Unprotected Left Main Interventions in The Era of Drug Eluting Stents

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Left Main Stenting

Background:

Left main stenting with bare stents

One-year clinical outcomes of protected and unprotected left main coronary artery stenting

Univariate and multivariate predictors of mortality and MACE

Univariate predictor	Odds ratio
Death	
Unprotected LM	6.9 (2.2-21.1), p<0.001
Cardiogenic shock	8.9 (2.0-40.0), p=0.009
CHF	3.2 (1.1-9.0), p=0.04
MACE	
Unprotected LM	2.9 (1.4-21.1), p=0.05
Cardiogenic shock	7.2 (1.4-37.2), p=0.3
CHF	1.5 (0.7-3.3), p=0.3
GP IIb/IIIa inhibitor	0.6 (0.3-1.3), p=0.2

Multivariate predictor adjusted for propensy score	
Death	
Unprotected LM	4.9 (1.5-15.5), p=0.008

Kelley et al. European Heart Journal (2003) 24, 1554–1559

LM stenting with bare stent
In-Hospital Mortality Rate

(excluding procedures during acute MI)

Ranging from
0 to 4.3%

« High-risk » group: 6-13% ≈ 9%
« Low-risk » group: 0-2% ≈ 1%

Follow-up time ranging from 7.3 to 25.5 months

Cardiac Mortality:

Ranging from 2% to 28 %

French Left Main Registry

Prospective observational multicenter registry

11 French centers

All Consecutive Pts with LM stenosis > 50%

On-line internet inclusion

1 year clinical Follow-up

Inclusion, May 2001 - June 2002

Courtesy of Thierry Lefèvre; ACC 2004

Profile Risk and Treatment Choice

	Stent	CABG
Patients (n)	192/479 (40%)	230 (48%)
Good candidate (%)	51.6	80.9*
Poor candidate (%)	44.2	14.3*
Contra-indication (%)	4.2	4.8

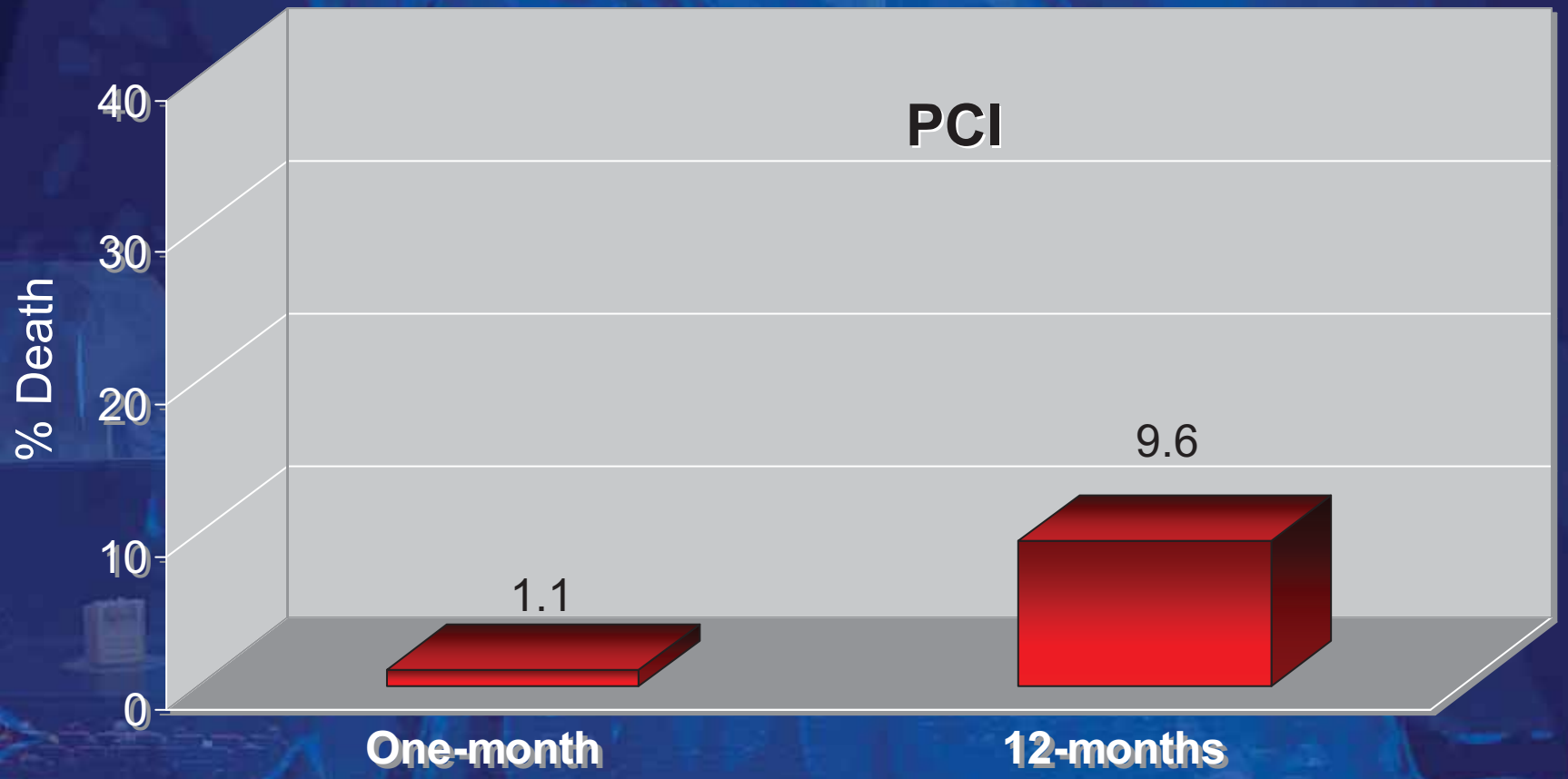
Poor candidate = age > 75 years, severe pulmonary failure, renal failure, severe peripheral disease, previous CABG, previous stroke, EF < 30%, ….

* p<0.001

Courtesy of Th. Lefèvre; ACC2004

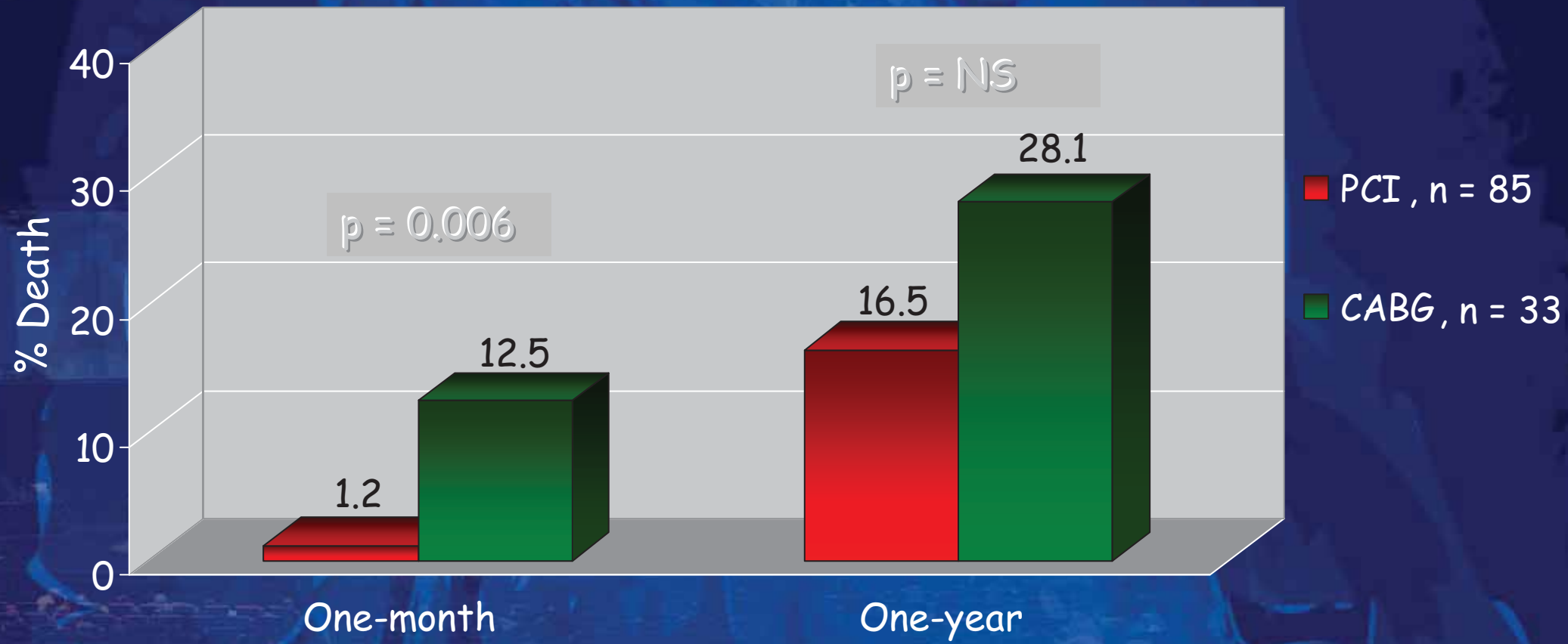
French Left Main Registry

French Left Main Registry Results

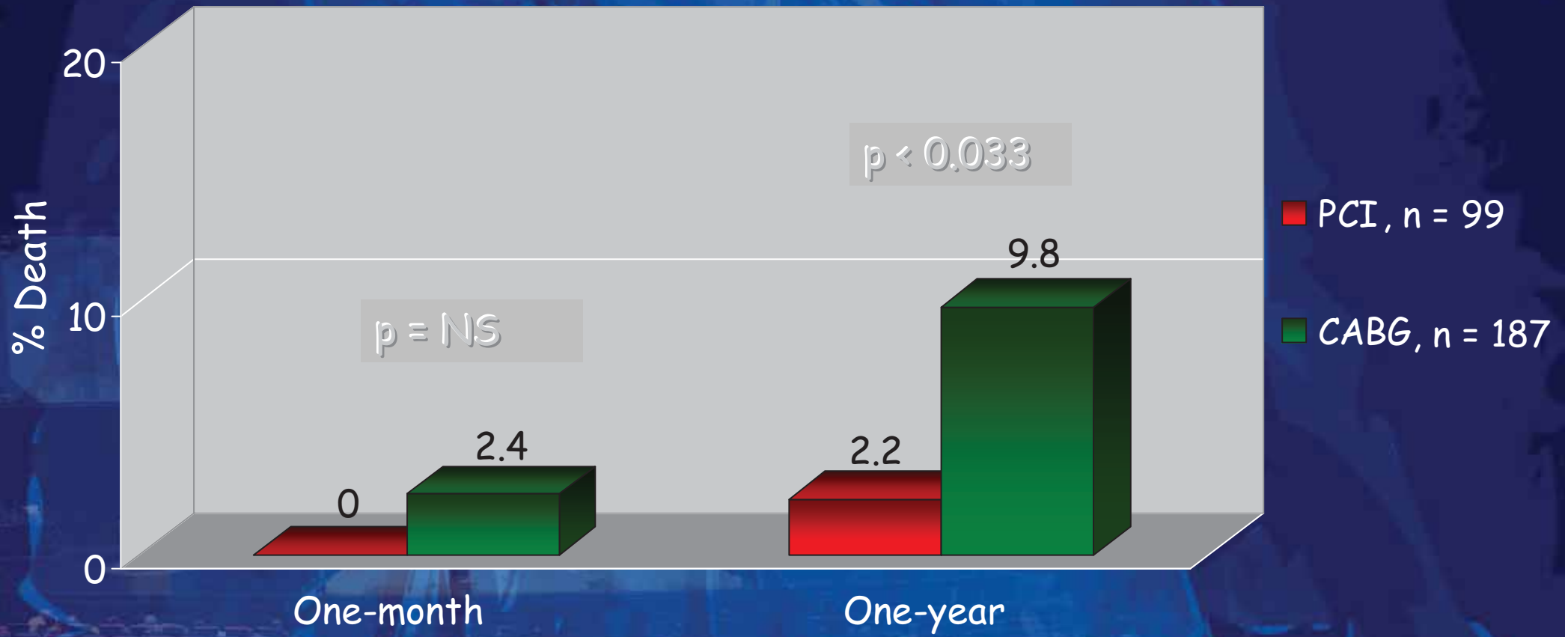


Courtesy of T. Lefèvre, ACC 2004

Poor Candidates for Surgery

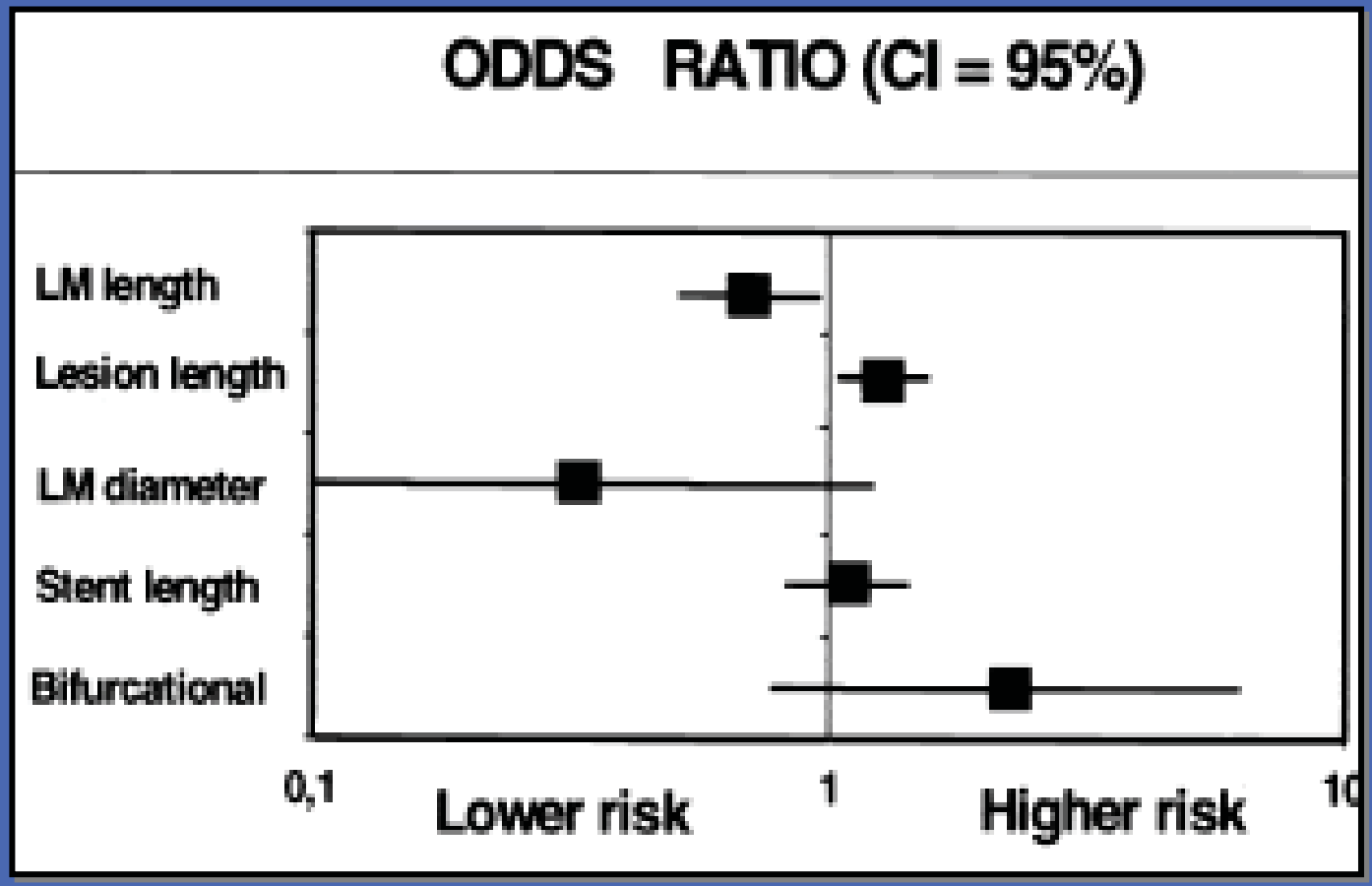


Good Candidates for Surgery



Unprotected Left Main Coronary Stenting:

Predictors of Restenosis



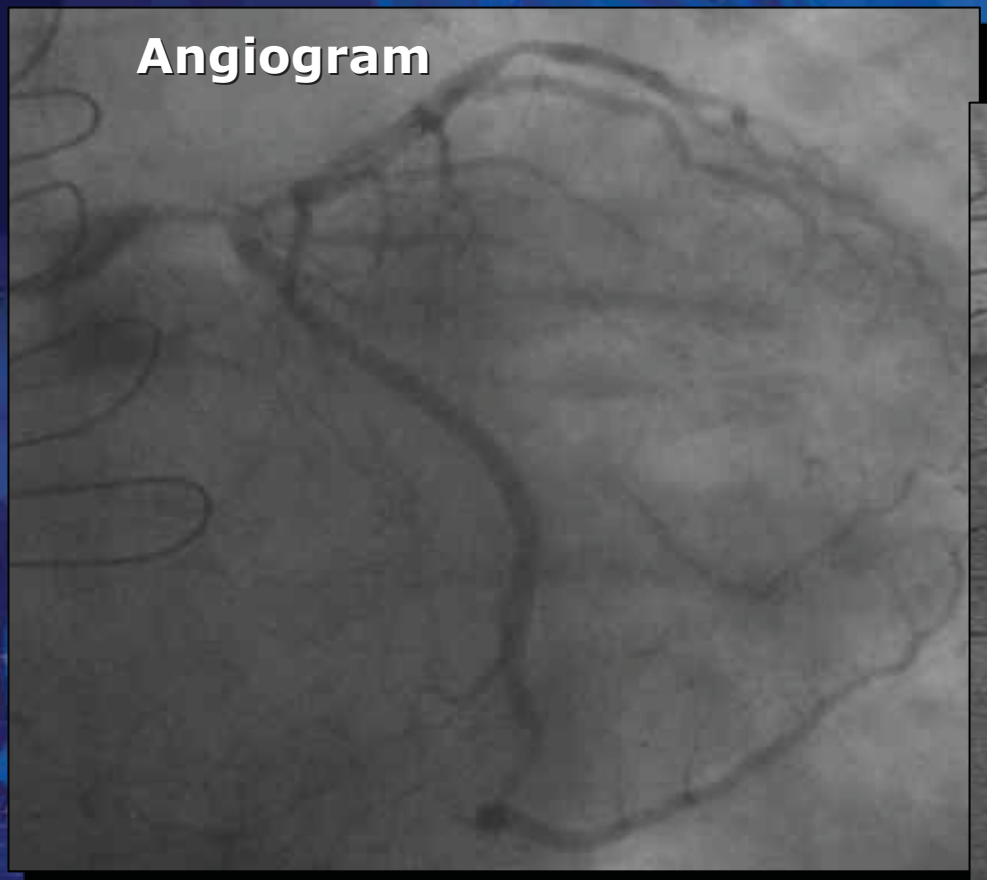
de Lezo J et al. Am J Cardiol 2001.

LM Stenting with bare stents

No data about:

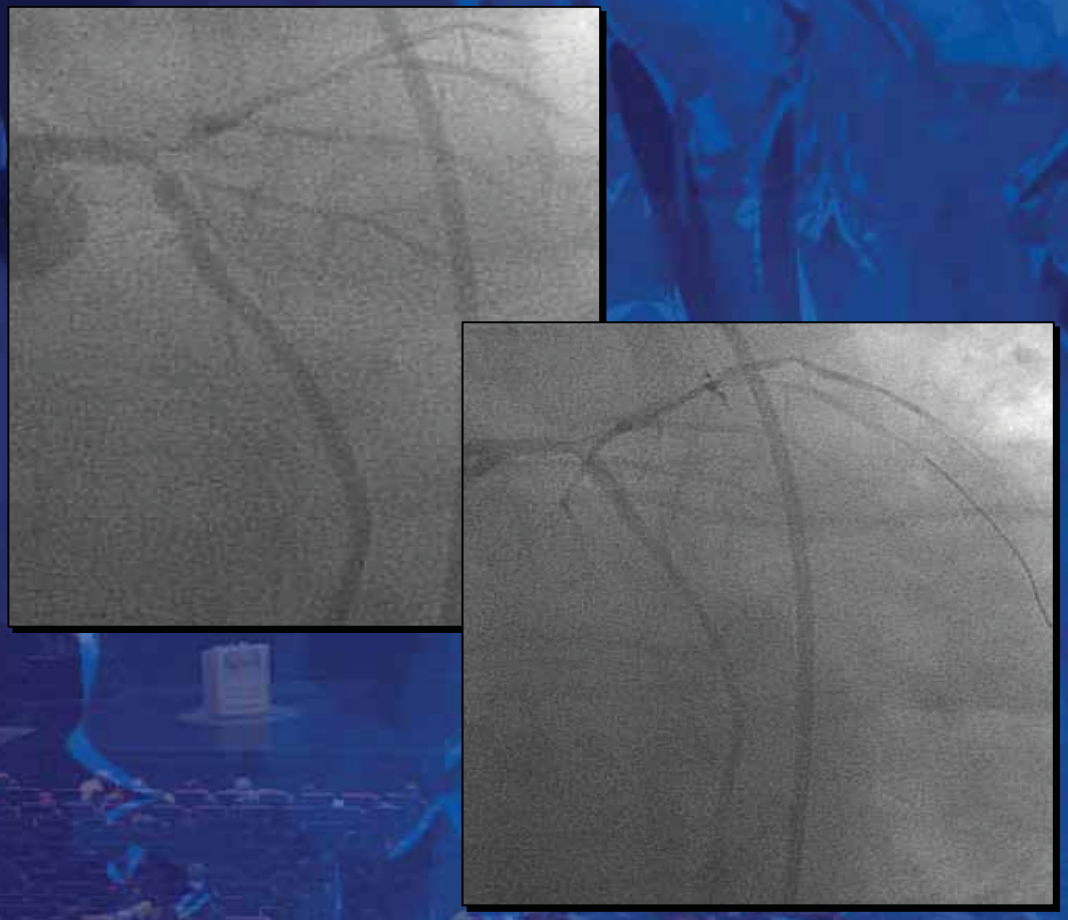
- The clinical presentation of in-stent restenosis.
- The consequences of in-stent restenosis on the LV function

Male, 56 y.o. ID Diabetes,
2001 : CABG
Mar 2002: Stable angina, LIMA-LAD patent, LCx graft occluded



May 2002 : ACS, Troponine I ++
Hemodynamic instability

Key issue:
ACS is a common clinical presentation of ISR



68% of pts with ISR present with ACS

Non-ST MI :	12%
S T MI :	8%
Other	7%
Rest Angina or MI:	68%
Thrombus visible :	9%

Distal embolization, slow-flow, shock, death

Walters D L. et al. Am J Cardiol 2002

LM Stenting: Restenosis

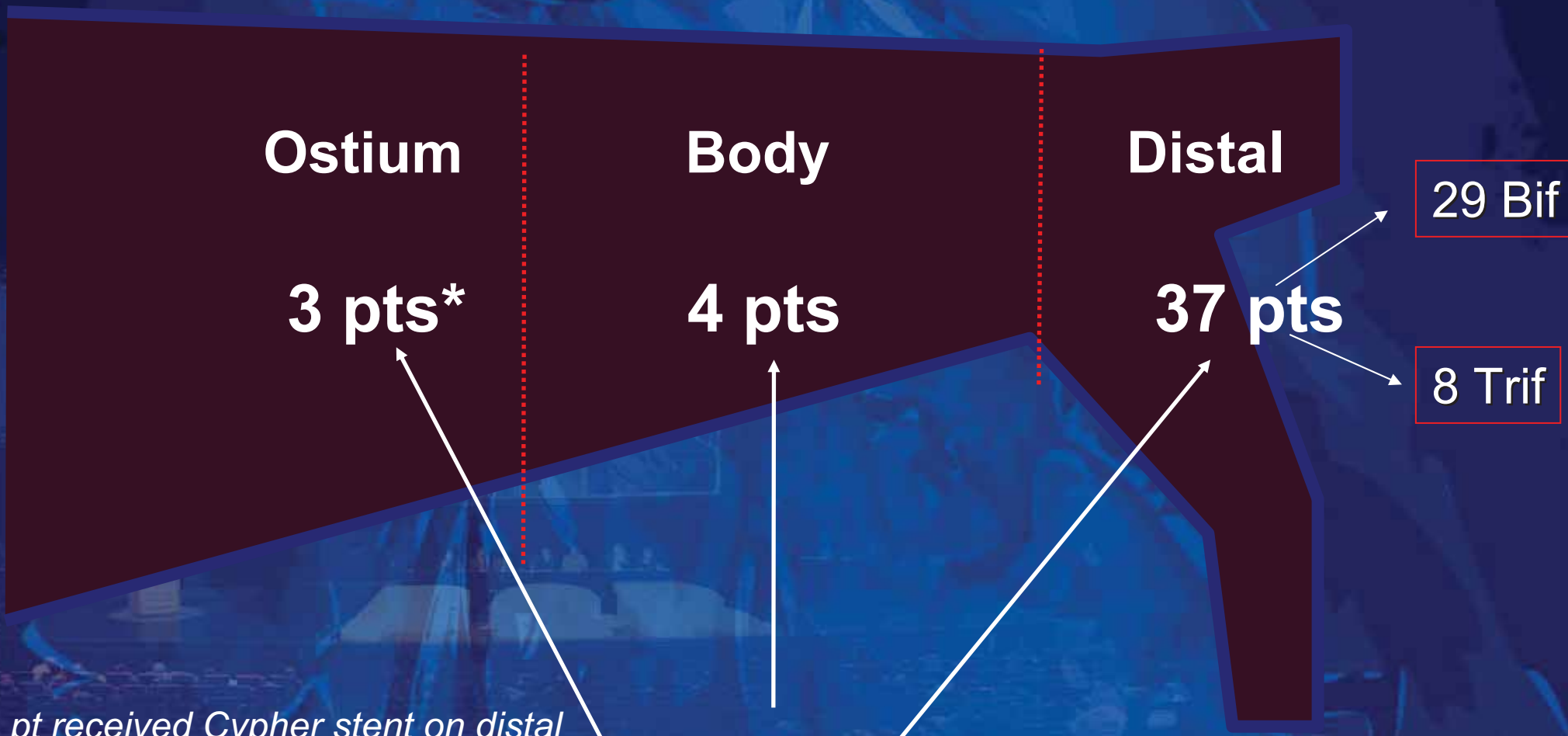
The fact that deaths occurred in the first 12 months highlights the dramatic way restenosis could manifest when PCI is performed on the LM.

The risk of sudden cardiac death should not be underestimated.

Unprotected LM stenting

The impact of DES

Early and Mid-term Results of Cypher stent in Unprotected Left Main



*1 pt received Cypher stent on distal and ostial LM

ACC 2004- Courtesy of A. Colombo

6-month MACE

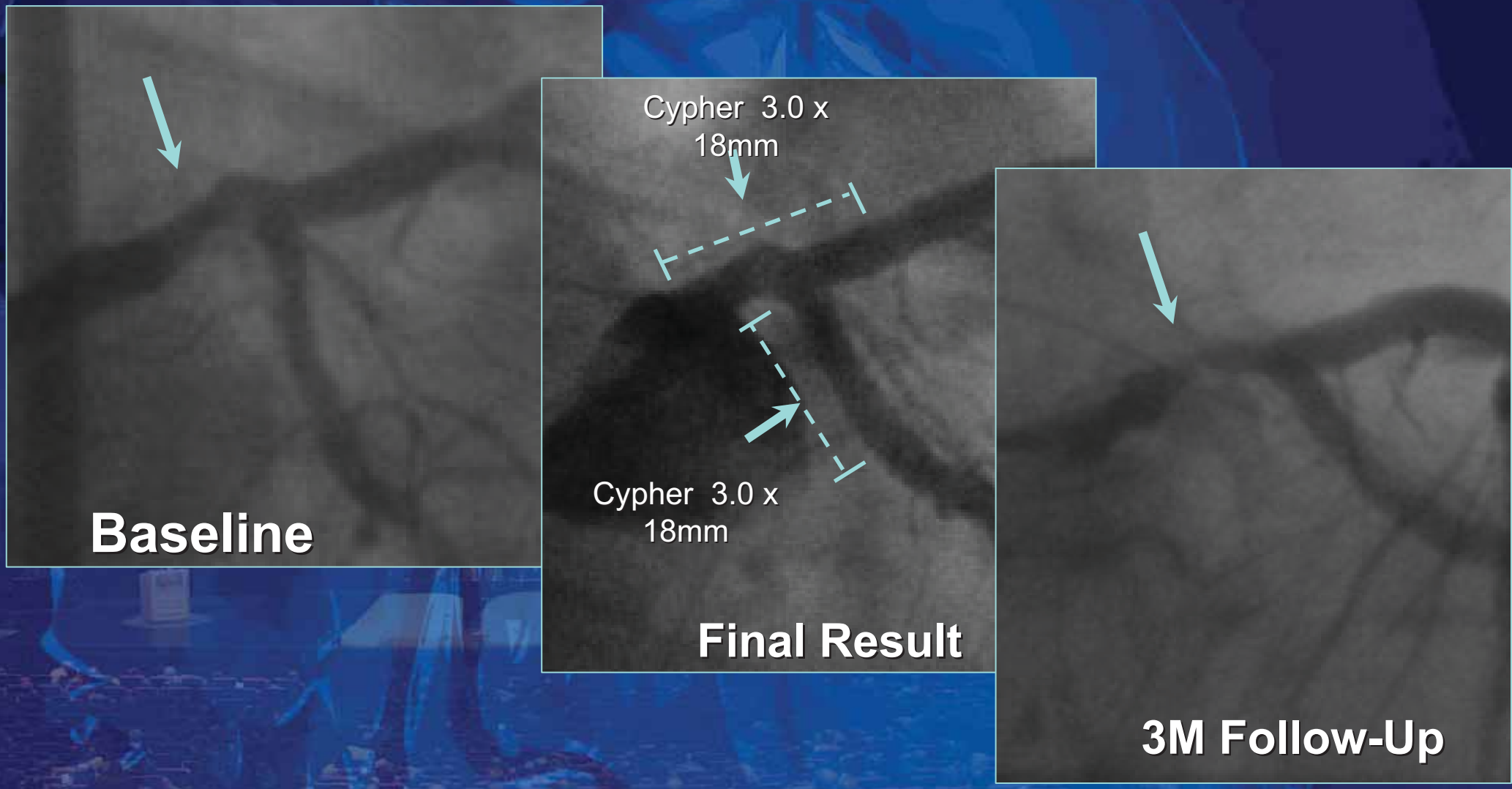
N = 39

• Death	2 (5%)*
• MI	1 (2.5%)
• TLR, per patient	9 (23%)
PCI	7
CABG	2

** 1 Death occurred 54 days after the procedure and 7 days after clopidogrel was suspended; 1 Death occurred because of pulmonary edema due to severe aortic regurgitation .*

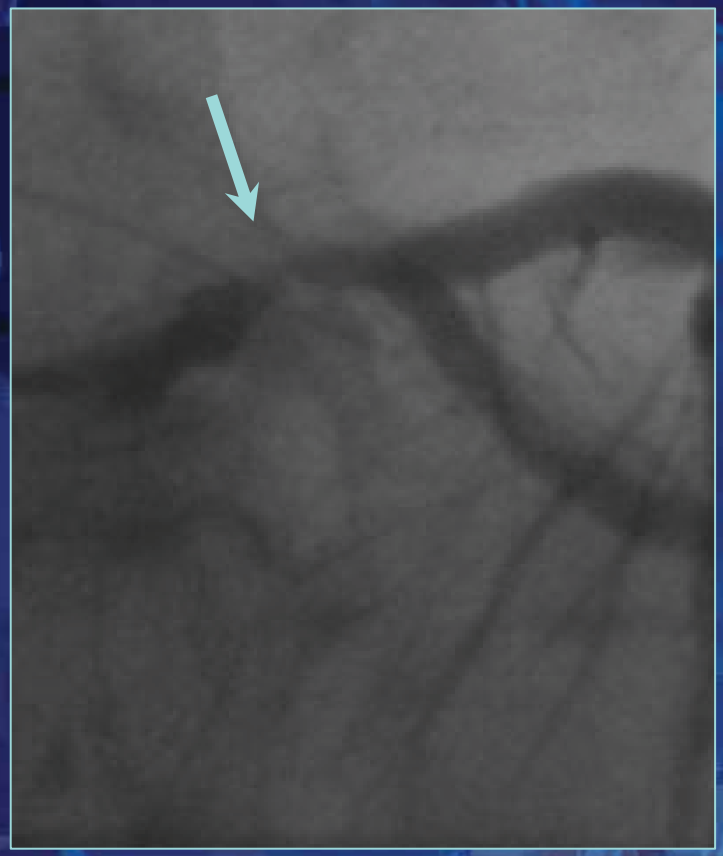
Courtesy of Antonio Colombo

Double Occurrence of Restenosis

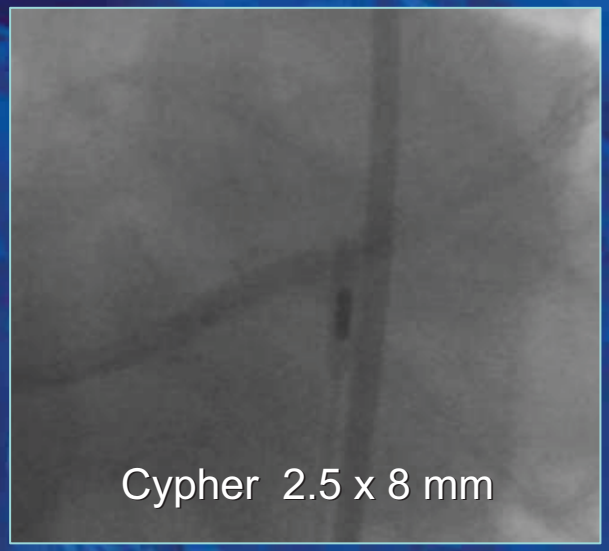


Courtesy of Antonio Colombo

Double Occurrence of Restenosis



Follow-Up



Second Cypher for ISR

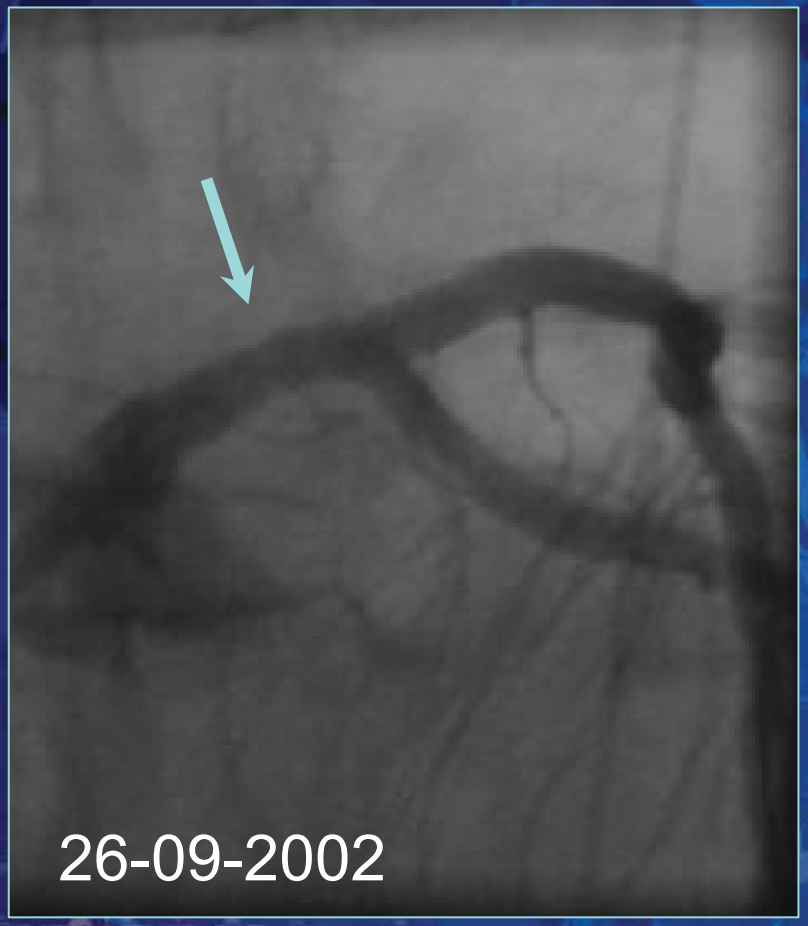
26-09-2002

Final Result

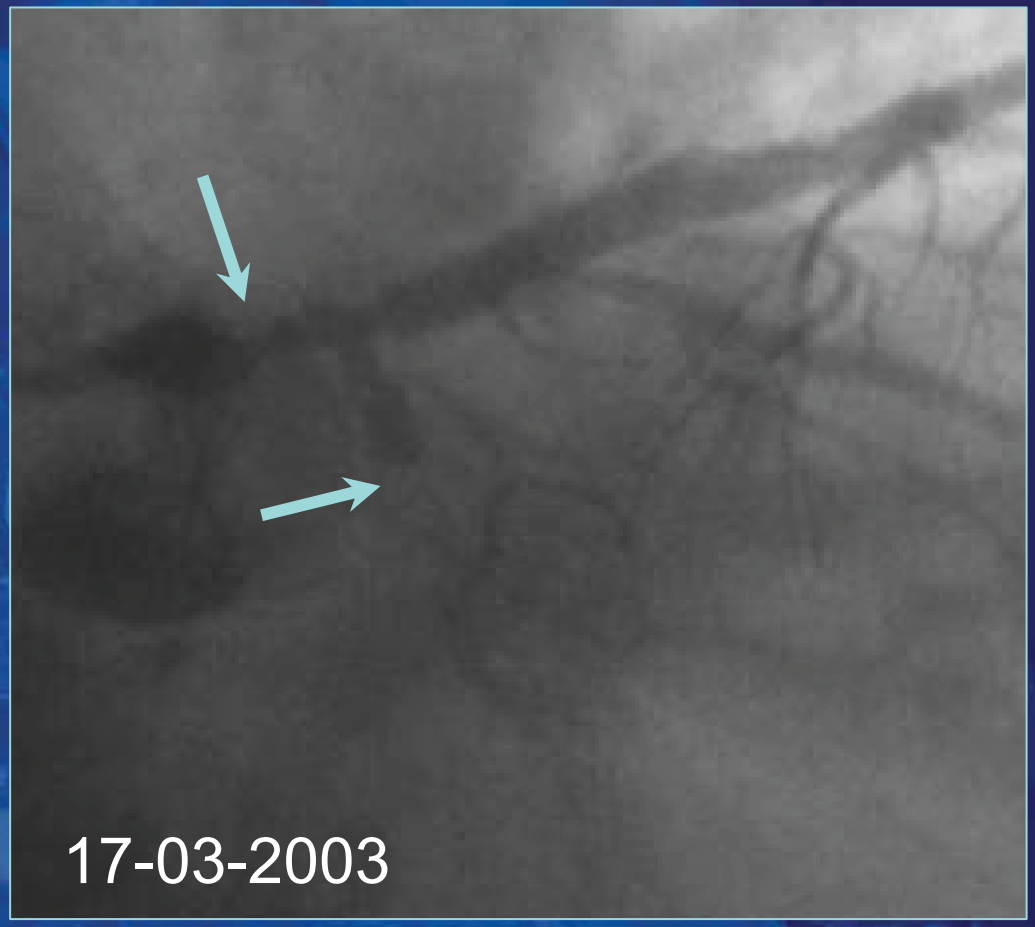
Courtesy of Antonio Colombo

30875 hsr

Double Occurrence of Restenosis



Final Result



Second Restenosis

Courtesy of Antonio Colombo

Characteristics of pts with TLR

	Diabetes	Cypher 3.5	Kissing	Technique
Pt 1	yes	yes	yes	Crushing
Pt2	no	no	no	Crushing
Pt3	no	no	yes	T-modified
Pt4	yes	no	yes	Crushing
Pt5	no	no	yes	V
Pt6	yes	no	yes	Crushing
Pt7	no	no	yes	V
Pt8	yes	no	no	Provisional
Pt 9	yes	no	yes	Crushing

TLR in diabetics is 71.4%

ACC 2004- Courtesy of A. Colombo

RESEARCH registry - LMC

Left main substudy (n=27)

Post-discharge events (mean follow-up 5.1 ± 1.8 mo.)

	Acute Myocardial Infarction (n=2)	Bailout stenting (n=9)	Elective (n=16)
Deaths	0%	0%	0%
Myocardial infarction	0%	0%	0%
Percutaneous revascularization	0%	0%	0%
Coronary bypass	0%	11%	0%
MACE	0%	11%	0%

Courtesy of P. Serruys

Unprotected Left Main stenting with DES
Clinique Pasteur experience

2003-04

45 patients

(Ostium: 12, shaft: 6, distal: 27)

In-hospital MACE : 0

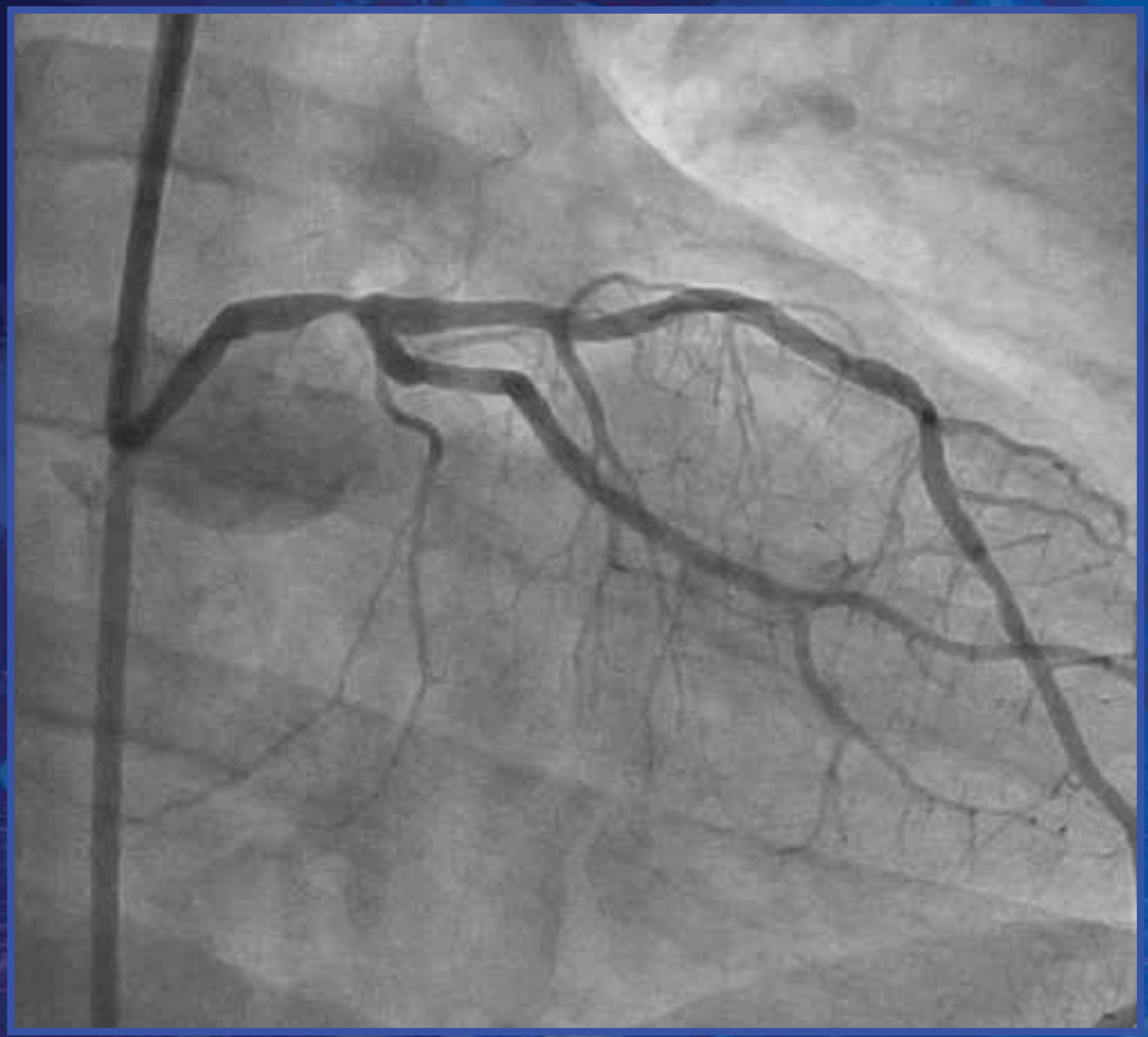
@ follow-up:

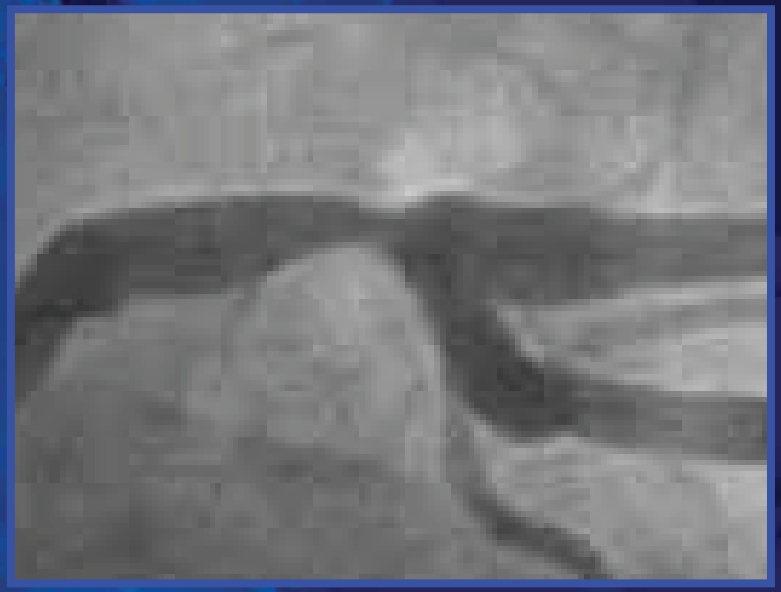
Death: 0

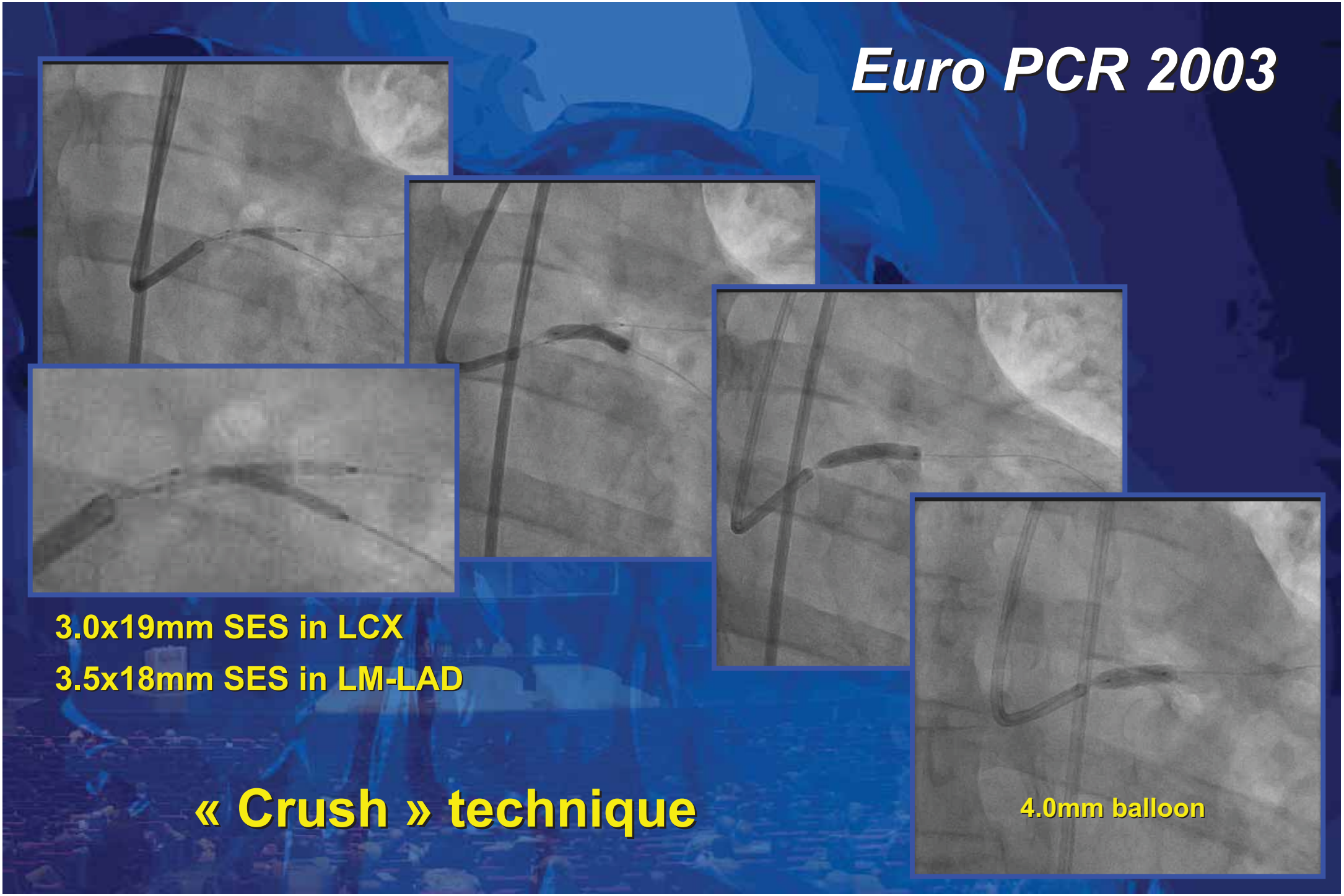
Restenosis: 2 (distal LM) ⟶ CABG

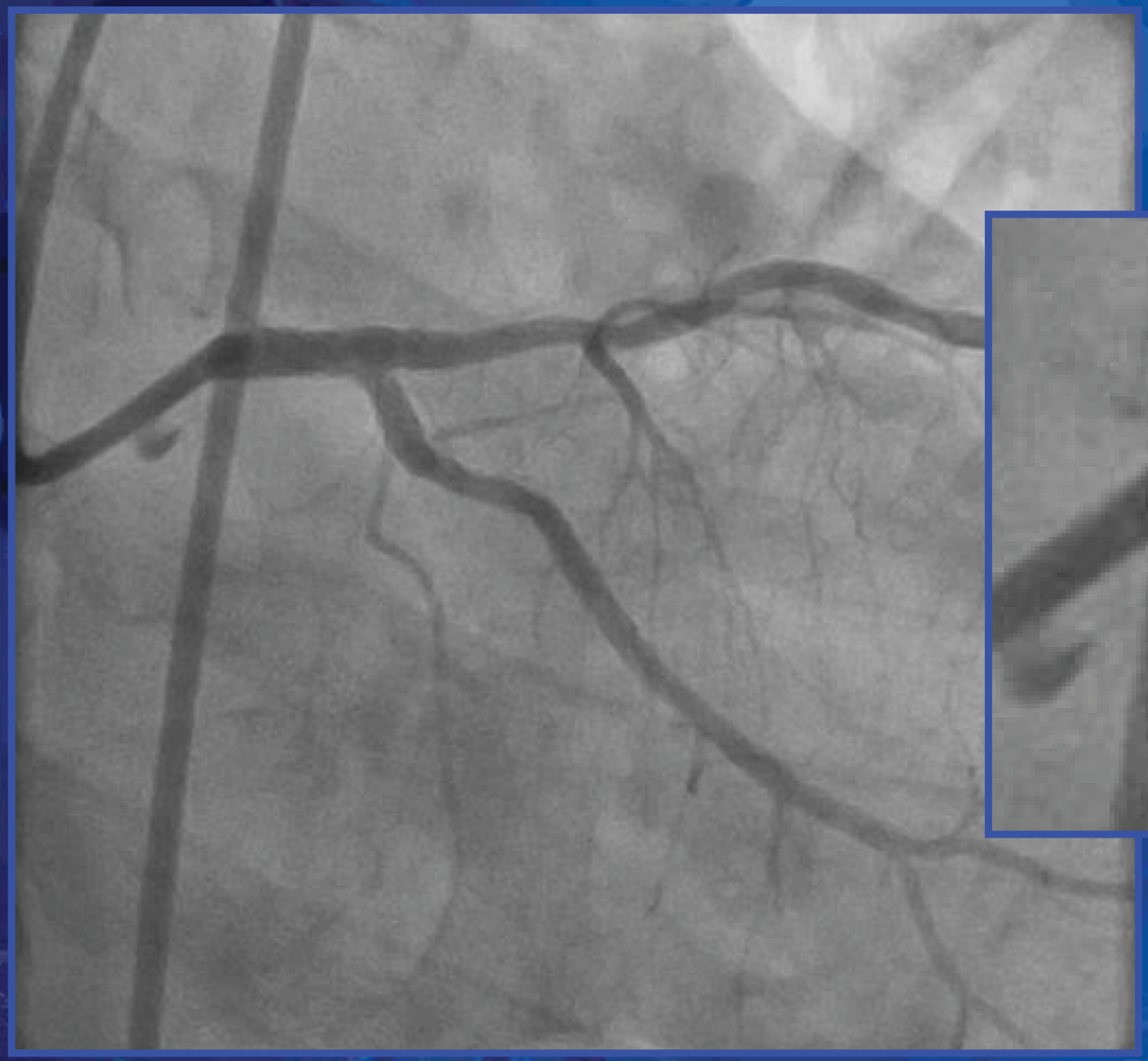
52 y.o. male,
May 2003: acute coronary syndrome
LVEF=66%, distal LM stenosis

Euro PCR 2003





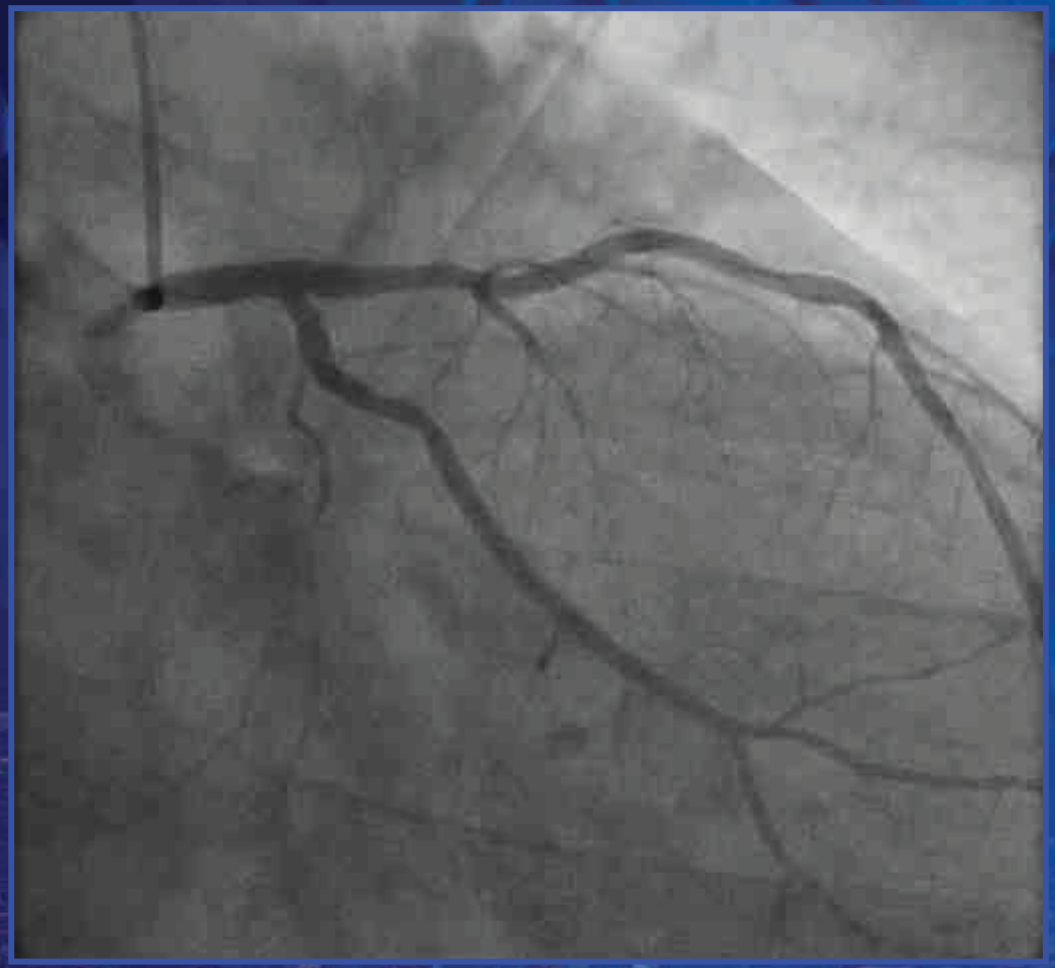

Euro PCR 2003
3.0x19mm SES in LCX
3.5x18mm SES in LM-LAD
« Crush » technique
4.0mm balloon

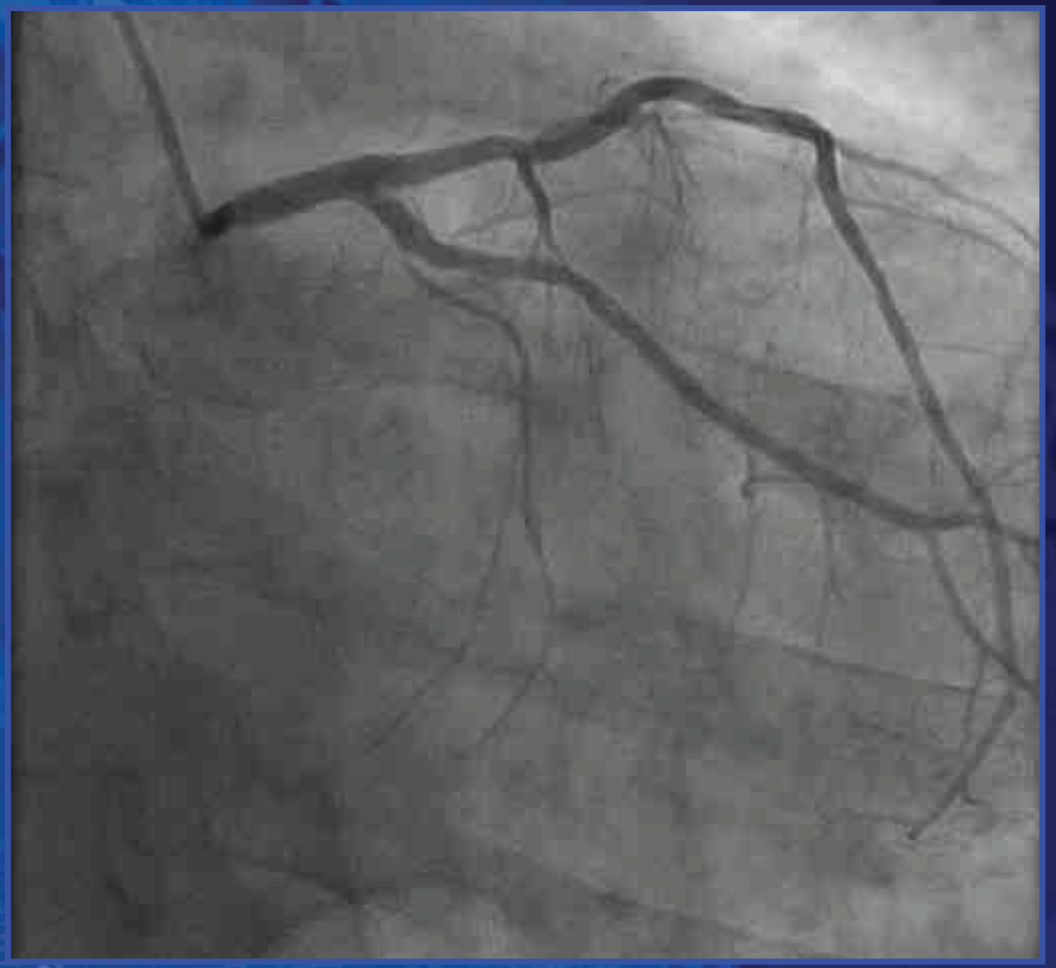


Final result

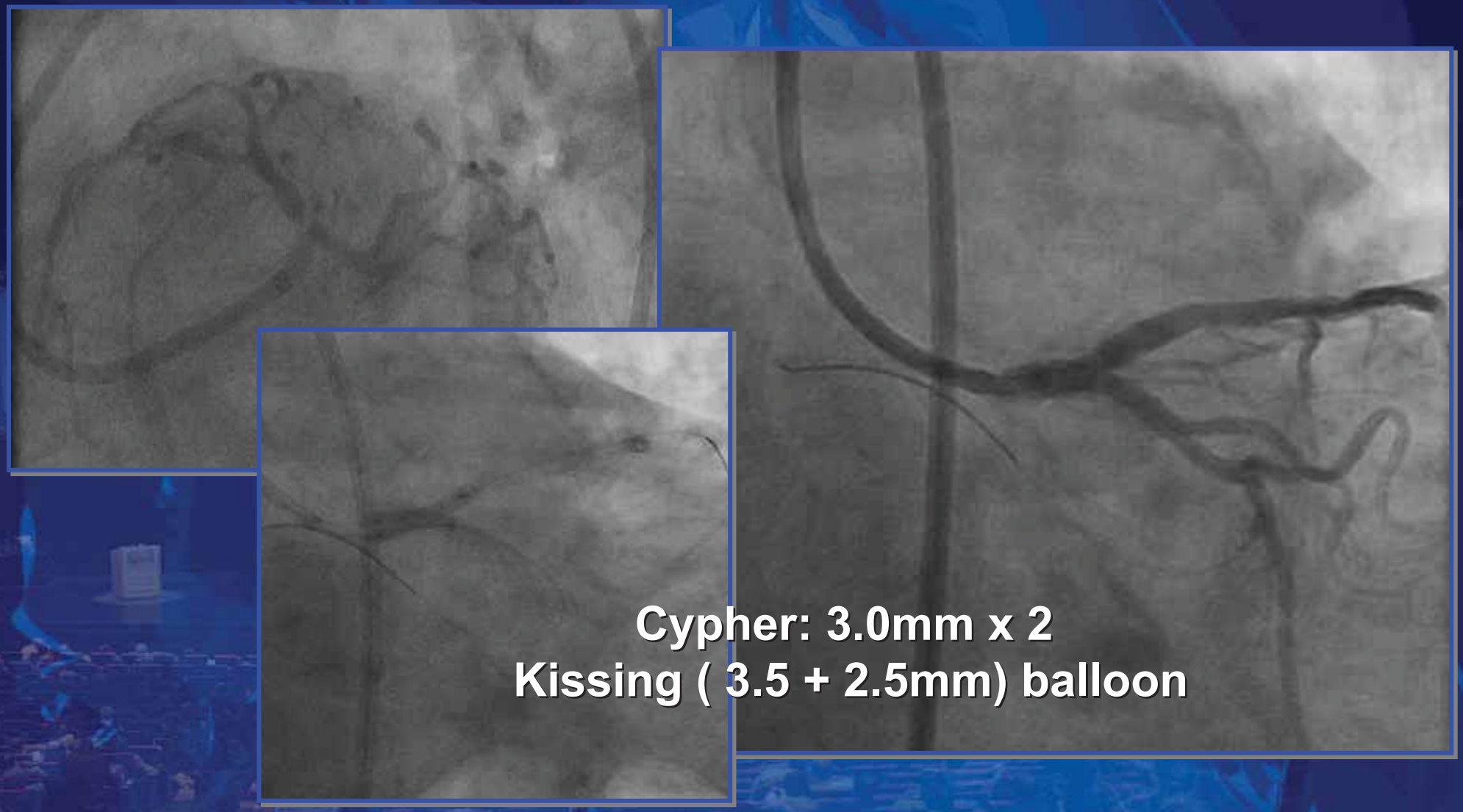
Follow-up
11/28/2003

Euro PCR 2003





Male , 71 yo, IRD, svere renal insufficiency, FC III angina.
LVEF: 70%, RCA: normal



Cypher: 3.0mm x 2
Kissing (3.5 + 2.5mm) balloon

4 months later: unstable angina at rest, troponin ++
LVEF: 40%, pro BNP: ++++

By-pass surgery without complications

Cypher stent for Unprotected Left Main Stenosis

Seoul experience (04/2004)

N=109	
Diabetes	30%
LVEF	58.9 ± 9.1% (26-76)
Proximal stenosis	26%
Ostium n=24	
Shaft n=4	
Distal stenosis	74%

Cypher stent for Unprotected Left Main Stenosis

Seoul experience (04/2004)

In-hospital outcome (%)

N=109	Proximal (n=28)	Distal (n=81)
Death	0	0
Q MI	0	0
Non Q MI	7	11
Stent thrombosis	0	0
CABG	0	0
PCI	0	0

Cypher stent for Unprotected Left Main Stenosis

Seoul experience (04/2004)

Hospital discharge to 30 days (%)

N=104	Proximal (n=26)	Distal (n=78)
Death	0	0
Q MI	0	0
Non Q MI	0	0
Stent thrombosis	0	0
CABG	0	0
PCI	0	0

Cypher stent for Unprotected Left Main Stenosis

Seoul experience (04/2004)

6-month clinical & angio. outcome (%)

N=45	Proximal (n=15)	Distal (n=40)
Death	0	0
Q MI	0	0
Non Q MI	0	0
Stent thrombosis	0	0
CABG	0	0
PCI	0	2.5
Restenosis	0/12	2/36 (5%)

TAXUS for Unprotected LM Disease

May 2003-February 2004

Patients (n)	69
Age (years)	66±10
Male gender (%)	81
Diabetes (%)	29
Unstable angina (%)	27
EF (%)	62±12
Euroscore (0-12)	4.0±3.0

Estimated CABG mortality rate (%) 5.0±8.4

Courtesy of T. Lefèvre, ACC2004

Left Main Taxus Registry

TAXUS for Unprotected LM Disease

Patients (n)	69
Ref. diameter left main (mm)	3.6±0.3
Ref. Diameter side branch (mm)	3.0±0.4
Main branch stent length (%)	16±3
Distal left main (%)	71
Other treated vessel (n)	1.0±0.9

Courtesy of T. Lefèvre, ACC2004

Left Main Taxus Registry

TAXUS for Unprotected LM Disease

In-hospital Outcome (n= 69)

Angiographic success (%)	100
SAT (%)	0
Non-Q-wave MI (%)*	1.5
Q-wave-MI (%)	0
Emergency CABG (%)	0
Stroke (%)	0
Death (%)	1.5
MACCE (%)	2.9

Courtesy of T. Lefèvre, ACC2004

* CPK 875 IU

Left Main Taxus Registry

TAXUS for Unprotected LM Disease

Hospital discharge to 1-month (n= 52)

SAT (%)	0
Non-Q-wave MI (%)*	0
Q-wave-Mi (%)	0
Emergency CABG (%)	0
Stroke (%)	0
Death (%)	0
MACCE (%)	0

Courtesy of T. Lefèvre, ACC2004

Left Main Taxus Registry

TAXUS for Unprotected LM Disease

6-month Follow-up (preliminary)

Patients (n)	21
Coronary angiogramm (n)	11
Left Main restenosis (n)	0
Reintervention target (n)	0
Reintervention non target (n)	4
Cardiac death (n)	1

Courtesy of T. Lefèvre, ACC2004

Left Main Taxus Registry

LM stenting with DES
Conclusion (march 2004)

1. DES do not solve the technical difficulties and approaches associated with distal LM involving LAD-LCx bifurcation lesions.

2. The problem of in-stent restenosis is reduced but still present mainly for distal left main and in diabetics.

ESC GUIDELINES

To improve the quality of clinical practice and patient care in Europe

EUROPEAN SOCIETY OF CARDIOLOGY

European Guidelines for Percutaneous Coronary Interventions

Chairman: ***Sigmund Silber (Germany)***

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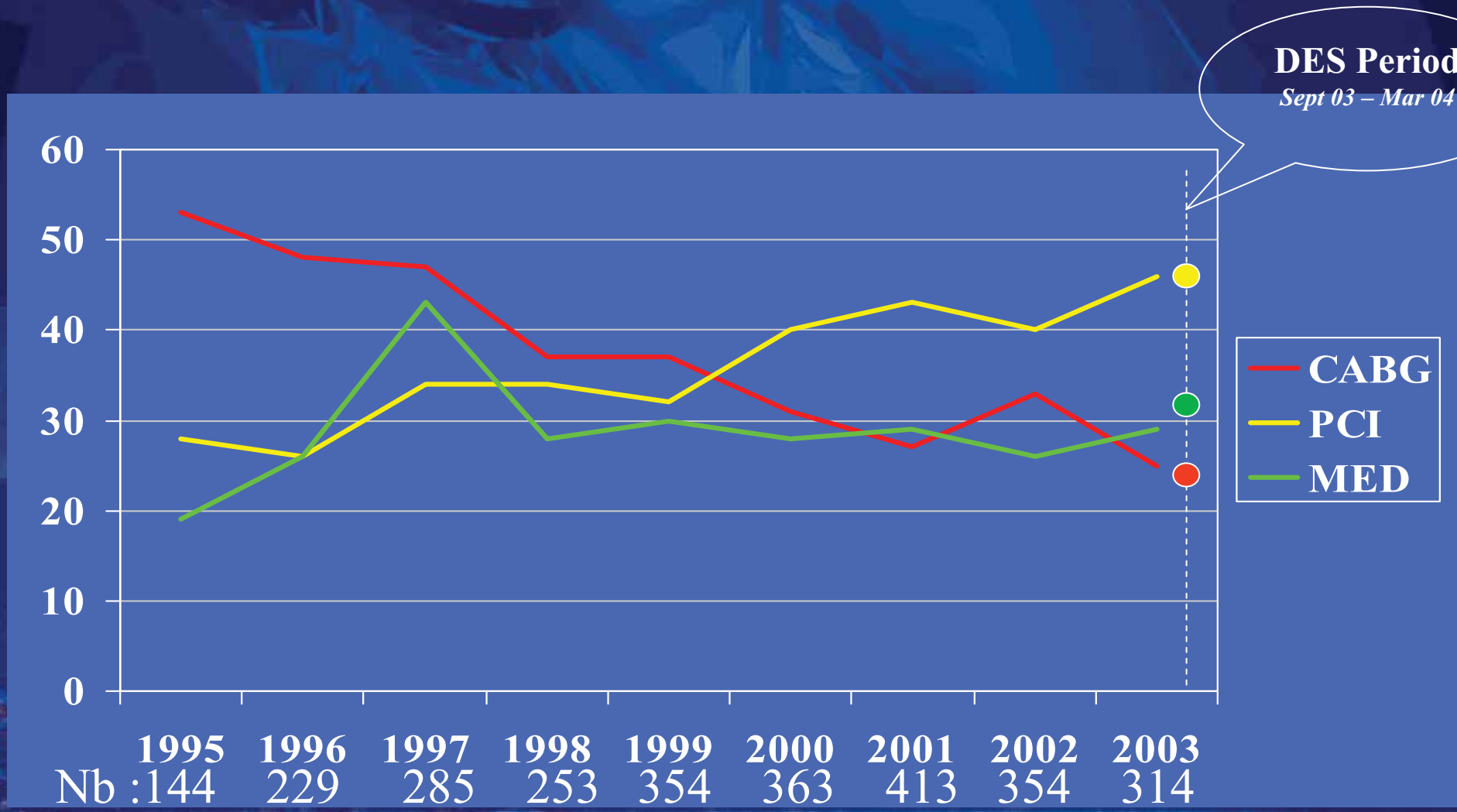
ESC Recommendations of PCI indications in stable CAD

Procedure	Indication	Recommendation	Studies for Levels A or B
Assuming suitable anatomy and patient's characteristics for PCI			
standard PCI	stable angina, class II, III or IV	I C	--
standard PCI	objective large ischaemia	I A	ACME ACIP
standard PCI	objective small (or absence of) ischaemia	II b B	AVERT
Specific subsets, assuming angina and/or ischaemia			
standard PCI (preferably with DES)	MV-D + diabetics	I C	--
standard PCI (preferably with DES)	chronic total occlusion	I C	--
standard PCI (preferably with DES)	unprotected LM	II b C	--
standard PCI	high surgical risk, incl. LV-EF < 35 % and diabetics	II a B	AWESOME

Left main disease



2003: PCI=1.8xCABG