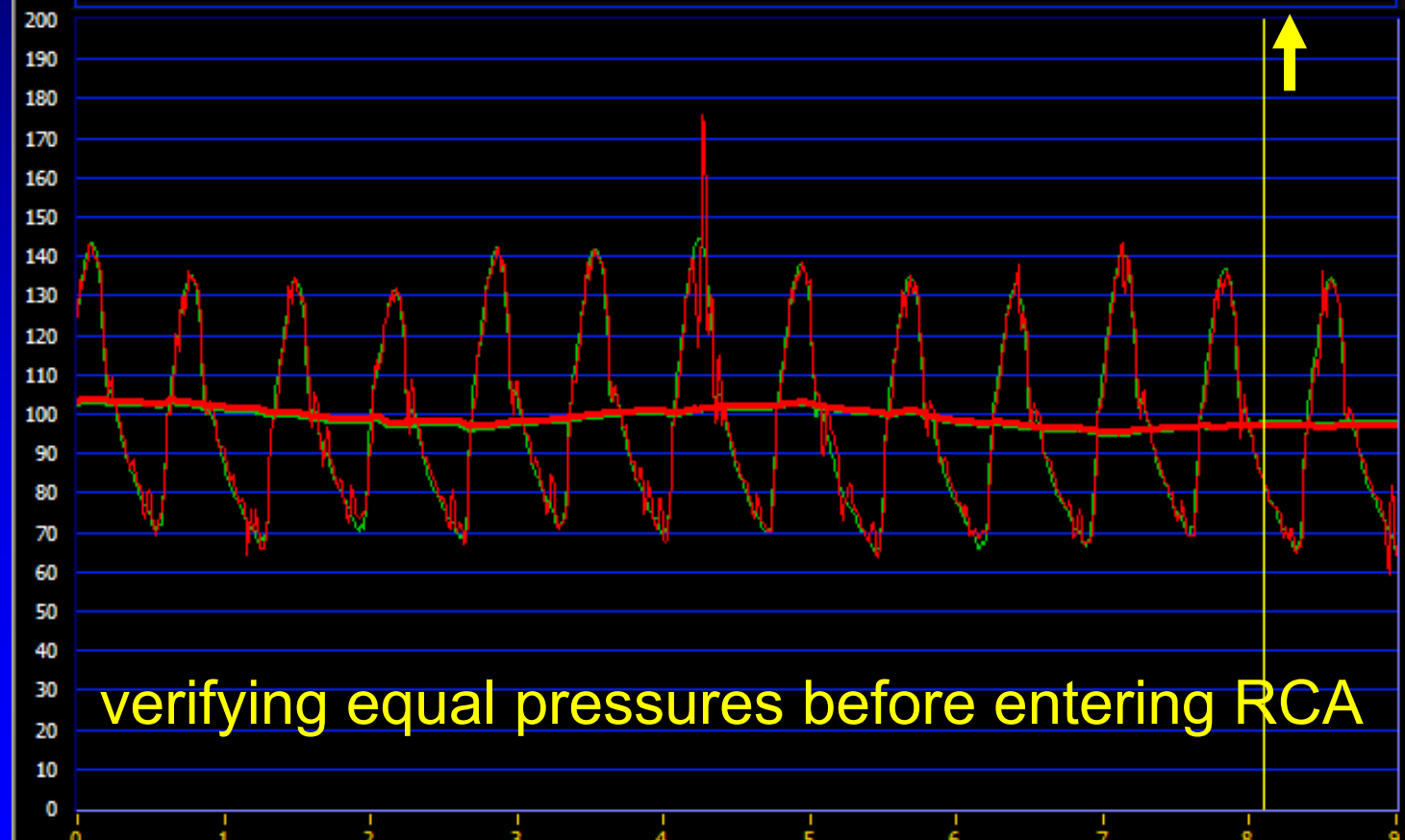
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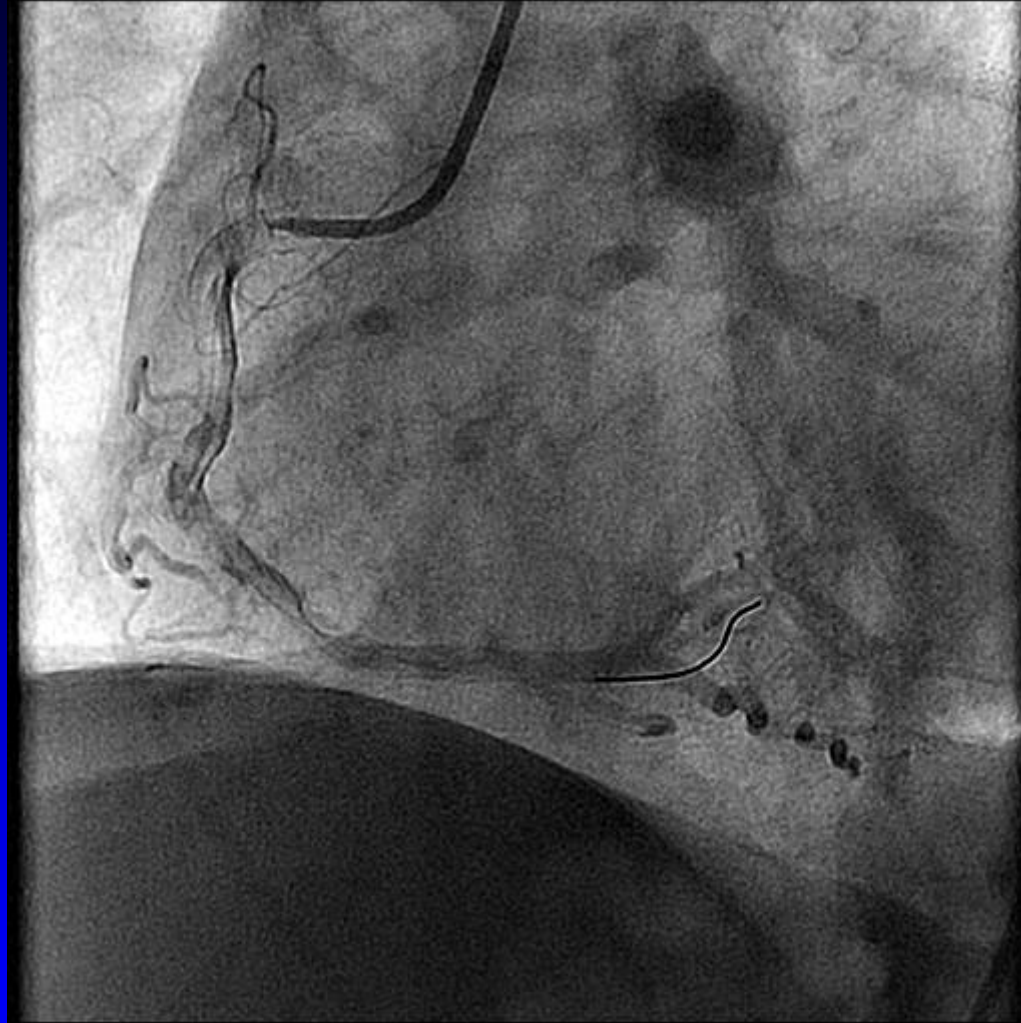


97
Pa mean
98
Pd mean
1,00
FFR

8,1
CURSOR

verifying equal pressures before entering RCA

+ [magnifying glass] [crosshair]
RESET



Pressure Wire in RCA

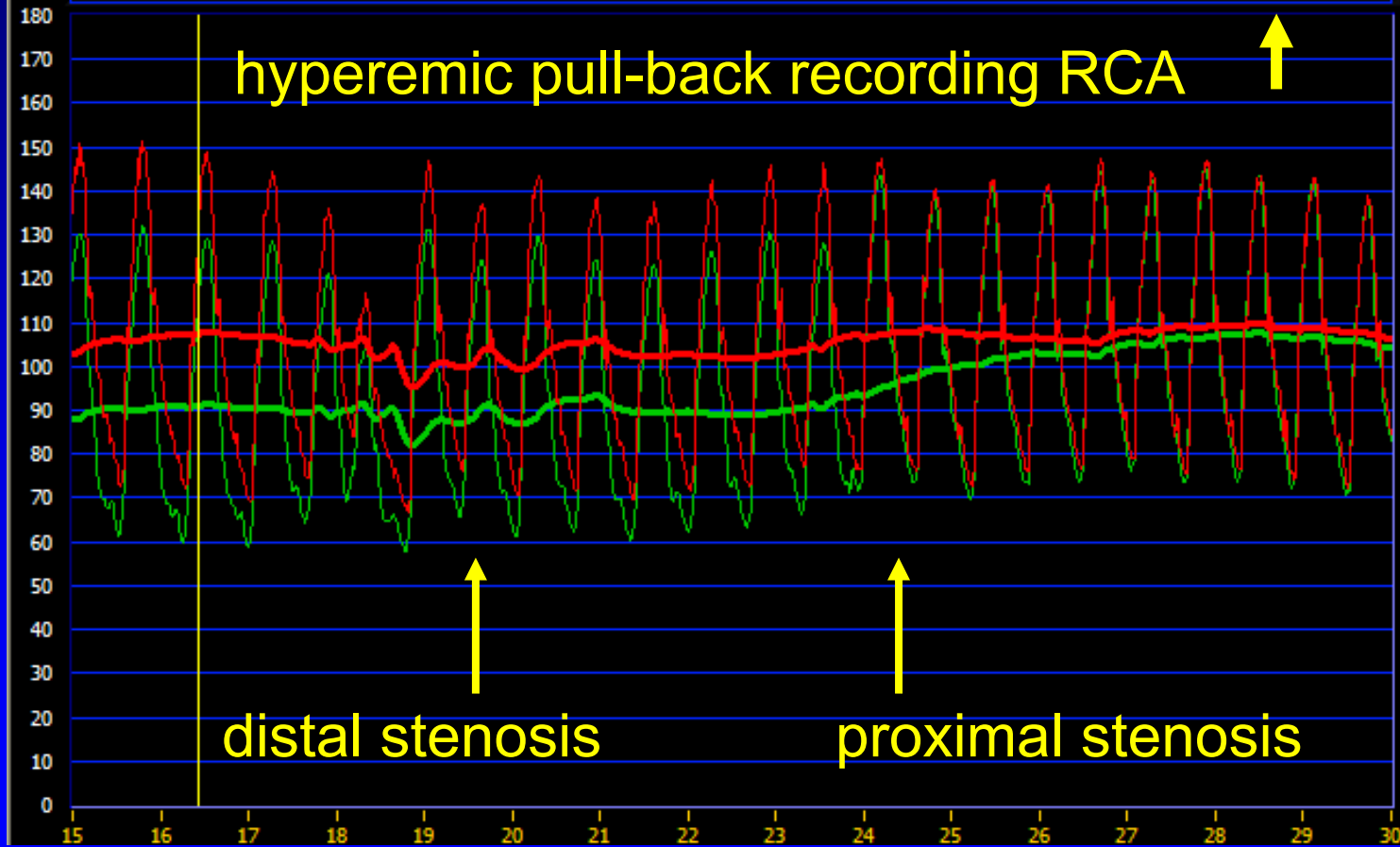


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RULO

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PRINT EDIT RENAME EXPORT ERASE SETUP

FAME1249 2007-06-25 13:17:30



108
Pa mean

91
Pd mean

0,85
FFR

16,4
CURSOR



LESSONS FROM THIS PATIENT:

- only 1 stent necessary ; cost-savings of *Euro 3300,-*
- if treatment was based upon angio and performed by “more aggressive” interventionalist (or had been randomized to angio-guided arm of FAME study), at least 3 and maybe 4 or 5 stents would have been placed, which would have increased risk and would have been unnecessary expensive

ANGIO-GUIDED MULTIVESSEL PCI

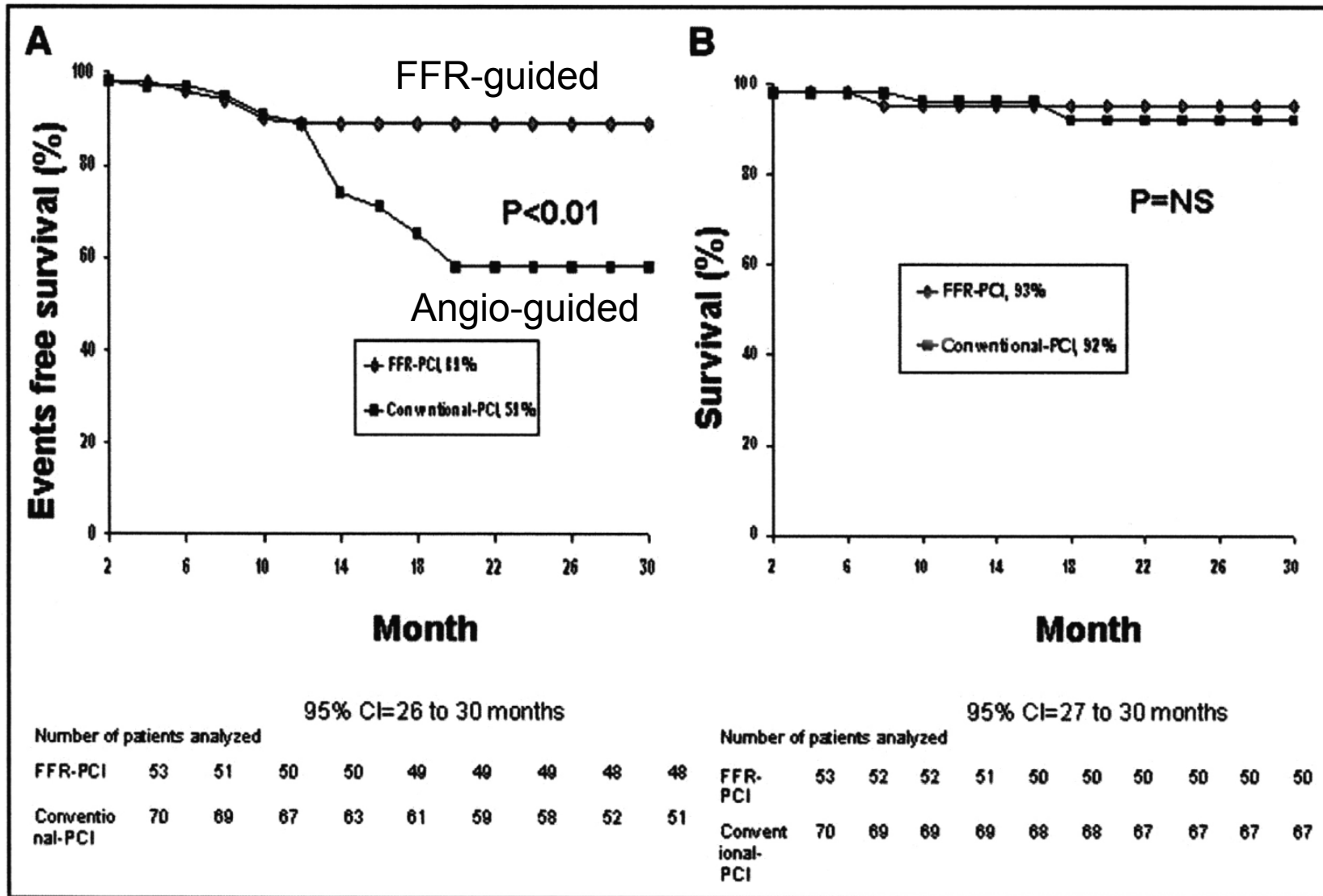
versus

FFR-GUIDED (= ischemia-guided) MULTIVESSEL PCI

What is better?

FAME study has to answer the question decisively

(FFR-guided ~ better, cheaper, quicker)



**FFR-guided vs. Angio-guided multivessel PCI (125 patients)
(event-free survival after 30 months)**

Leesar et al, JACC 2005



FAME STUDY

Functional vs Angiographic Multivessel Evaluation

→ *Prospective and randomized multicenter trial in 1000 patients undergoing multivessel PCI*

angio-guided: all lesions > 50% DES-stented

FFR-guided: DES-stents in lesions with FFR < 0.80

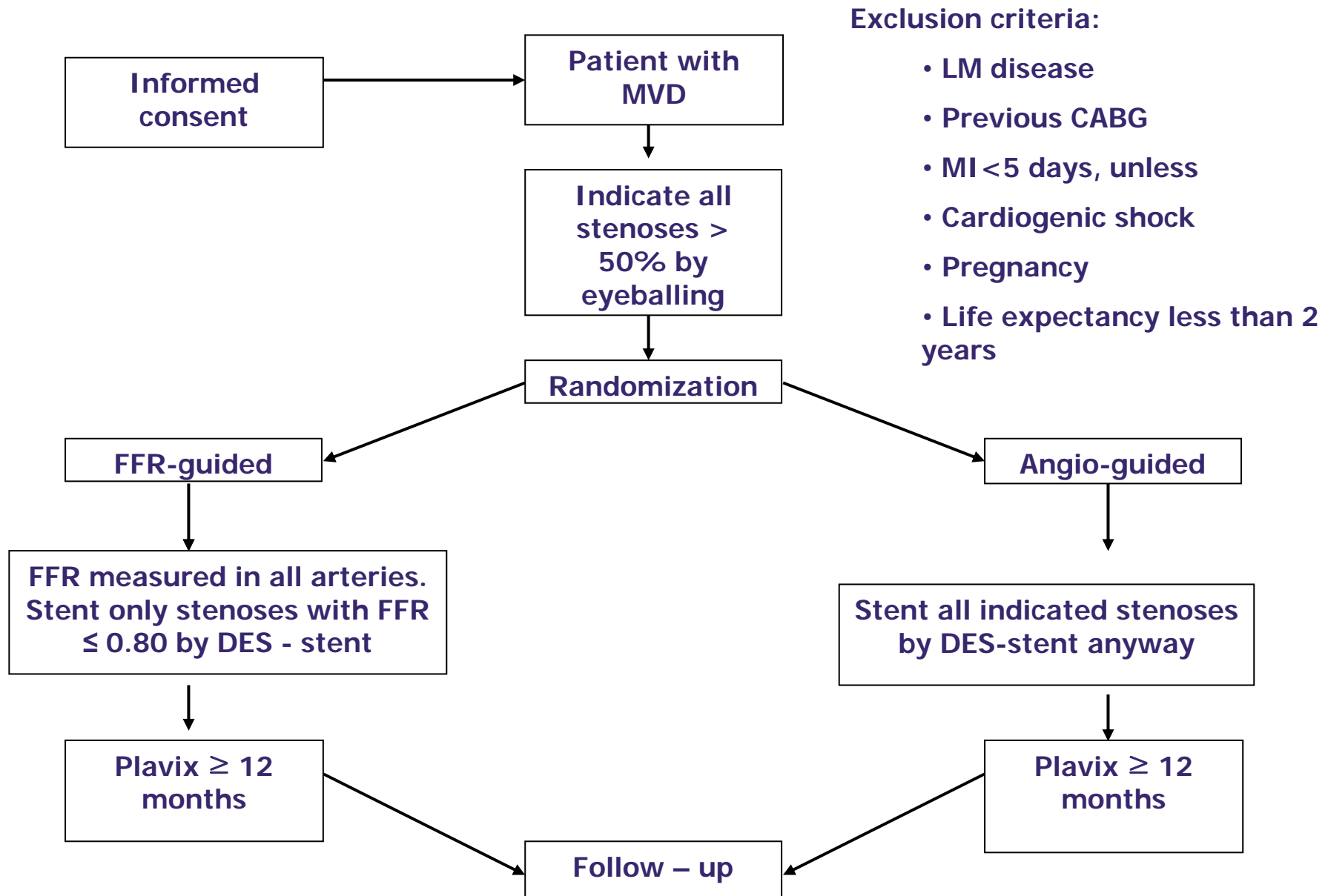
Endpoints: *outcome, symptoms, cost-efficiency*

20 centers in USA and Europe

Inclusion has been completed now

Follow-up completed at TCT 2008

Flow Chart





FAME STUDY

Functional vs Angiographic Multivessel Evaluation

- *Prospective and randomized multicenter trial in 1000 patients undergoing multivessel PCI*
- *Hypothesis: FFR-guided multivessel PCI is superior to angio-guided multivessel PCI*

FOLLOW-UP WILL BE COMPLETED ON SEPTEMBER 27th

COMPLETE RESULTS AT TCT 2008

FAME: Preliminary baseline data – Europe (1)

~ **60% of all screened patients were included !!!**

	<i>FFR-group (n=368)</i>	<i>Angio-group (n=352)</i>
<i>Age (yrs)</i>	66	64
<i>Male</i>	74%	70%
<i>CCS Class</i>	2,4	2,4
<i>Diabetes</i>	20%	23%
<i>LV ejection fraction</i>	57%	58%
<i>Ischemia detected</i>	40%	42%

FAME: Preliminary baseline data - Europe

	<i>FFR-group (n=368)</i>	<i>Angio-group (n=352)</i>
<i>Acute chest pain with EKGΔ</i>	14%	19%
<i>Acute chest pain no EKGΔ</i>	12%	12%
<i>Previous PCI</i>	27%	24%
<i>Previous MI</i>	35%	35%
<i>Lesions indicated</i>	2,8	2,7
<i>Stents per patient</i>	1,9	2,9

FAME: Preliminary baseline data - Europe

	<i>FFR-group (n=368)</i>	<i>Angio-group (n=352)</i>	
<i>QCA: Stenosis %</i>	58,8	56,3	
<i>QCA: Ref. diameter (mm)</i>	2,46	2,41	
<i>Procedure time (min)</i>	67	66	NS
<i>Contrast agent used (ml)</i>	263	293	P<0.01

SUMMARY

Coronary pressure measurement is a helpful, easy, and relatively cheap tool in multivessel disease to:

- *select the “culprit” spots and segments out of the many abnormalities which are often present*
- *discriminate if PCI of a particular spot or segment makes sense*
- *evaluate the result of stenting with prognostic implications*
- *and to avoid additional interventions which increase risk without benefit for the patient*

Complete vs Incomplete Revascularization:

What was wrong the wrong concept in the (mostly retrospective) studies performed so far ?!

e.g. ARTS-studies:

30% incomplete revascularization, but....

“arbitrary” choice of no revascularization, or even worse: no revascularization because of technical difficulties → *considerable number of the non-revascularized lesions were ischemic lesions*

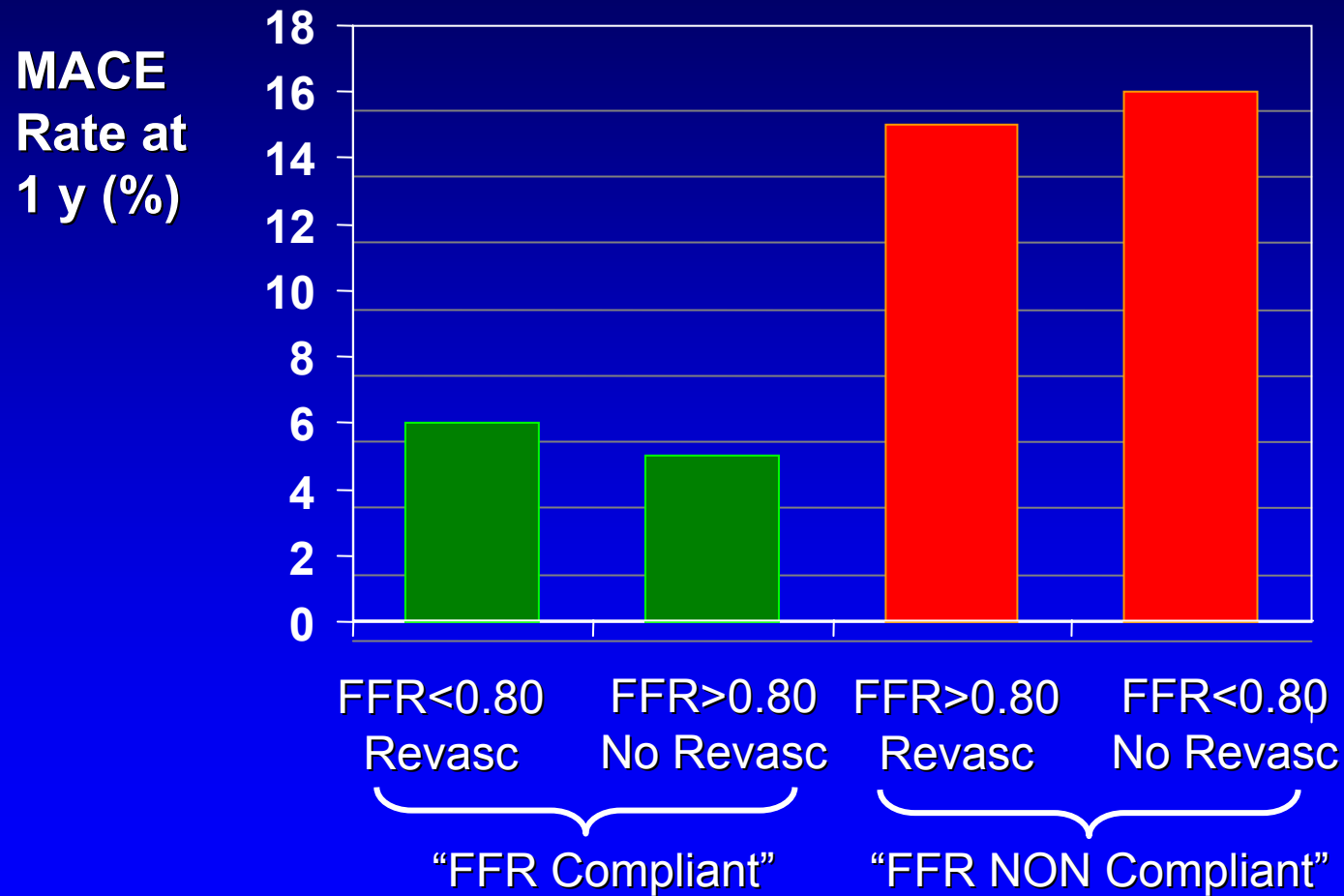
Whereas among the treated lesions, *quite a bit of non-ischemic lesions must have been stented*

Does routine measurement of FFR influence our strategy in MVD ??

- Study by Dr F. Mendes, Cabo Frio, Brasil
- all consecutive patients with MVD during 3 months (september – december 2004): 195 patients
- revascularization strategy based upon angio assessed by 3 operators
- FFR measured in all stenoses and used for final decision making
- change in strategy in 34% of lesions and 45 % of patients

Clinical Outcome According to the Compliance with FFR

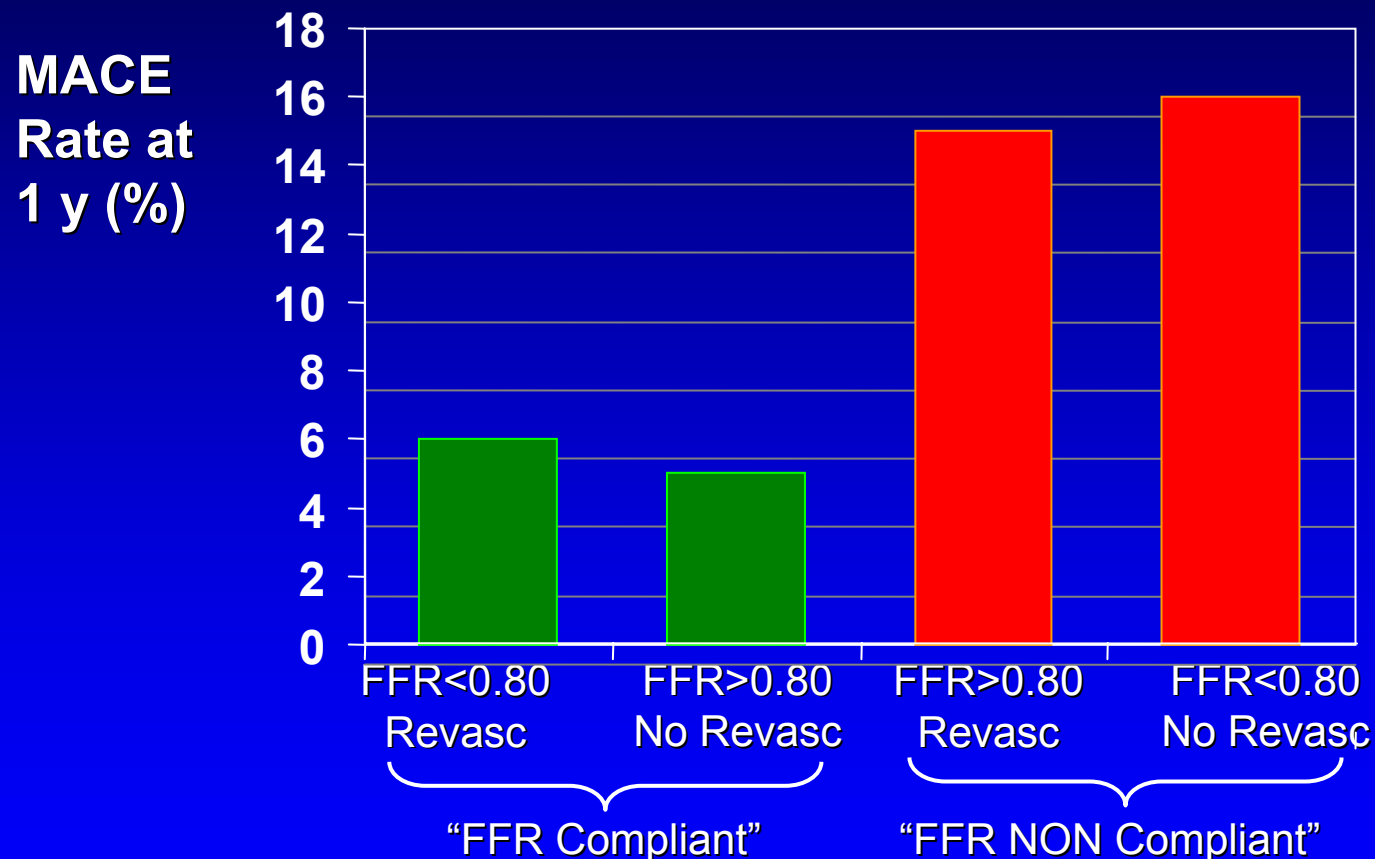
- 409 patients + FFR measurements
- Clinical outcome at one year



Clinical Outcome According to the Compliance with FFR

Legalery et al Eur Heart J 2005

- 409 patients + FFR measurements
- Clinical outcome at one year



FFR < 0.80 : PCI results in **3 x lower** event rate
FFR > 0.80 : PCI results in **3 x higher** event rate

COURAGE TRIAL: SOME CRITICAL NOTES

- How representative is the Courage Trial?
 → *only 6% of eligible patients were truly included*
- **Two-way negative bias for PCI group:**
 1. *In PCI group, selection of lesions to be stented was on the basis of angiography → at least 30% unnecessary stents, which unfavourably affects prognosis*
 2. *In PCI group, also a number of ischemic lesions must have been missed, which also unfavourably affects prognosis (ACIP-trial, Circulation 1996)*

In terms of functional class the PCI group did better than the medical group, ***particularly in patients with proven ischemia !***