

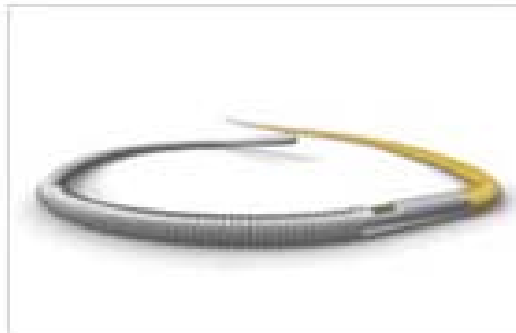
1. **Unprotected LM** intervention will become class 1 indication.
2. **Multi-vessel disease**
 - low SYNTAX score (<22) will have as good of an out come as CABG with DES stenting.
 - high SYNTAX score are better treated with surgery.

Revascularizing lesions **only if it is causing ischemia** is very important. (Based on the **Courage sub-study** and **FAME**). In multi-vessel disease when any of the lesions is intermediate, it is wise to evaluate the lesion with **FFR** before committing to a stent or a graft.

3. **Percutaneous AVR** has improved a great deal and may become main stay of treatment with in 10 years for severe AS.
4. **PFO closure** for any indication is still a weak indication.
5. **STEMI PCI with DES** is safe enough to take the advantage of reduced TVR.
6. **Reducing bleeding in STEMI** patient (either by performing a radial procedure or using Bivalurudin) may improve mortality at one year significantly.

Multi-vessel elective PCI

heartwire



INTERVENTIONAL/SURGERY

FAME! FFR-guided PCI significantly reduces clinical events

TCT 4 COMMENTS - OCT 14, 2008 17:45 EDT

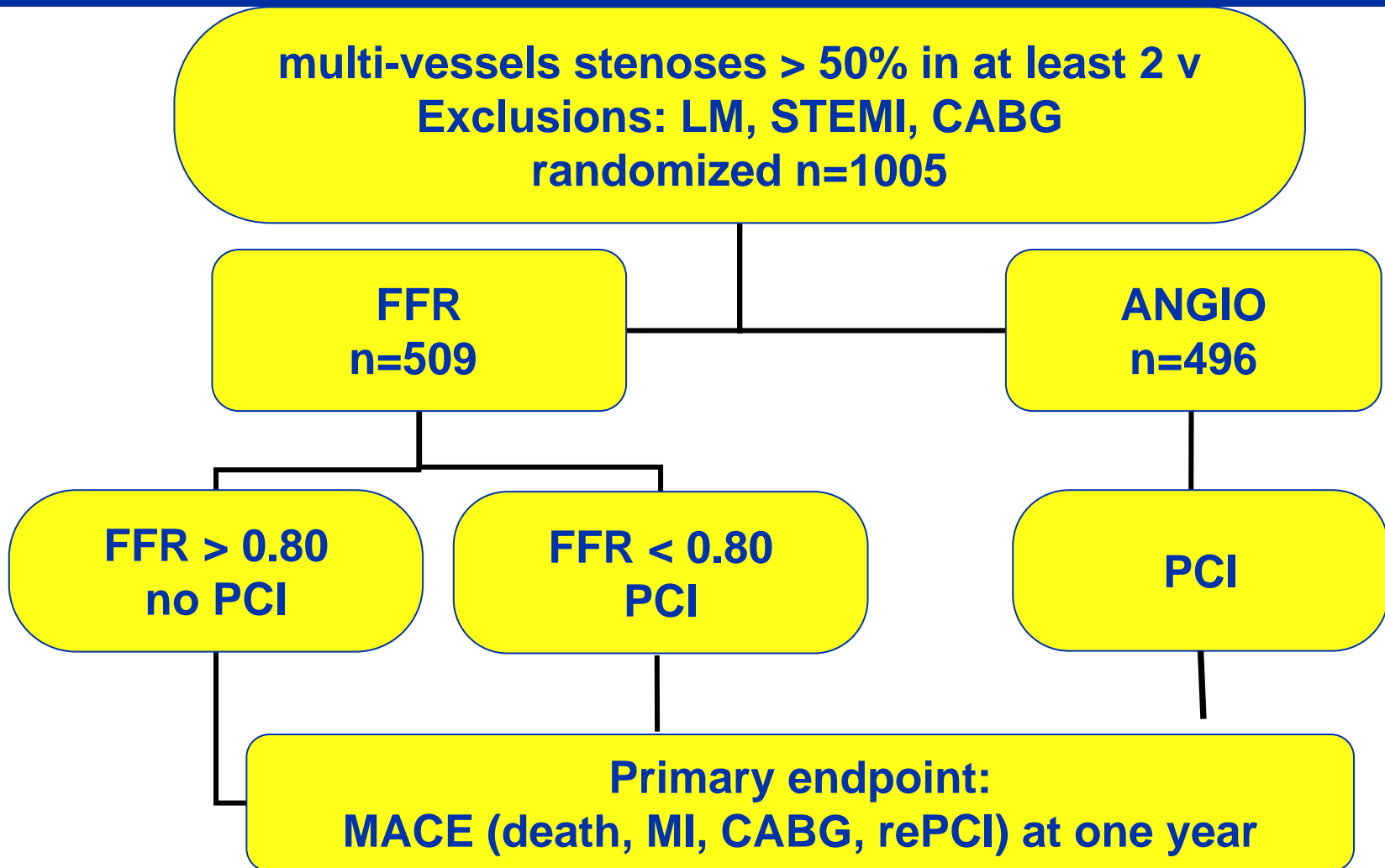
Investigators report that fractional flow reserve-guided PCI reduced the risk of death, MI, or repeat revascularization by 30% and death or MI by 35%, when compared with the current practice of using angiography to guide stenting decisions. (TCT 2008.)

FAME trial : FFR vs Angiography for Multivessel Evaluation

Pijls N. TCT 2008; October 14, 2008; Washington, DC.

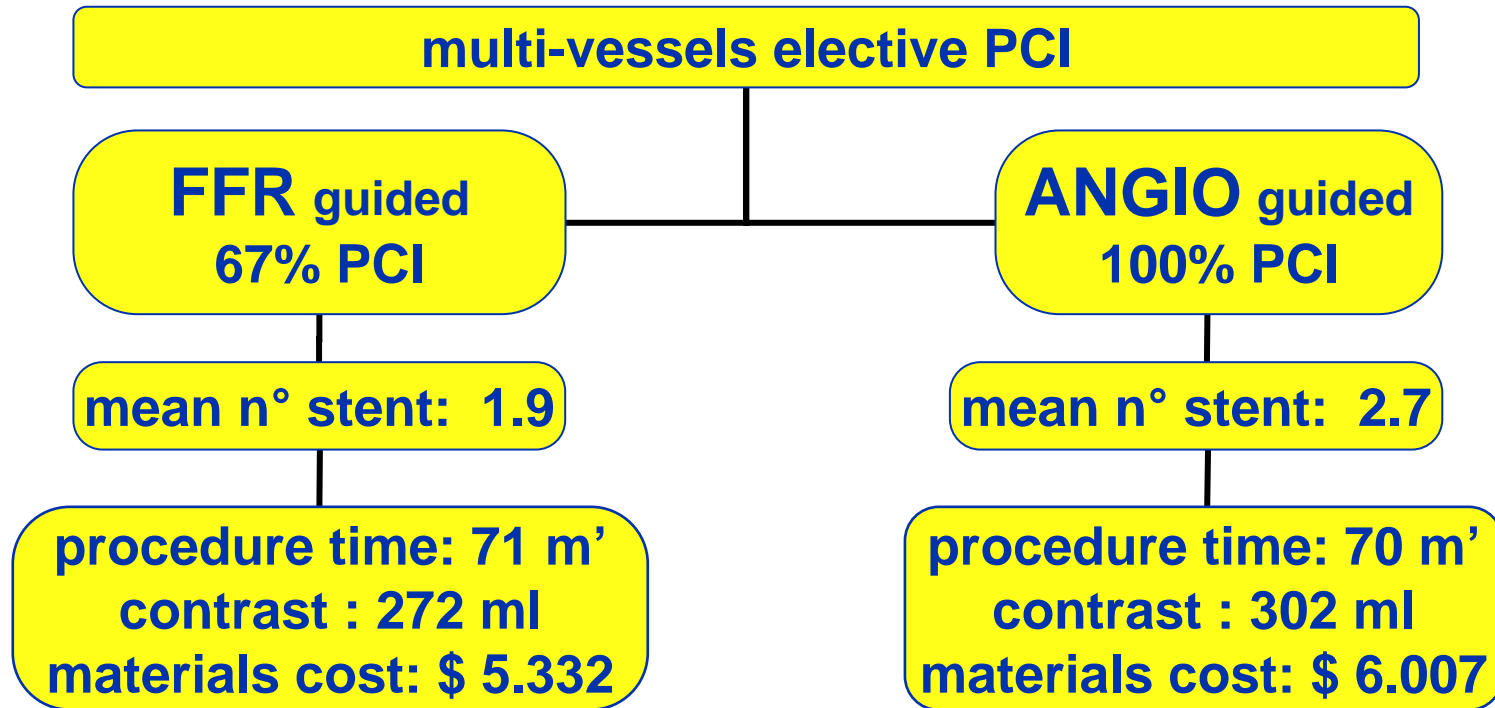
The FAME trial

multi-vessel elective PCI, FFR guided



The FAME trial

multi-vessel elective PCI, FFR guided



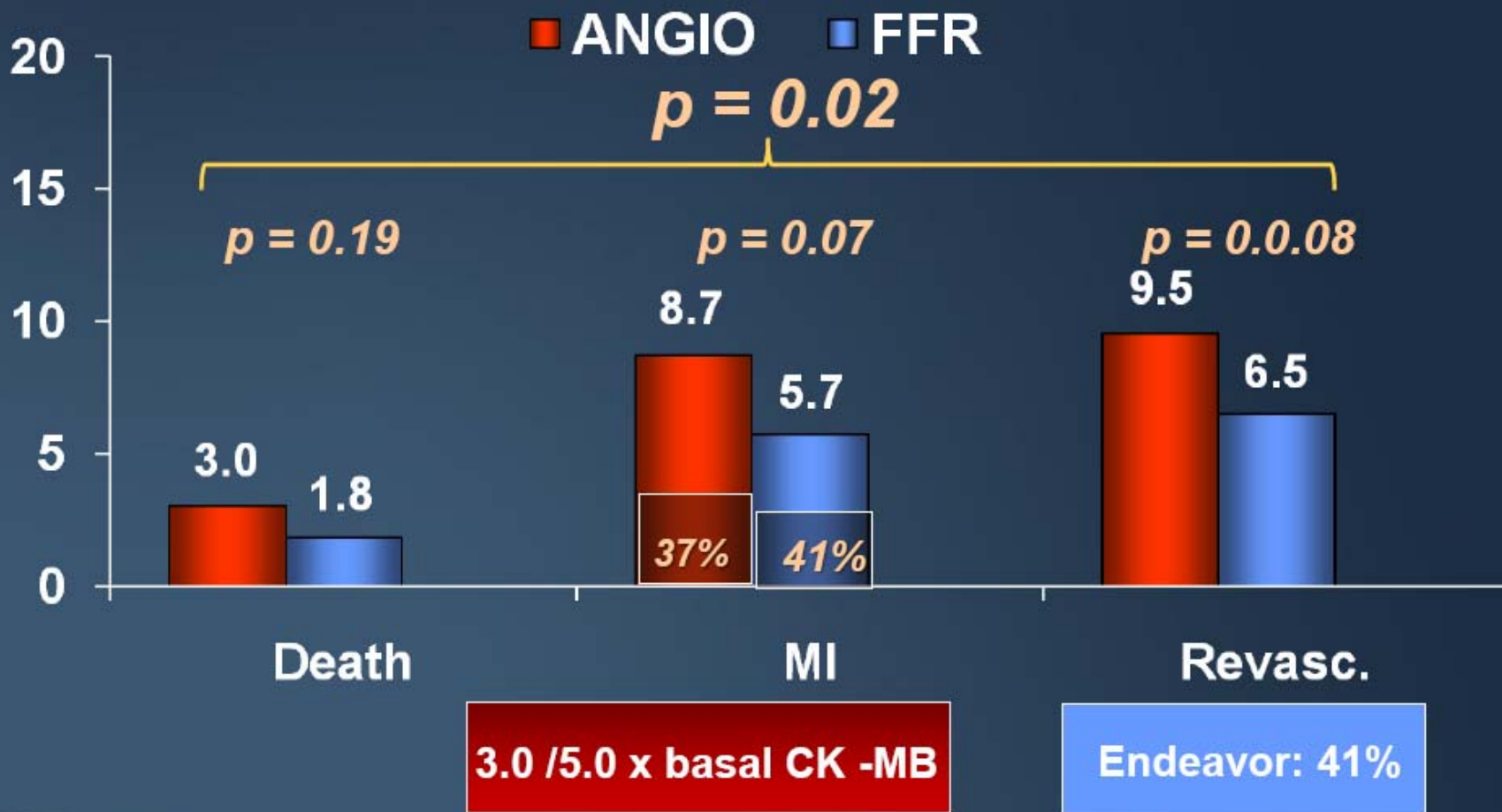
The FAME trial results

End point	Angiography guided PCI n=496 (%)	FFR guided PCI n=509 (%)	p
Death, MI, CABG, re PCI	18.4	13.2	0.02
Death	3.0	1.8	0.19
Death or MI	11.1	7.3	0.04
CABG - re PCI	9.5	6.5	0.08

Angina free and quality of life were similar between the two arms

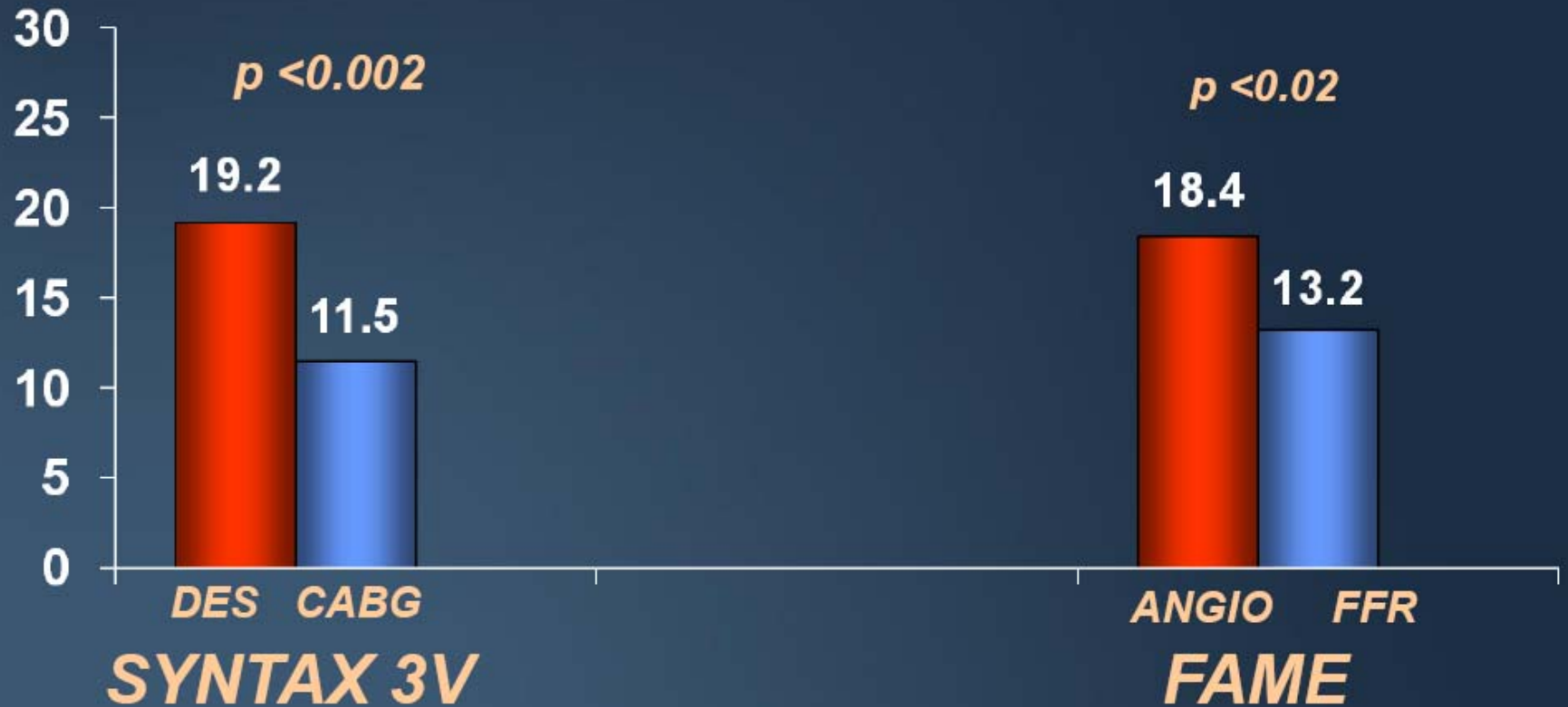
Individual Endpoints

1 Year Follow-Up



MACE 1 Year

1 Year Follow-Up



The FAME trial conclusions

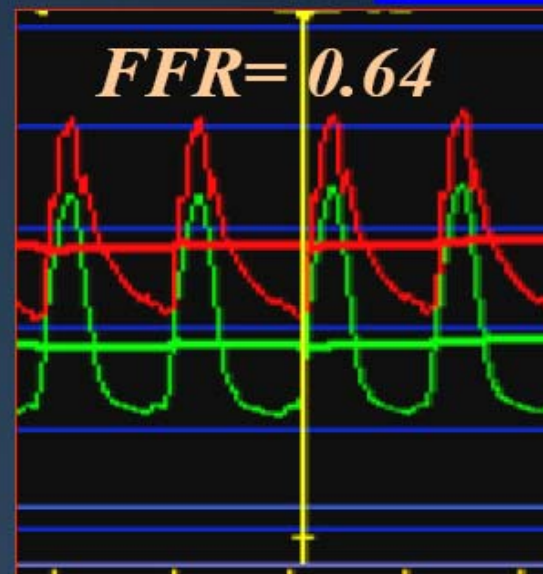
“ If you have a lesion that isn't causing ischemia, the intrinsic risk of the stenosis is very low, lower than the risk of placing the stent ”

“ we place stents everywhere, and the benefits of placing the stent in the right position is countered by the damage we do by placing stents where it is not necessary ”

"These data really show that FFR should be an integral part of every interventional procedure."

Dr Nico Pijls (Catharina Hospital, Eindhoven, the Netherlands)

The FAME Trial: Critique and Clinical Perspectives



Carlo Di Mario, MD

*Royal Brompton Hospital & Imperial
College, London, UK*

FAME: Take Home Message

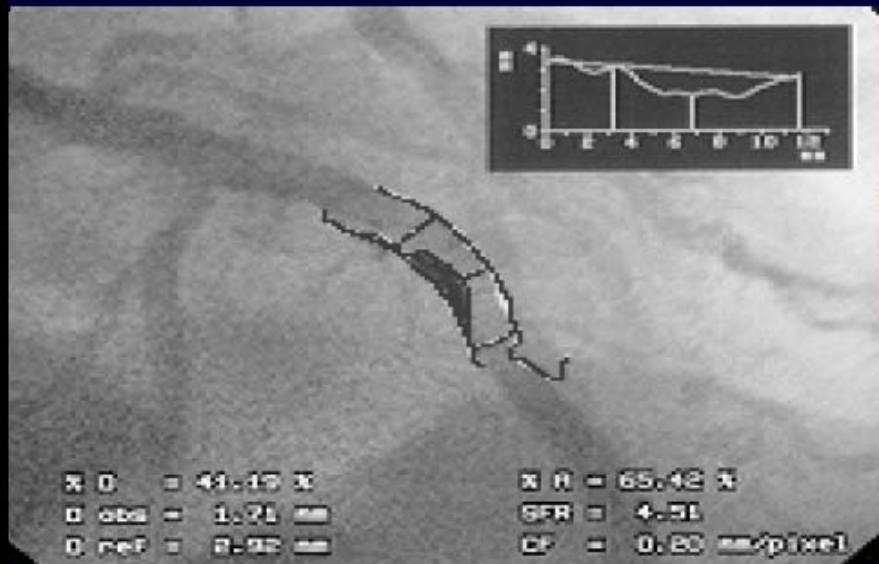
In MV disease Stenting all borderline lesions

because “you never know”, “it may suddently progress”, “we are doing one already”, “you must take aspirin and clopidogrel anyway” is not justified.

An FFR guided approach to MV disease treatment

reduces cost and optimise clinical outcome.

The Rational for using in-lab Physiology (e.g. FFR): Avoiding The Angiographer's dilemma



“I don't know whether this lesion is significant.”

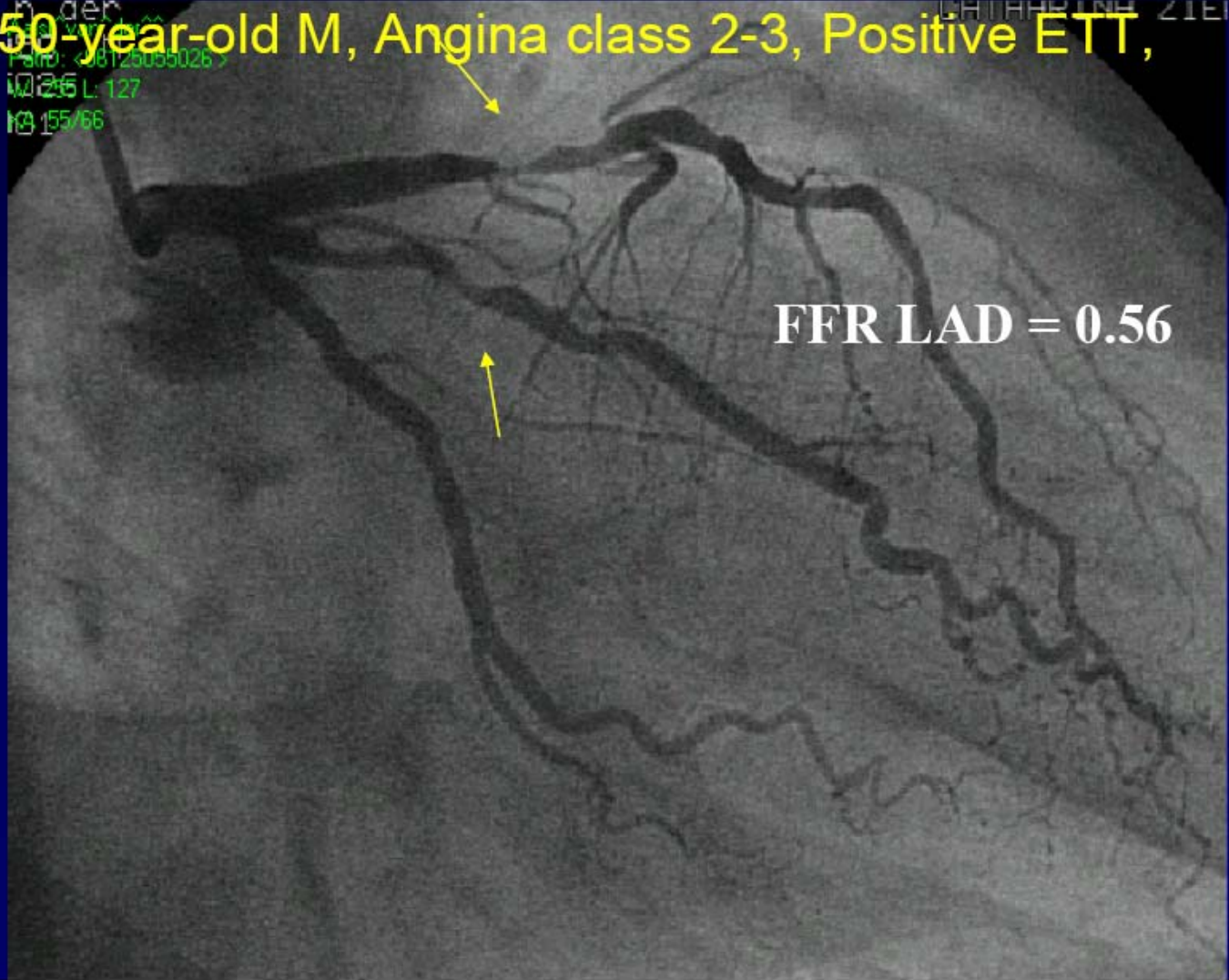
“Let's look at another view”

“Just one more view, I still can't tell”

The solution is not another view but rather measure physiologic lesion significance.

FFR assists in Selecting lesions for Multivessel DES Interventions

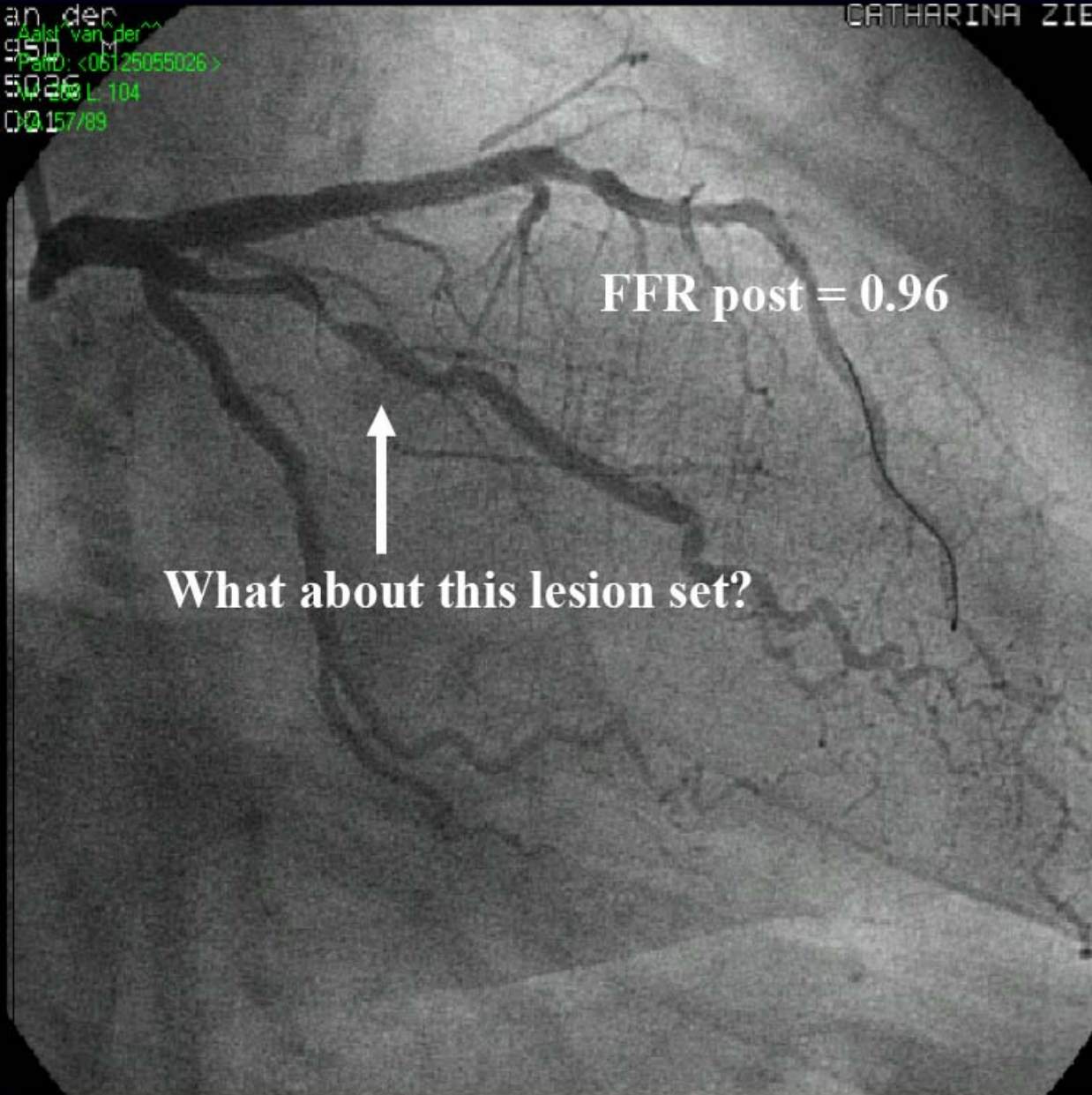
50-year-old M, Angina class 2-3, Positive ETT,
10/26 L: 127
10/15/66



FFR LAD = 0.56

an der
Els van der
950
5026
00157/89

CATHARINA ZIE



FFR post = 0.96

What about this lesion set?

After
stenting LAD

OM needs Rx

ARCHIVE **CUSTOM**

C:\RADI\DOWNLOAD\2001-04-11\2001-08-21

FOLDER	#	PATIENT ID	DATE	TIME	VESSEL	PROCEDURE	ACTION	SIZE
vd sandt	6	Hr.v.A	2001-08-20	17:42:38	LAD MOD			26Kb
heintges	9	Hr.v.A	2001-08-20	17:39:09	LAD MOD	PRE PTCA	ADD IV	4Kb
DEBEER	5	Hr.v.A	2001-08-20	17:35:53	IM		PULLBACK	9Kb
2001-08-21	9	Hr.v.A	2001-08-17	08:55:56	IM			8Kb
2001-06-15	2	Hr.v.A	2001-08-17	08:45:30				9Kb

PRINT

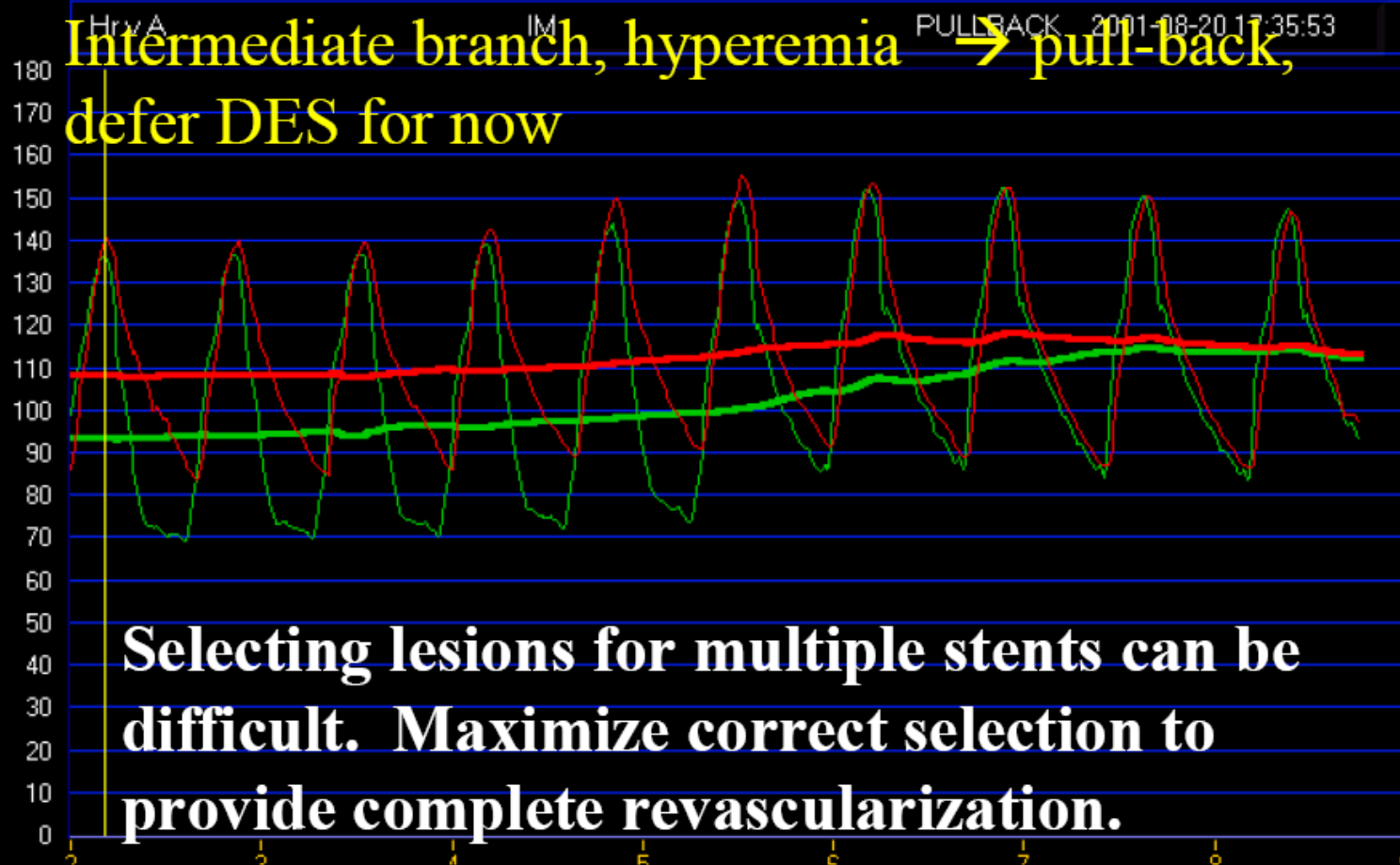
EDIT

RENAME

EXPORT

ERASE

SETUP



108
Pa mean

93
Pd mean

0,86
FFR

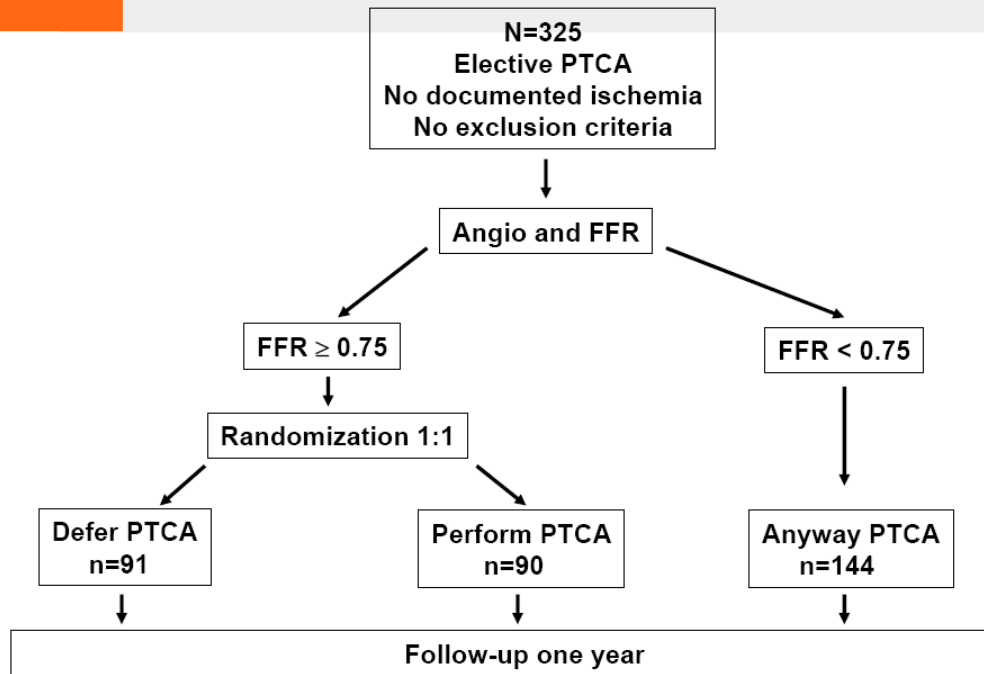
2,2
Cursor



FFR in single vessel disease

EURO PCR06

The DEFER Study: Flow Chart



Percutaneous Coronary Intervention of Functionally Nonsignificant Stenosis

5-Year Follow-Up of the DEFER Study

Five-year outcome after deferral of PCI of an intermediate coronary stenosis based on $\text{FFR} \geq 0.75$ is excellent. The risk of cardiac death or myocardial infarction related to this stenosis is $<1\%$ per year and not decreased by stenting. (J Am Coll Cardiol 2007;49:2105-11) © 2007 by the American College of Cardiology Foundation

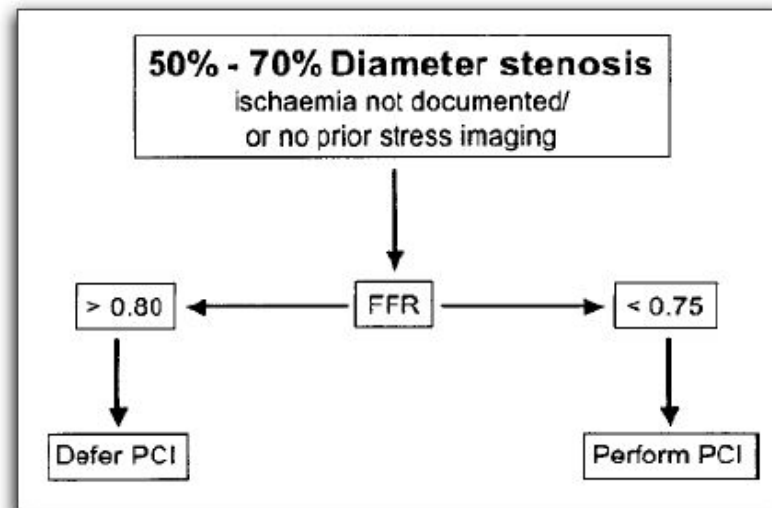
Adjunctive Diagnostic Technology for PCI:

Fractional Flow Reserve (FFR):

Although non-invasive stress imaging with its sensitivity of 76% - 88% and its specificity of 80% - 88% should be the gold standard before cardiac catheterisation, many patients in the real world come to the catheterisation laboratory without prior functional tests. If ever possible, an appropriate functional test should be done before the procedure. If contraindications to non-invasive stress imaging exist or when exercise-induced ischaemia cannot be excluded in the perfusion bed of a coronary artery with “intermediate” stenosis, the measurement of FFR is helpful.

Figure 4:

Decision-making for the management of angiographically intermediate coronary stenoses without documented myocardial ischaemia (absence of any localising information, such as resting ECG-changes, new wall motion abnormalities or prior stress imaging). For FFR values between 0.75 and 0.80, a gray zone” exists..



ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention

5.6.2. Coronary Artery Pressure and Flow: Use of Fractional Flow Reserve and Coronary Vasodilatory Reserve

Class IIa

It is reasonable to use intracoronary physiologic measurements (Doppler ultrasound, fractional flow reserve) in the assessment of the effects of intermediate coronary stenoses (30% to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. (*Level of Evidence: B*)

Physiological Assessment of Coronary Artery Disease in the Cardiac Catheterization Laboratory

TABLE 8. Applications of Physiologic Measurements in the Catheterization Laboratory

A. PCI Guideline recommended uses*

1. Assessment of the effects of intermediate coronary stenoses (30% to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. (Class IIa, *Level of Evidence: B*)
2. Assessment of the success of PCI in restoring flow reserve and to predict the risk of restenosis (Class IIb, *Level of Evidence: C*)
3. Evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion (Class IIb, *Level of Evidence: C*)
4. Routine assessment of the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study is not recommended. (Class III, *Level of Evidence: C*)

Uso FFR in Italia

	2006	2007	diff %
IVUS	3,148	4,461	+ 42%
FFR	1,129	1,830	+ 62%
PCI	124,091	128,428	+ 3%
coro	260,276	264,516	+ 2%

Uso FFR in Italia

centri maggiori

2007				
	coro	PCI	IVUS	FFR
San Raffaele	3,469	1,613	147	0
Monzino	3,551	1,905	273	0
Niguarda	1,935	829	51	19
Mercogliano (Av)	4,710	2,527	17	7

PCI in stable multi-vessels disease

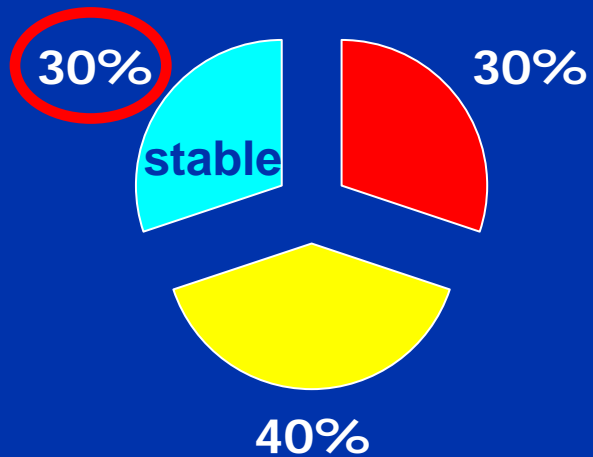
Multi-vessels PCI in no pPCI pts (mean):

- National : 26%
- Liguria : 28%
- SMH : 44%

San Martino

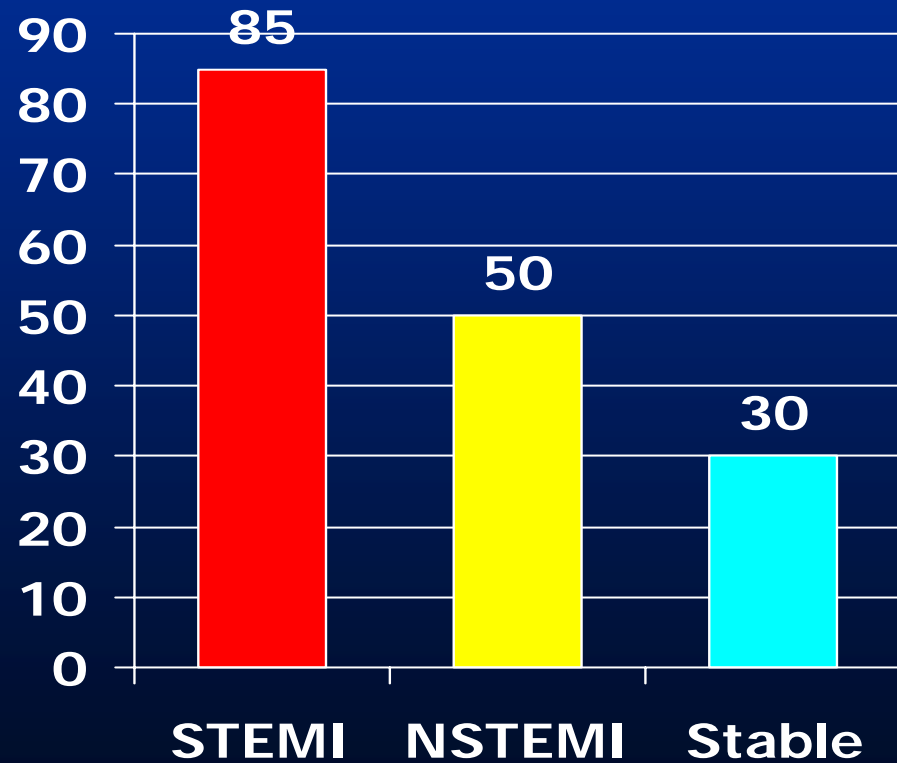
% PCI in stable CAD

% PCI disease



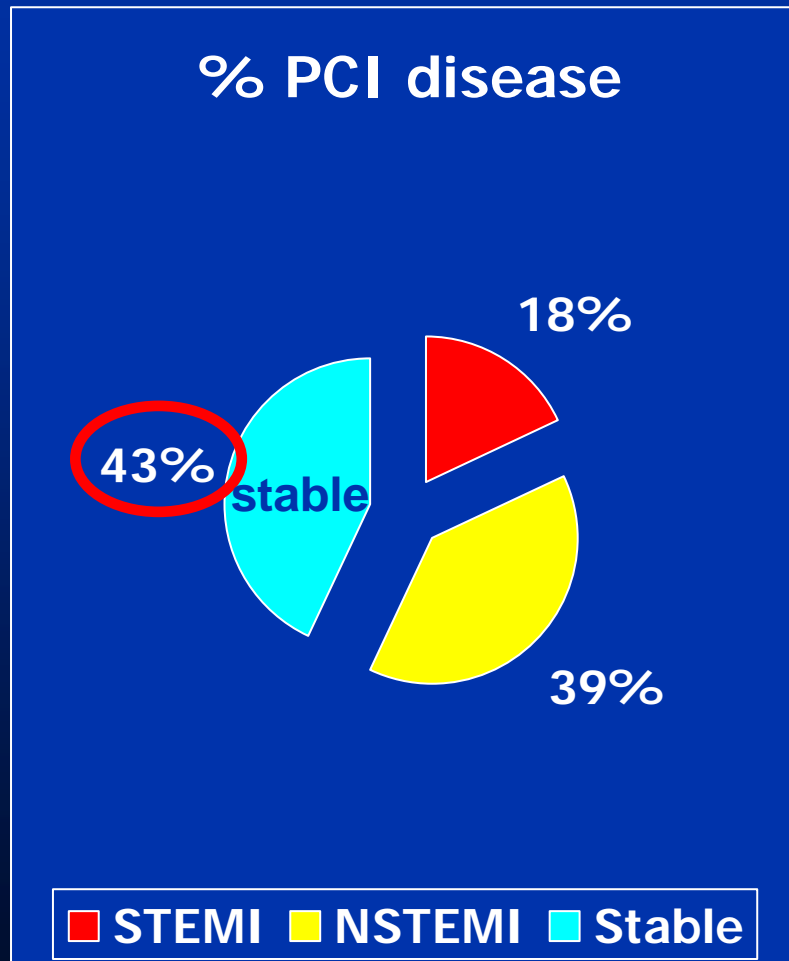
■ STEMI ■ NSTEMI ■ Stable

% PCI/coro



Euro Heart Survey on PCI

% PCI in stable CAD



In U.S.

The NEW ENGLAND
JOURNAL of MEDICINE

Optimal Medical Therapy with or without PCI
for Stable Coronary Disease

Courage trial

.. recent registry data in United States indicate that approximately 85% of all PCI procedures are undertaken electively in patients with stable coronary artery disease.

This article (10.1056/NEJMoa070829) was published at www.nejm.org on March 27, 2007.



Frequency of Stress Testing to Document Ischemia Prior to Elective Percutaneous Coronary Intervention

Grace A. Lin, MD, MAS
R. Adams Dudley, MD, MBA
F. L. Lucas, PhD
David J. Malenka, MD
Eric Vittinghoff, PhD
Rita F. Redberg, MD, MSc

Context: Guidelines call for documenting ischemia in patients with stable coronary artery disease prior to elective percutaneous coronary intervention (PCI).
Objective: To determine the frequency and predictors of stress testing prior to elective PCI in a Medicare population.
Design, Setting, and Patients: Retrospective, observational cohort study using claims data from a 20% random sample of 2004 Medicare fee-for-service beneficiaries aged 65 years or older who had an elective PCI (N=23 887).

- Retrospective study from 2004 Medicare pts
- 23 887 pts > 65 y with stable CAD and elective PCI
- 55.5 % do not have pre-PCI documentation of ischemia:

55.5 % of PCI were anatomic guided
oculo-stenotic reflex



Lower rates of stress testing:

Patient characteristics:

- Older female
- Prior catheterization
- Comorbid conditions

Physician characteristics:

- Younger physicians
- High volume PCI

The Disconnect Between Practice Guidelines and Clinical Practice—Stressed Out

George A. Diamond, MD; Sanjay Kaul, MD
Cedars-Sinai Medical Center LA California

Despite increasing evidence supporting plaque instability as the proximate cause of atherosclerotic events, treatment strategies continue to focus on the anatomic stenosis.

This preoccupation with coronary luminology causes clinicians to perform stress tests and angiograms to identify flow-limiting lesions, even among asymptomatic patients

Editorial

JAMA, October 15, 2008



Luminologia

Our preoccupation with coronary luminology.

The dissociation between clinical and angiographic findings in ischemic heart disease.

Eric J. Topol, Steven E. Nissen

Circulation. 1995; 92:2333-2342.

Evolution of Atherosclerosis model

a Gradual luminal narrowing

b Plaque rupture

c Inflammation

a

b

c



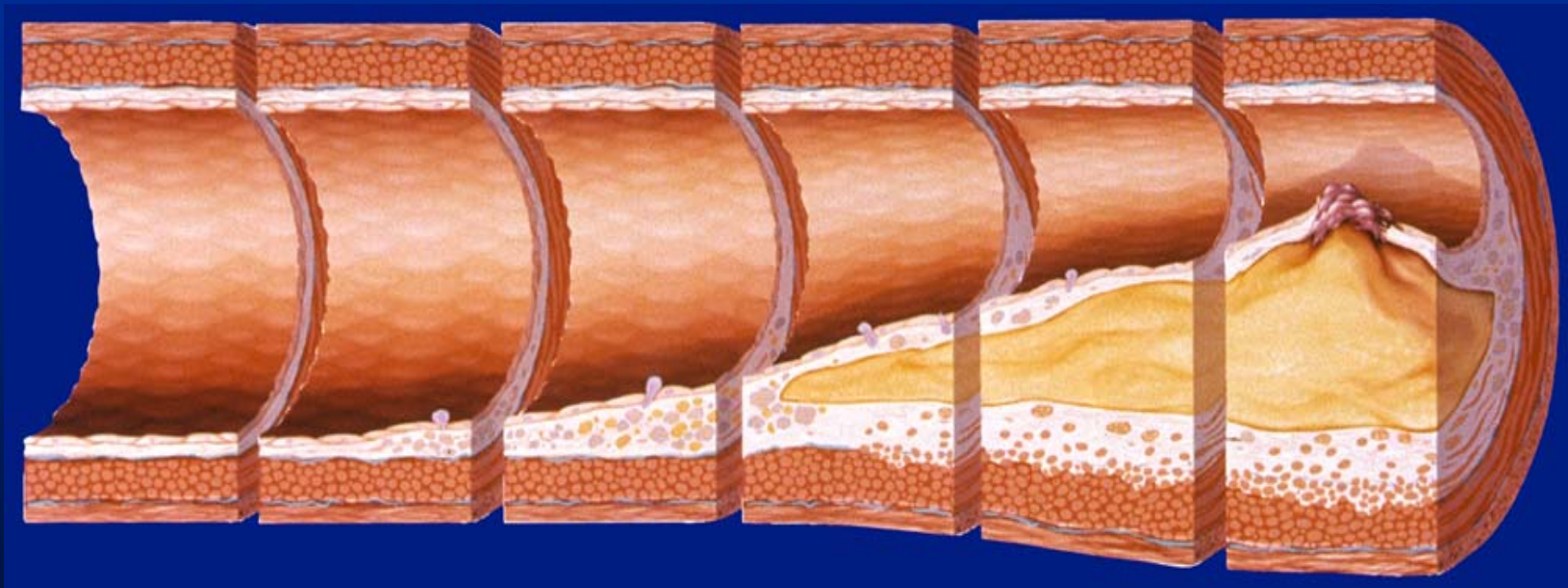
years

1980

2000

Atherosclerosis: traditional model

Atheroma accumulation leads to luminal narrowing from the onset of the disease process



Gradual luminal narrowing



The Origins of Atherosclerosis



Peter Libby
Brigham & Women's Hospital
Harvard Medical School



Lessons from the Lipid Legends

www.theheart.org

2004

“ like rust in a pipe”

The Traditional View of Atherosclerosis



Atherosclerosis is more than luminal narrowing

- 99% of atherosclerotic disease is in vessel wall
- Does not narrow the lumen
- Hidden from angiographic view



Steven Nissen

Relationship Plaque/Lumen

- Plaque size in itself is not the sole predictor of luminal narrowing:
- Marked compensatory enlargement of the coronary artery with plaque progression
- Lumen size is not correlated with plaque size



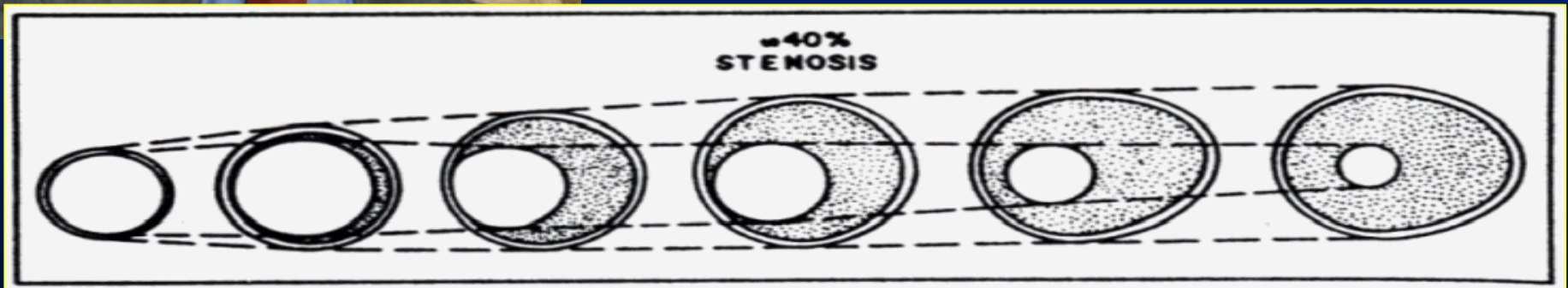
Renu Virmani

Armed Forces Institute of Pathology,
Washington, DC

Interazione placca-parete: Rimodellamento



Seymour Glagov
pathologist
Chicago

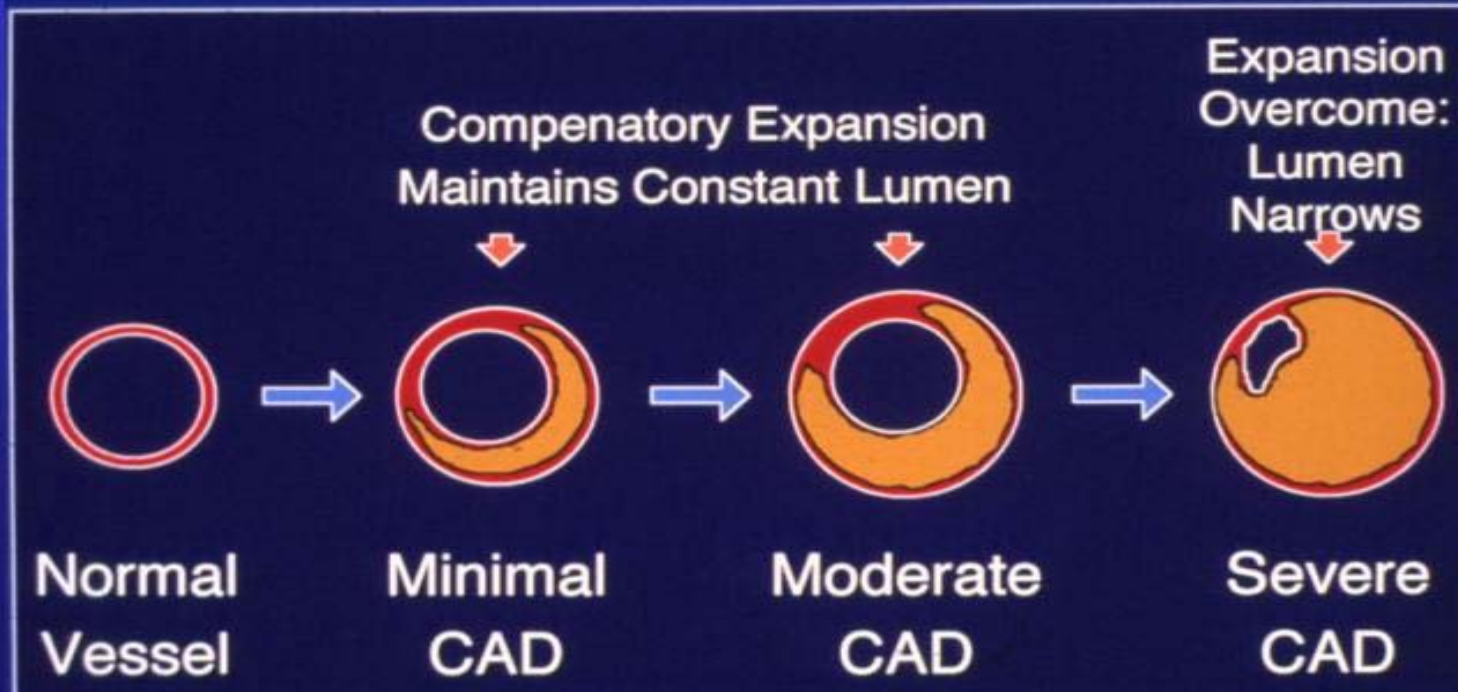


“Compensatory enlargement of human atherosclerotic coronary artery”

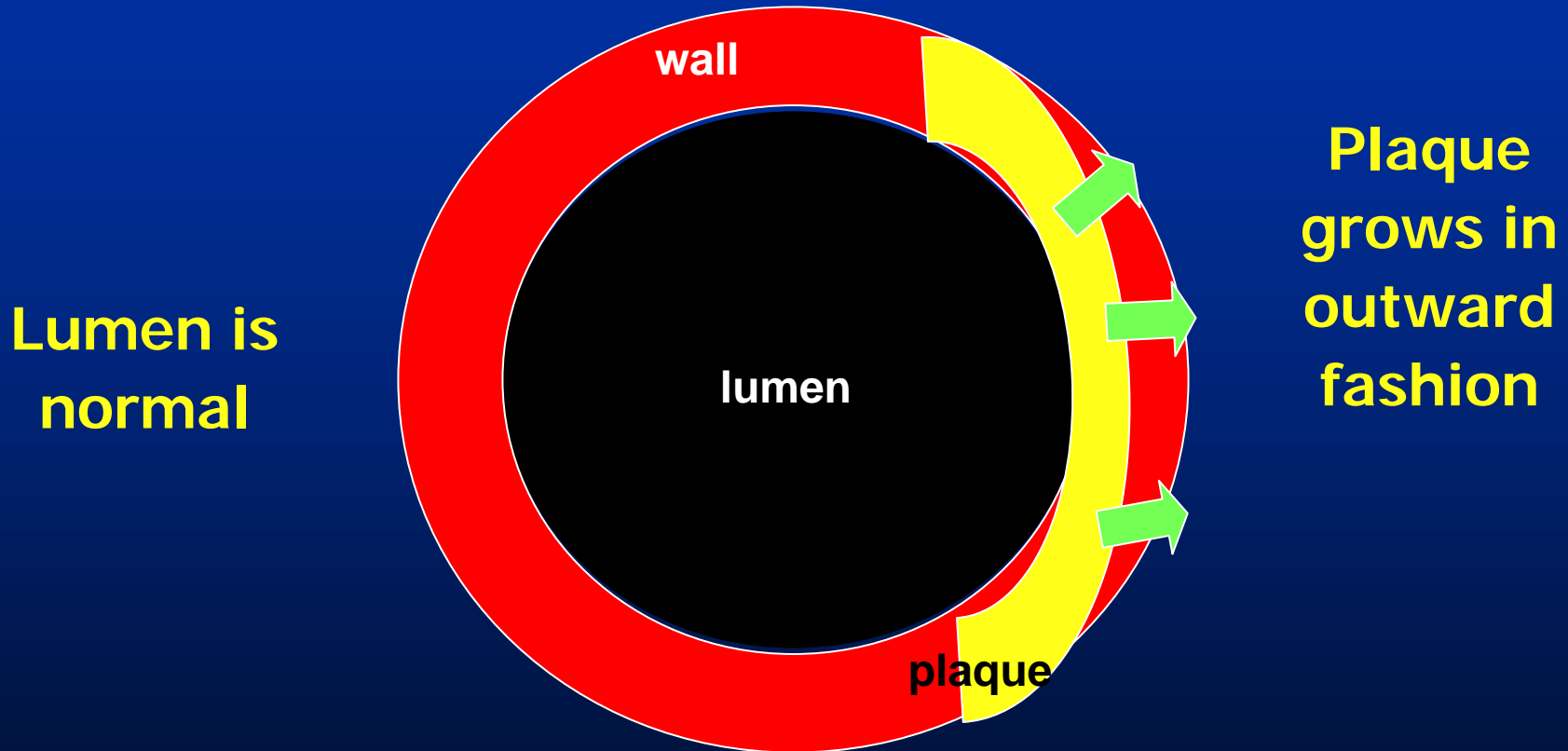
Seymour Glagov et al, N Engl J Med 1987; 316:1371-5.

Glagov hypothesis

Coronary Remodeling Hypothesis

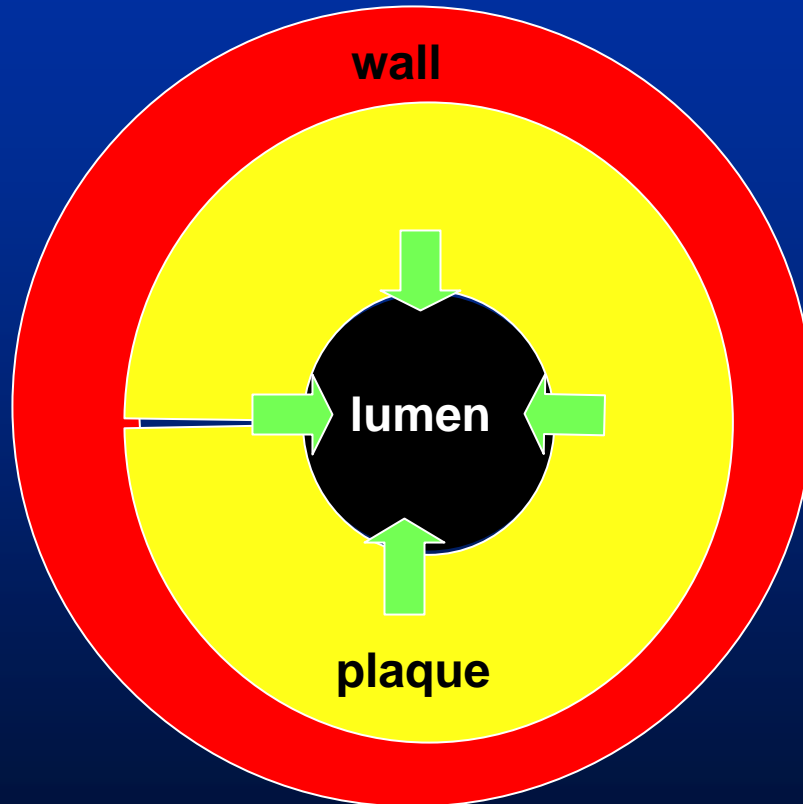


Remodeling: compensatory enlargement



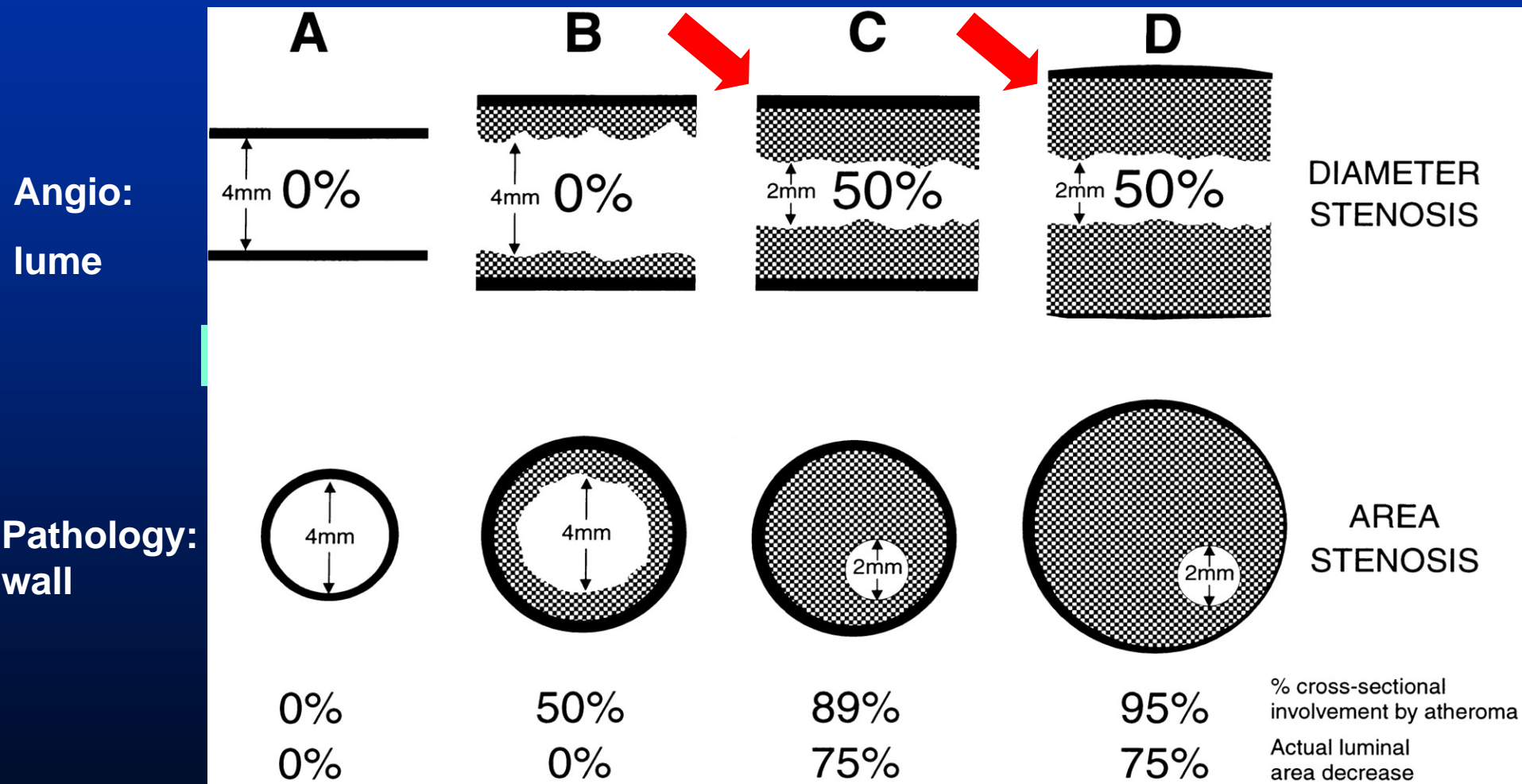
Remodeling permits large accumulation before lumen narrowing

Stenosis



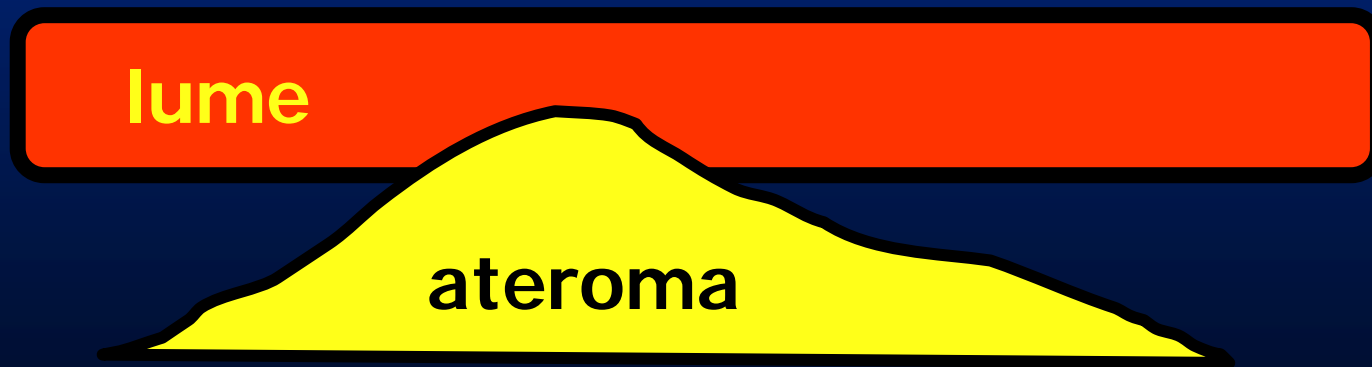
Lumen stenosis is delayed until the lesion occupies 40% of the potential lumen area

Atherosclerosis and vascular remodeling



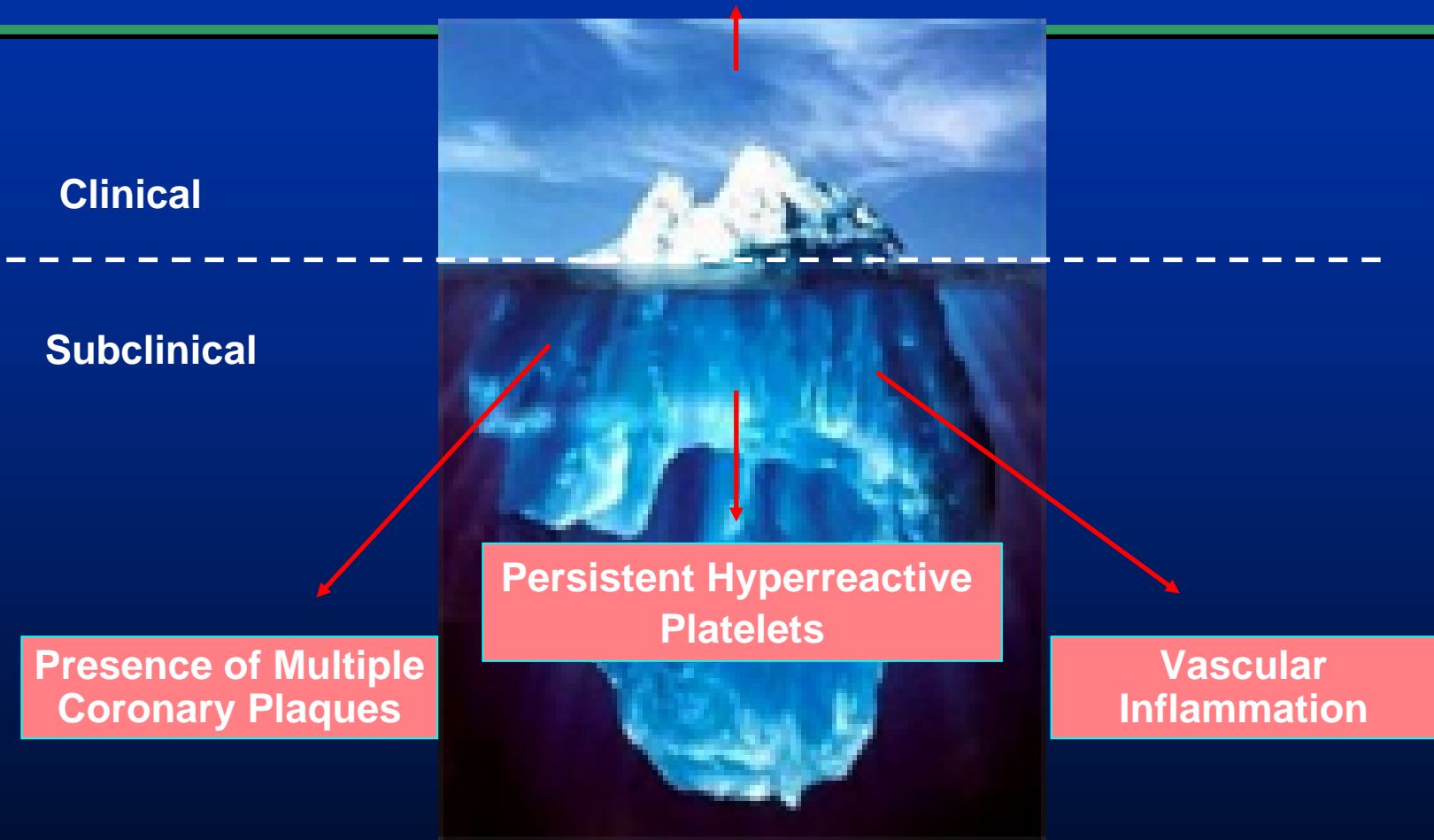
Placca/stenosi patologia/angiografia

- La stenosi visibile all'angiografia è un'impronta nella proiezione del lume
- punta affiorante dell'ateroma parietale
- falsa impressione di interessamento focale



ACS: Tip of the Atherothrombotic "Iceberg"

Acute Plaque Rupture ACS (UA/NSTEMI/STEMI)



ACS, acute coronary syndrome; UA, unstable angina; NSTEMI, non-ST-segment elevation myocardial infarction; STEMI, ST-segment elevation myocardial infarction.

Adapted from Goldstein JA. *J Am Coll Cardiol.* 2002;39:1464-1467.

Irregolarità lumenali: significato patologico

Il riscontro angiografico di alterazioni del lume indica quindi un'estensione della placca di almeno il 40% dell'area del vaso.

In questo caso la maggior parte dell'intero albero coronarico è già interessata dall'aterosclerosi

Quadro anatomico: imaging coronarico

Tecnica	obiettivo
coronarografia	lume
IVUS - OCT	lume e parete
Coro CT	lume e parete

Conclusioni (1/3)

- Negli USA lo studio FAME, come recentemente anche il COURAGE, ha suscitato interesse e interrogativi riguardo l'appropriatezza di una quota di PCI elettive.
- In Europa, dove probabilmente l'appropriatezza è maggiore rispetto agli USA, per via del diverso sistema di finanziamento, il problema è di minore entità ma non trascurabile.

Conclusioni (2/3)

- Il nuovo attuale scenario prevede infatti una crescente disponibilità di dati anatomici coronarici non invasivi : coro CT, in assenza di corrispettivi dati funzionali.
- L'interesse ad una valutazione coronarica esclusivamente anatomica, senza adeguata valutazione clinica e funzionale, può mettere a rischio l'appropriatezza di una quota di PCI elettive, riportando ad una concezione dell'aterosclerosi di oltre 20 anni fa, ampiamente superata dalle attuali conoscenze e senza vantaggi per i pazienti.

Conclusioni (3/3)

Nei pazienti multi-vasali,
l'identificazione delle stenosi ischemizzanti,
spesso è difficilmente accertabile con i test non
invasivi,
ma è necessaria prima di un eventuale PCI .

Può essere effettuata, in modo efficace,
direttamente durante la procedura interventistica.