Bifurcation and Left Main With Taxus

T. Lefèvre, Massy, France

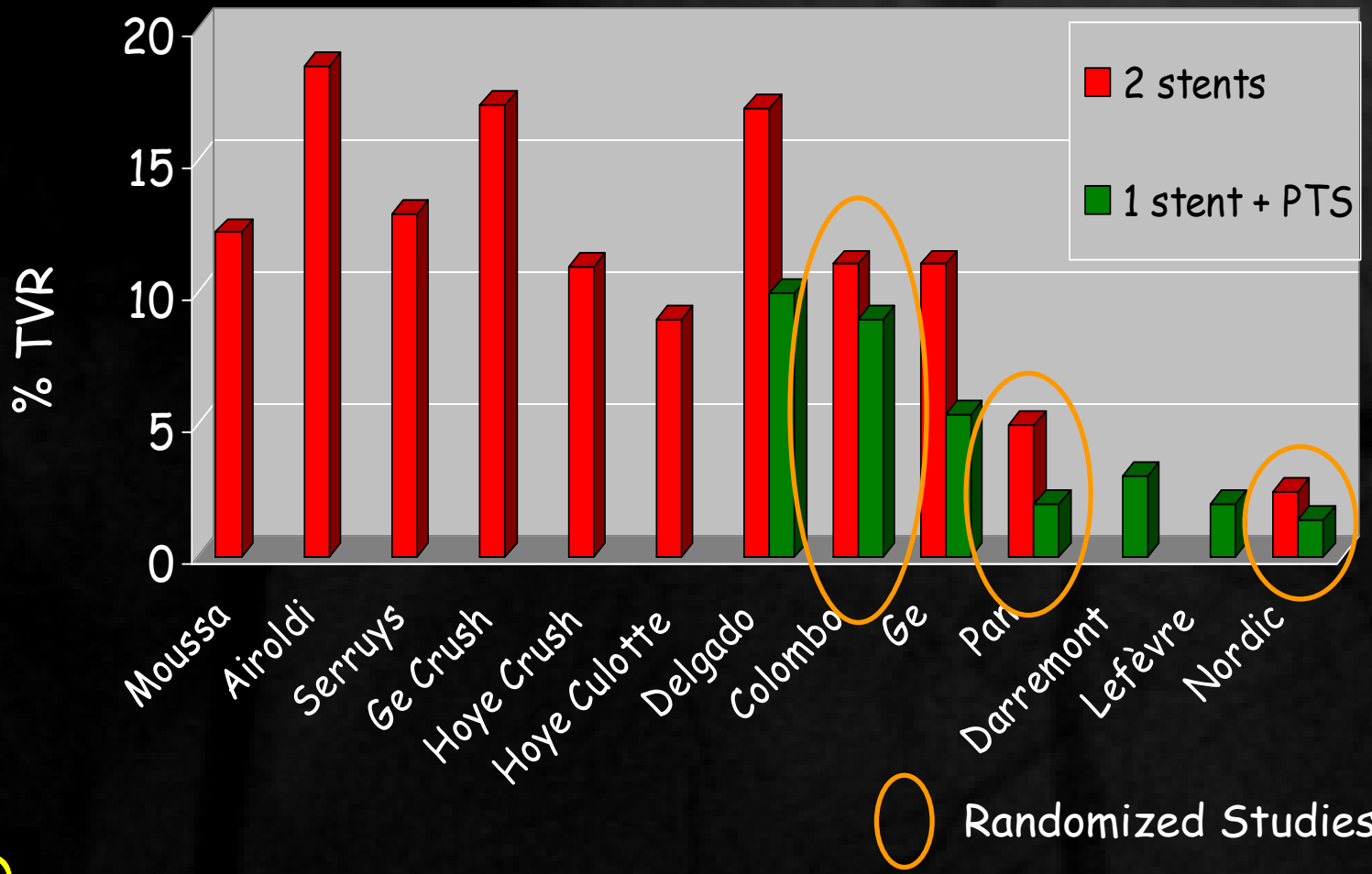
Taxus in Bifurcation Lesion

1. What Do We Know at The Era of DES ?

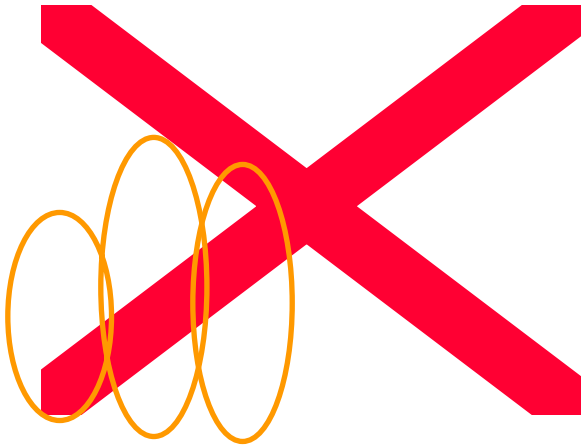
" Even true bifurcation lesions can be treated with one stent in the majority of cases … "

A. Colombo, AHA 2005

Efficacy (Clical Data)



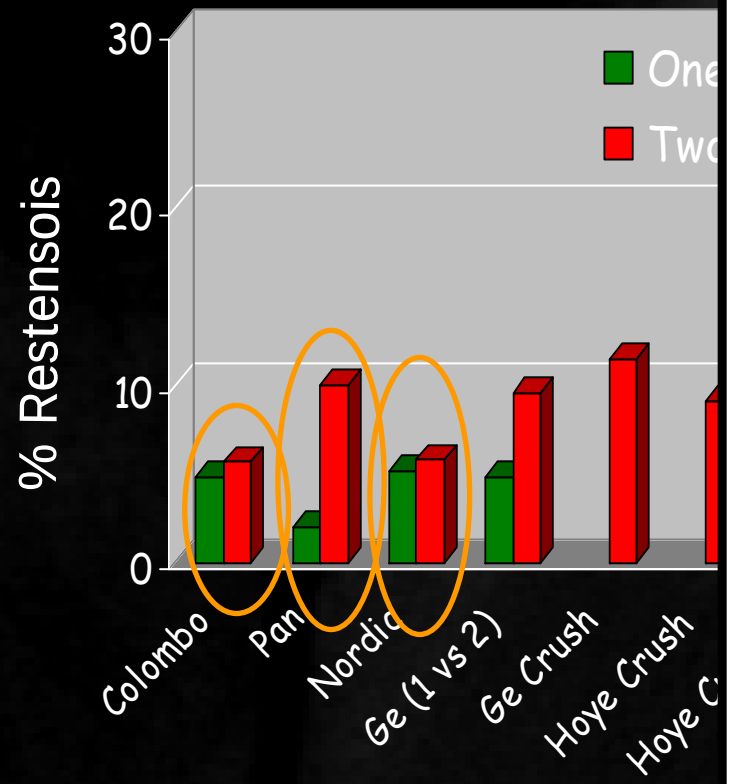
Efficacy (Angiographic Data)

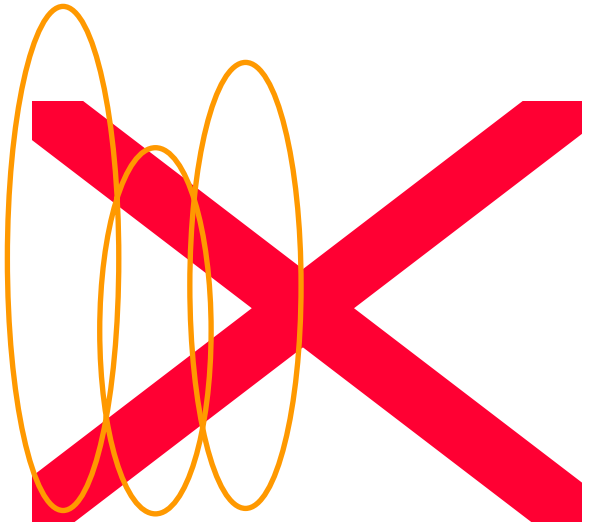


Main Branch

Randomized Studies

Efficacy (Angiographic Data)



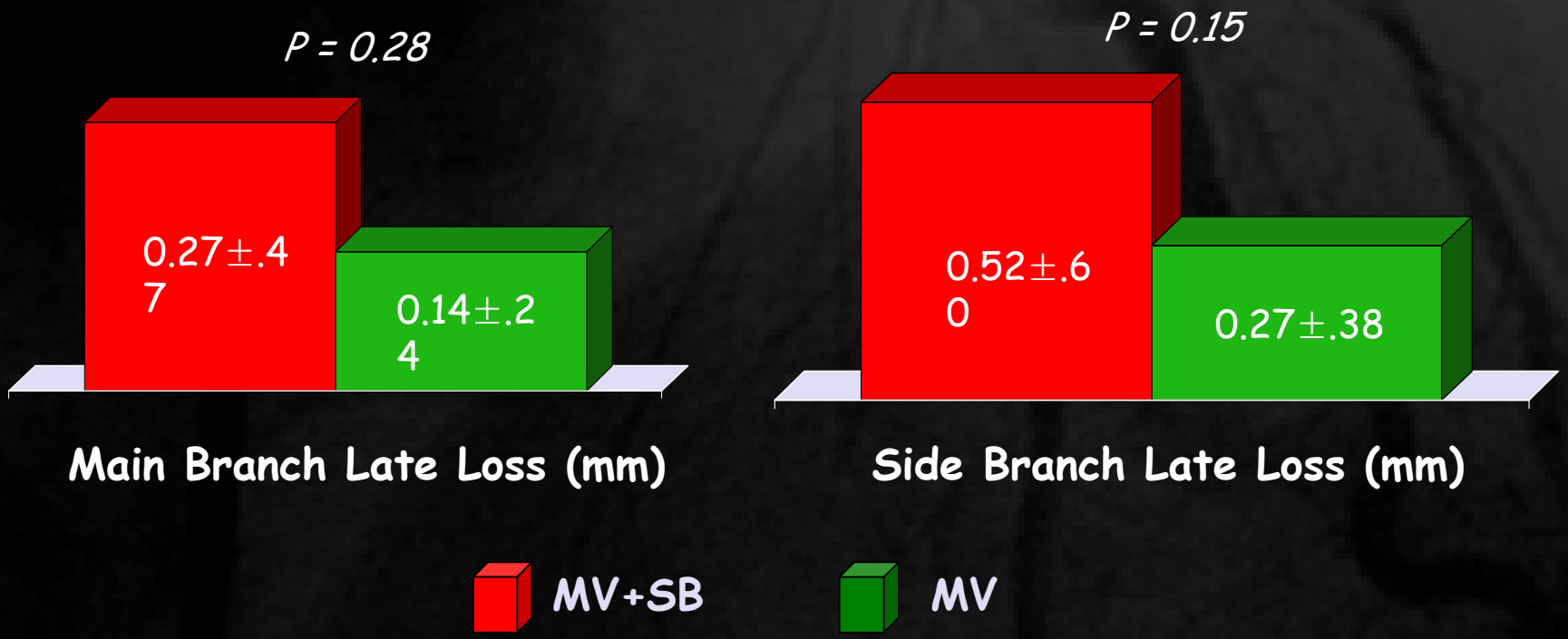


Main Branch

Randomized Studies

Late Loss in MB and SB

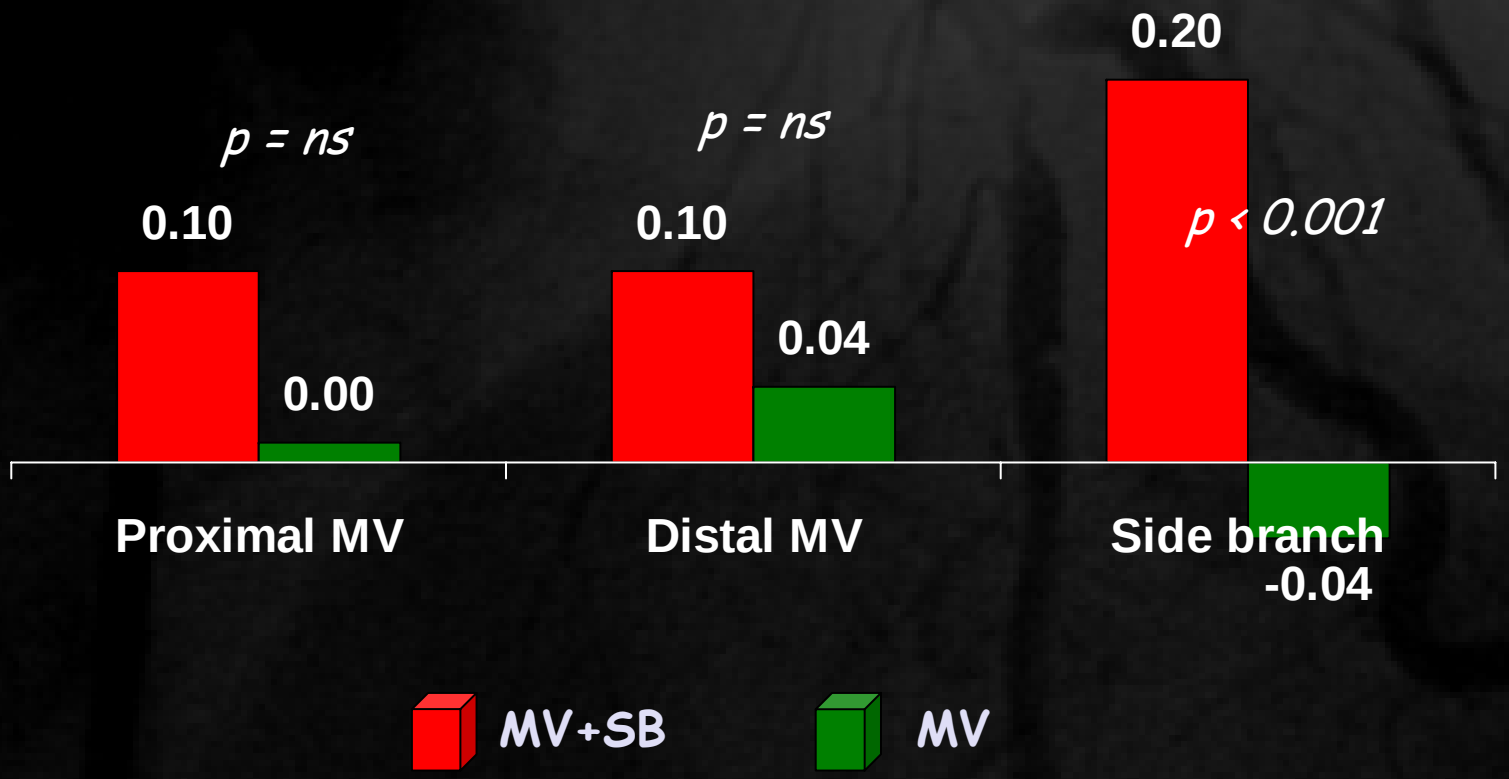
Bifurcation Sirolimus Study



Colombo et al. Circulation 2004; 109: 1244-49

Late Loss in MB and SB

Nordic Study



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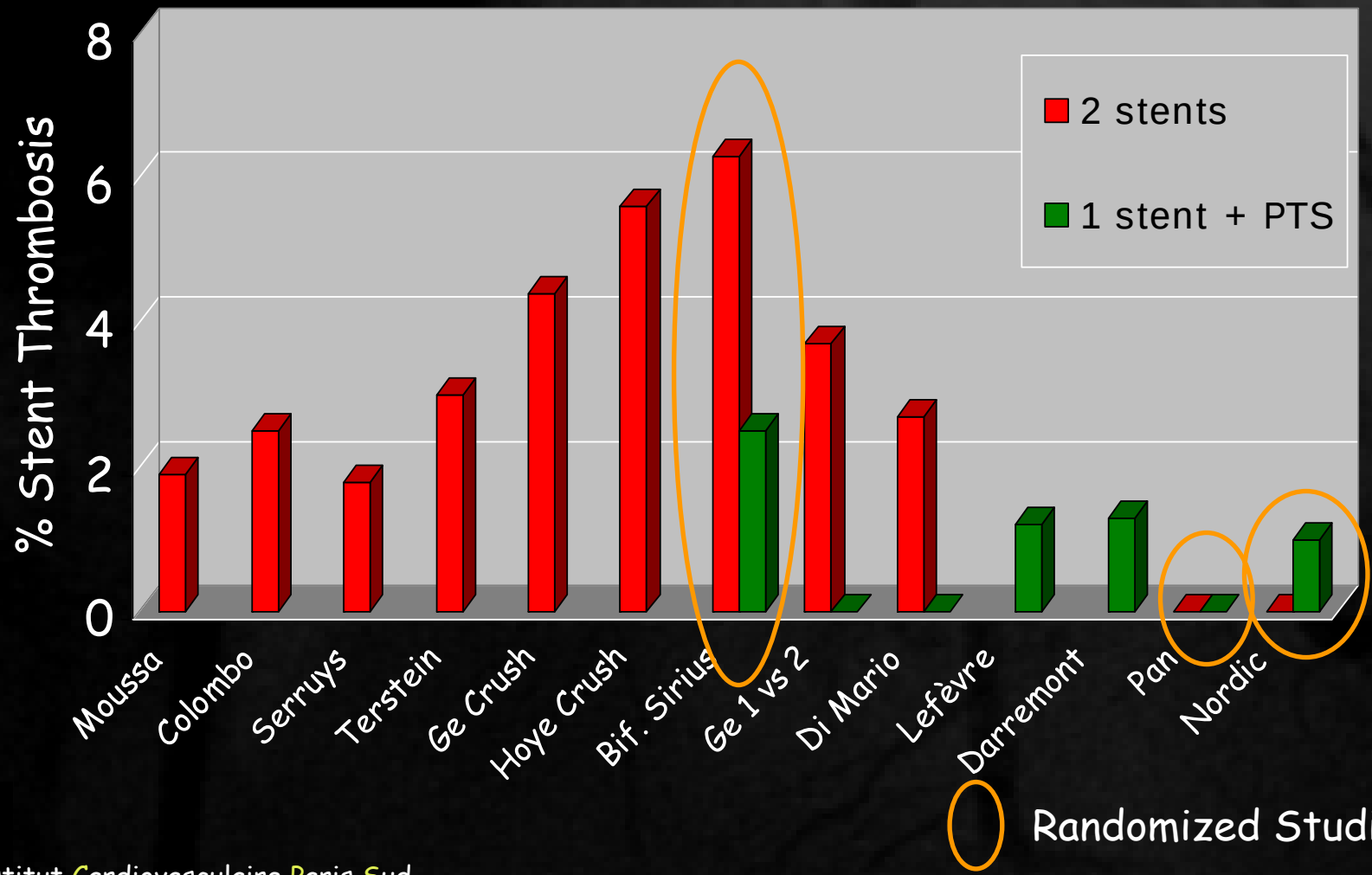
Terje K Steigen. Circulation 2006;114;1955-1961

Safety


% Stent Thrombosis
0
2
4
6
8
2 stents
1 stent + PTS
Moussa
Colombo
Serruys
Terstein
Ge Crush
Hoye Crush
Bif. Sirius
Ge 1 vs 2
Di Mario
Lefèvre
Darremont
Pan
Nordic
Randomized Studies

2. PES in Bifurcation Lesions ?

SURF Registry : design

- ✓ One year (2004) observationnal and prospective registry
- ✓ 3 French experienced centers
- ✓ Consecutive bifurcation lesions treated :

  with Taxus Express2

  using an homogeneous strategy of treatment : Provisional Side branchT-stenting
- ✓ Acute angiographic and clinical results
- ✓ Clinical status at 12 months

The consensus conclusion

... the simple approach of drug-eluting stenting of the main branch with provisional stenting of the side branch remains a reasonable option with a very acceptable profile of safety and effectiveness.

Williams DO. Abbott JD. JACC 2005; 46: 621-4.

...That was the SURF registry with Taxus attempt to prove.

SURF : Clinical Characteristics

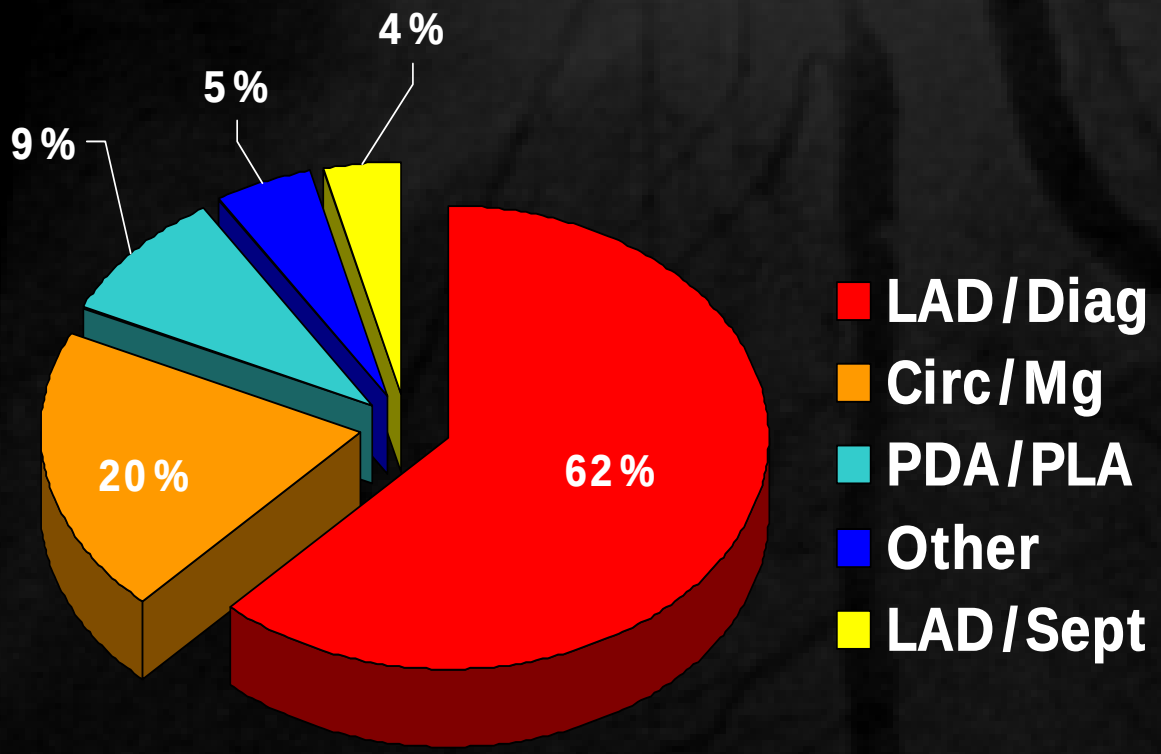
Patients (n)	218
Age (years)	66±11
Male gender (%)	80
Risk factors (%)	
Diabetes	28
Hypertension	56
Hypercholesterolemia	65
Smoker	39
Family history	29

SURF : Clinical Characteristics (cont)

Previous MI (%)	12
Previous PCI (%)	28
Previous CABG (%)	4
Unstable angina (%)	36
Recent MI (%)	9
Silent ischemia (%)	9
Multi vessel disease (%)	63.3
Diseased vessels (n)	1.88±0.78
EF (%)	61±12

SURF : Bifurcation Lesion location

218 patients with 222 bifurcation lesions
True Bifurcation Lesions 73%
T Shape (> 70°) in 21%



SURF : QCA data pre procedure

218 patients with 222 bifurcation lesions

	Main Branch	Side Branch
RVD (mm)	2.85±0.39	2.29±0.35
MLD (mm)	0.76±0.45	1.14±0.71
% Stenosis	75.3±13.4	51.4±29.6
L. Length (mm)	12.7±5.3	5.5±5.2

SURF : Procedural Data

Radial approach (%)		68
Guiding size	6F (%)	97
	7F (%)	3
Gp2b3a inhibitors (%)		6
Other treated vessel (n)		1.05±1.01
Total stent length (mm)		44±13

SURF : Procedural Data (cont.)

Main Branch Direct stenting (%)	47
Main Branch stent length (mm)	20.5±5.5
Side Branch predilatation (%)	18
Side Branch stented (%)	14
Side Branch stent length (mm)	11.3±2.8
Jailed guide wire (%)	77
Final Kissing Balloon (%)	88

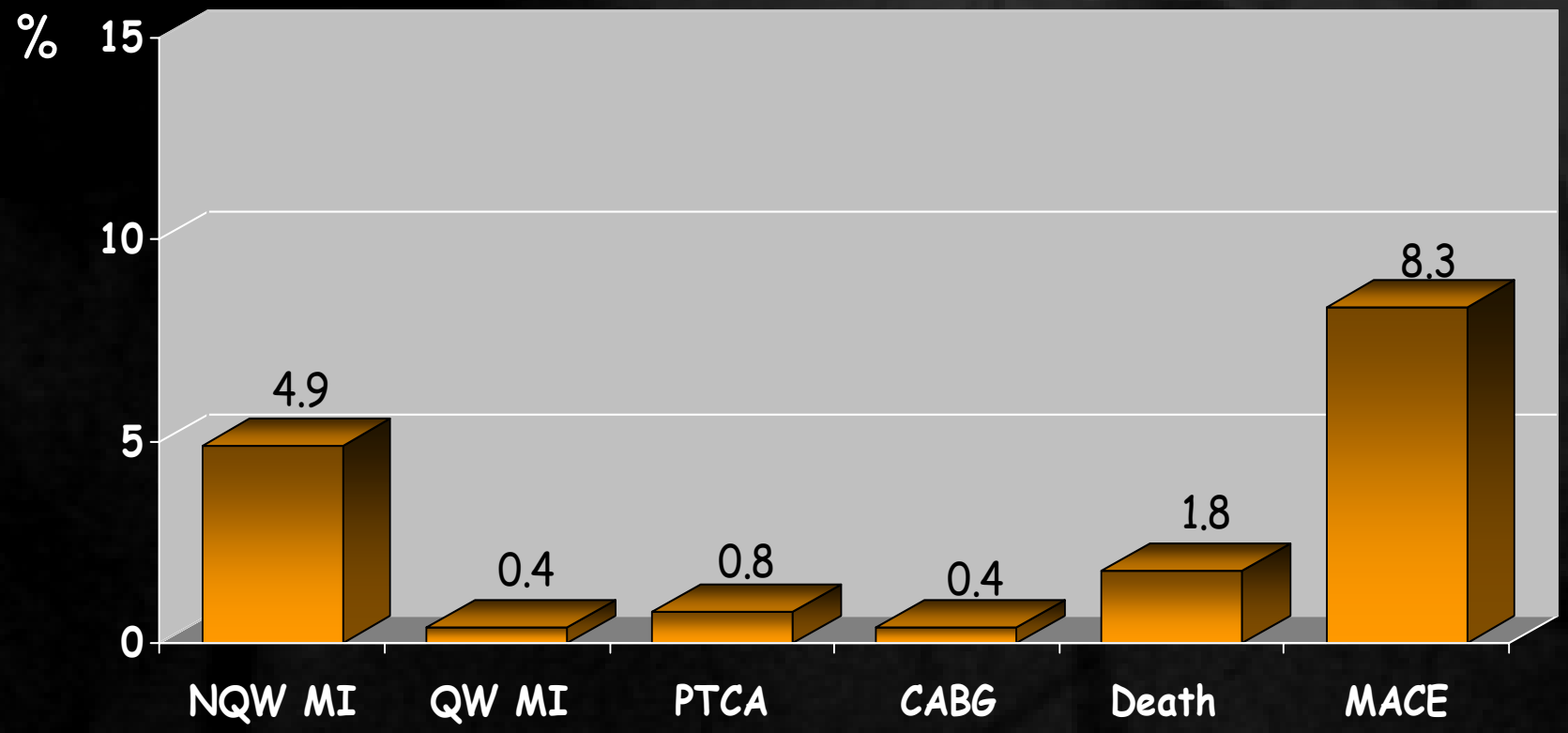
SURF : Post procedural data

	Main Branch	Side Branch
Final MLD (mm)	2.72±0.49	1.98±1.70
Final % Stenosis (%)	7.3±6.7	21.9±20.5
Angiographic success (%)	99.1	86*

** Residual stenosis ≤ 40%*

SURF : Clinical Results

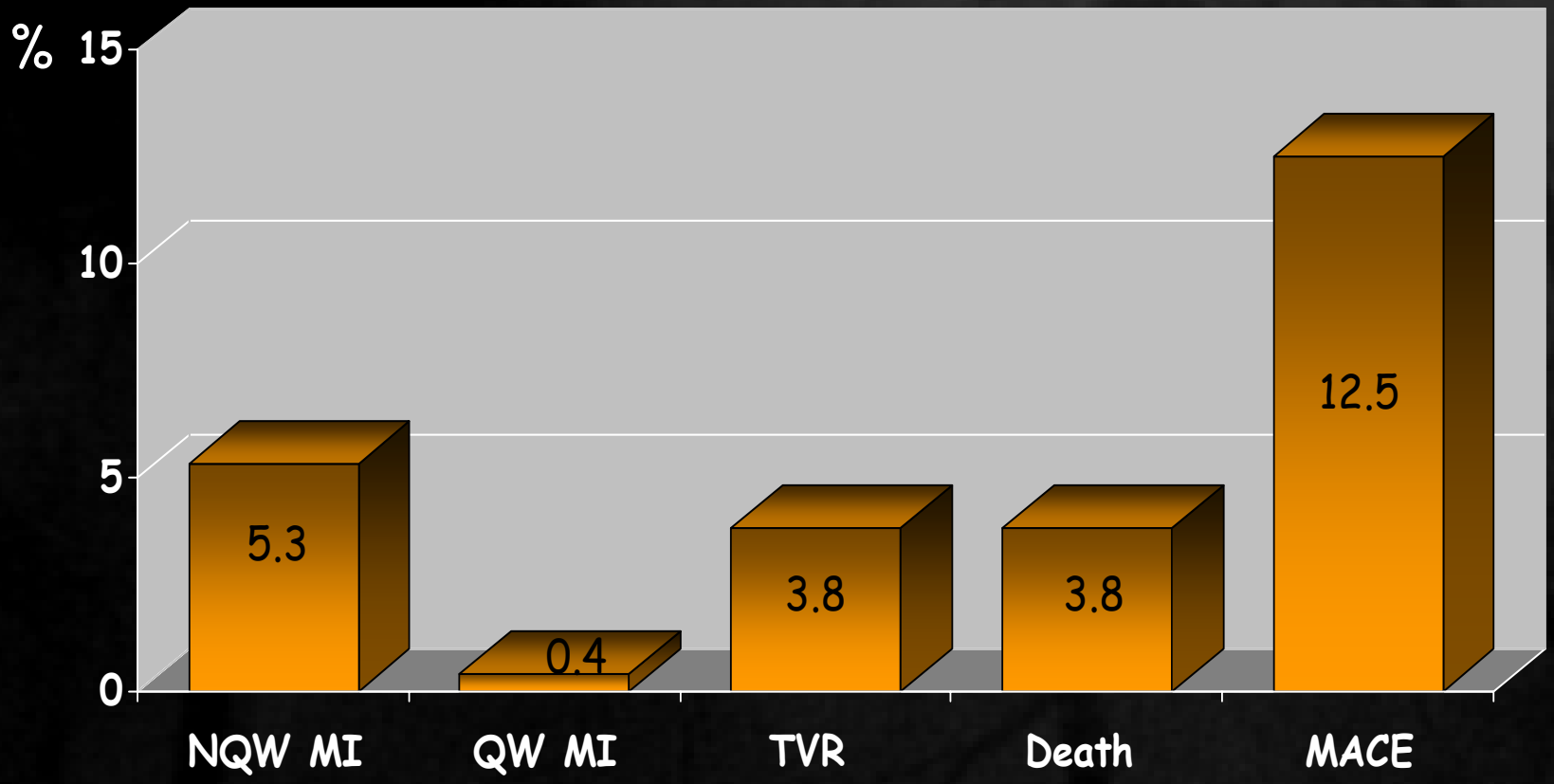
In-hospital Outcome (n=218/218)



Hierarchical ranking

SURF : Clinical Results

12 months follow-up (n=210/218) = 96%



Hierarchical ranking

SURF : Clinical Results

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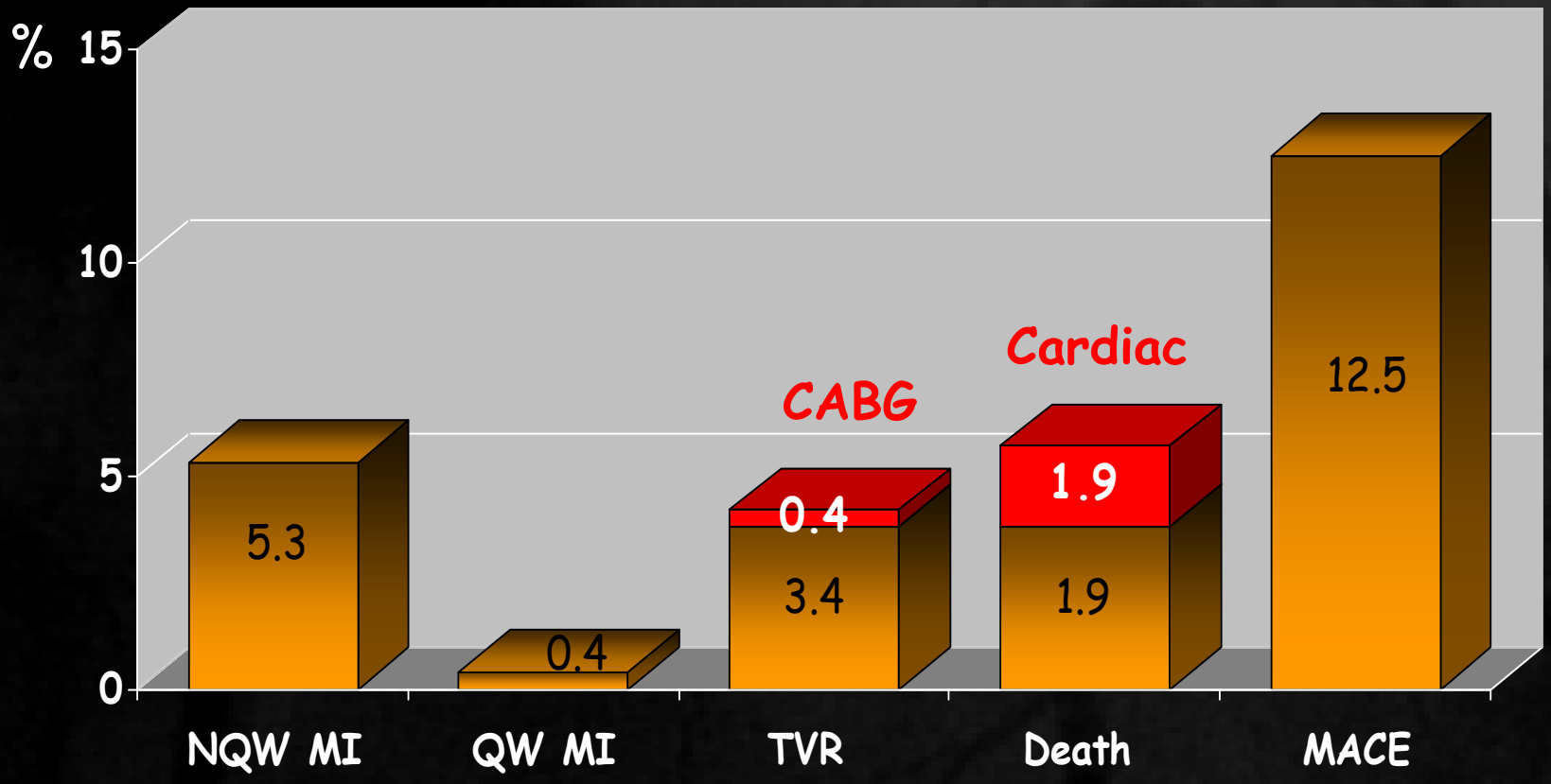


Hierarchical ranking

Predictive Factors of Death at 12 months

Death=8 patients

	OR	95%CI	P value
Age	2.94	1.57-4.59	0.08
SB Lesion Length	4.91	3.76-6.36	0.02
MB Lesion Length	7.20	5.34-9.28	0.008

Predictive Factors of TVR at 12 months

TVR=8 patients

	OR	95%CI	P value
Diabetes	5.09	3.37-6.97	0.02
SB Lesion Length	1.11	0.76-1.67	0.20
SB Stent	1.10	0.68-1.78	0.27
Bifurcation Type	0.59	0.23-0.98	0.61

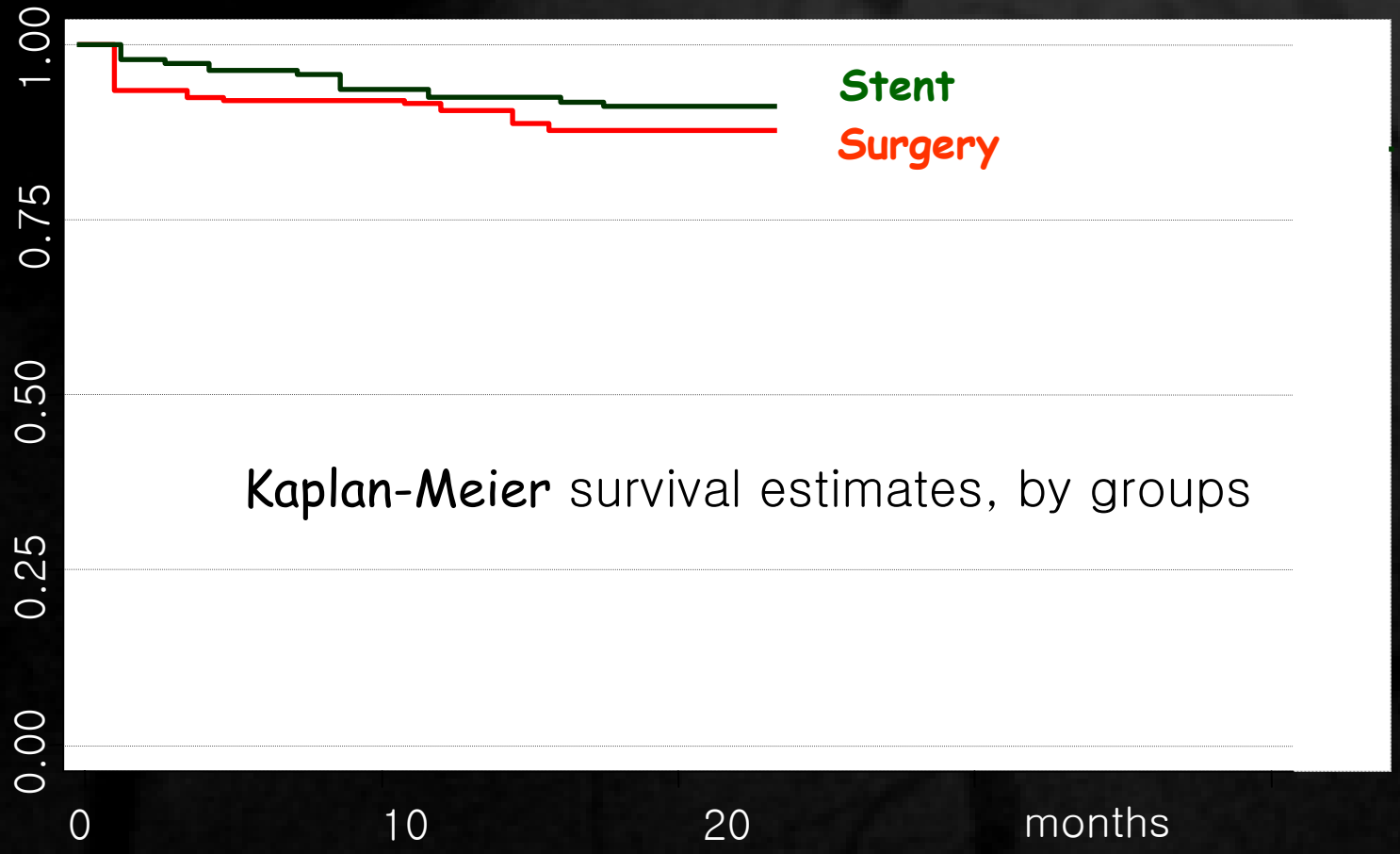
Conclusion

- ✓ In the « real life », use of the Taxus Express stent in the treatment of bifurcation lesion with a «simple» strategy of provisional side branch stenting, is safe and effective.
- ✓ Lesion Length of both branches have to be highly considered before stenting !

3. PES in Left Main Disease ?

French Registry of LM Coronary Treatment

BMS May 2001-April 2002



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Silvestri et al ESC 2003

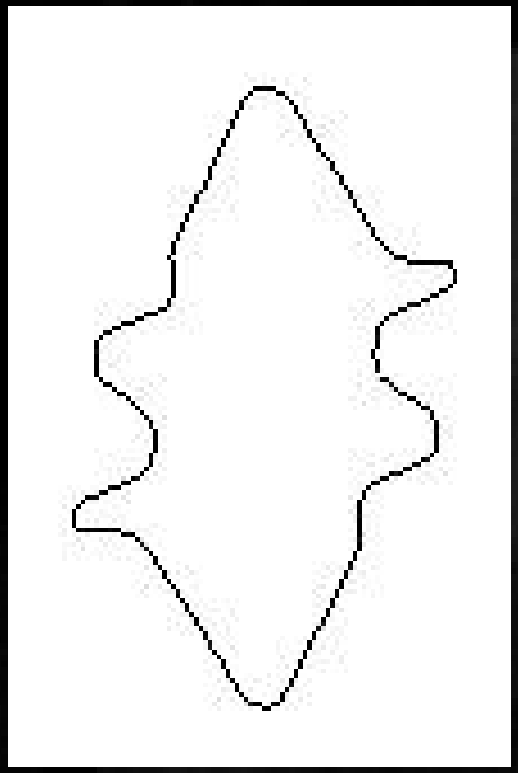
French Registry of LM Coronary Treatment

One-year Outcome

	Stent	CABG	p value
Patients (n)	192	230	-
Poor surgical candidates (%)	44.2	14.3	<0.001
Follow-up obtained (%)	96.8	94.8	NS
MI (%)	1.6	6.9	0.017
Stroke (%)	0	2.3	0.094
Death (%)	9.6	11.4	NS
TVR left main (%)	13.4	3.7	0.001
Any PCI (%)	28.5	3.7	<0.001

Silvestri et al ESC 2003

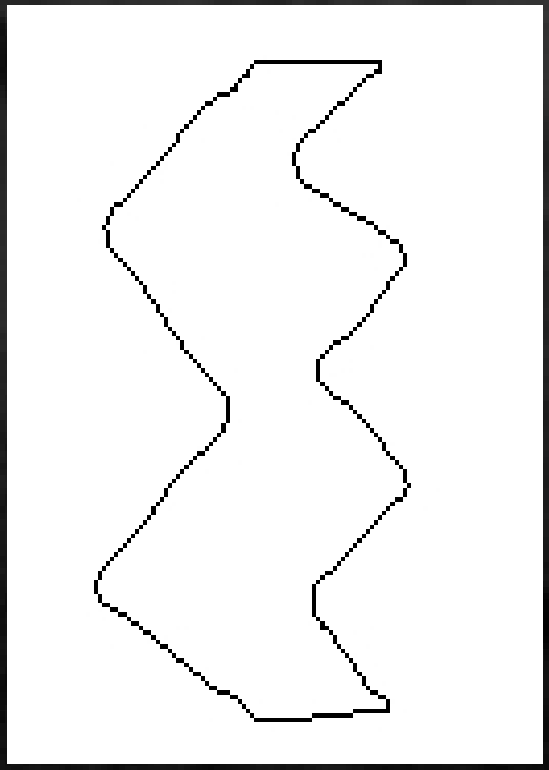
DES for LM Bifurcation Lesions



Cypher 3.5

Max. strut diam. 3.0 mm

Max. stent diam. 4.75 mm



Taxus 3.5

Max. strut diam. 3.7 mm

Max. stent diam. 4.25 mm

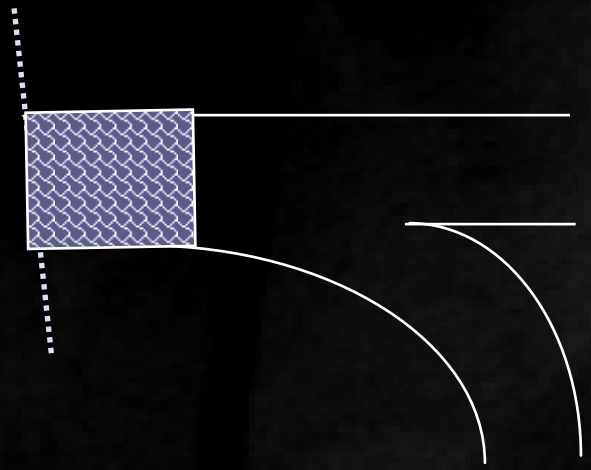
French Left Main Taxus Pilot Study

Design of the Study

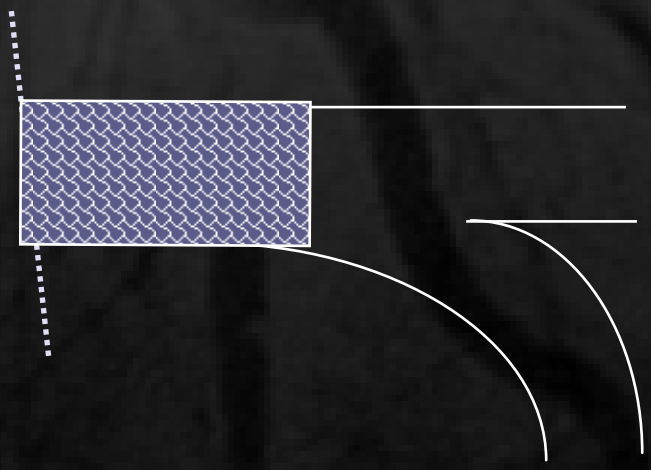
- ✓ May 2003–June 2005
- ✓ Feasibility and Safety Study
- ✓ 4 experienced centers
- ✓ Consecutive patients with de novo lesions
- ✓ Informed consent
- ✓ Standardized approach
- ✓ Plavix + Aspirin $\geq$ 6 months

French Left Main Taxus Pilot Study

Strategy and Lesion Type



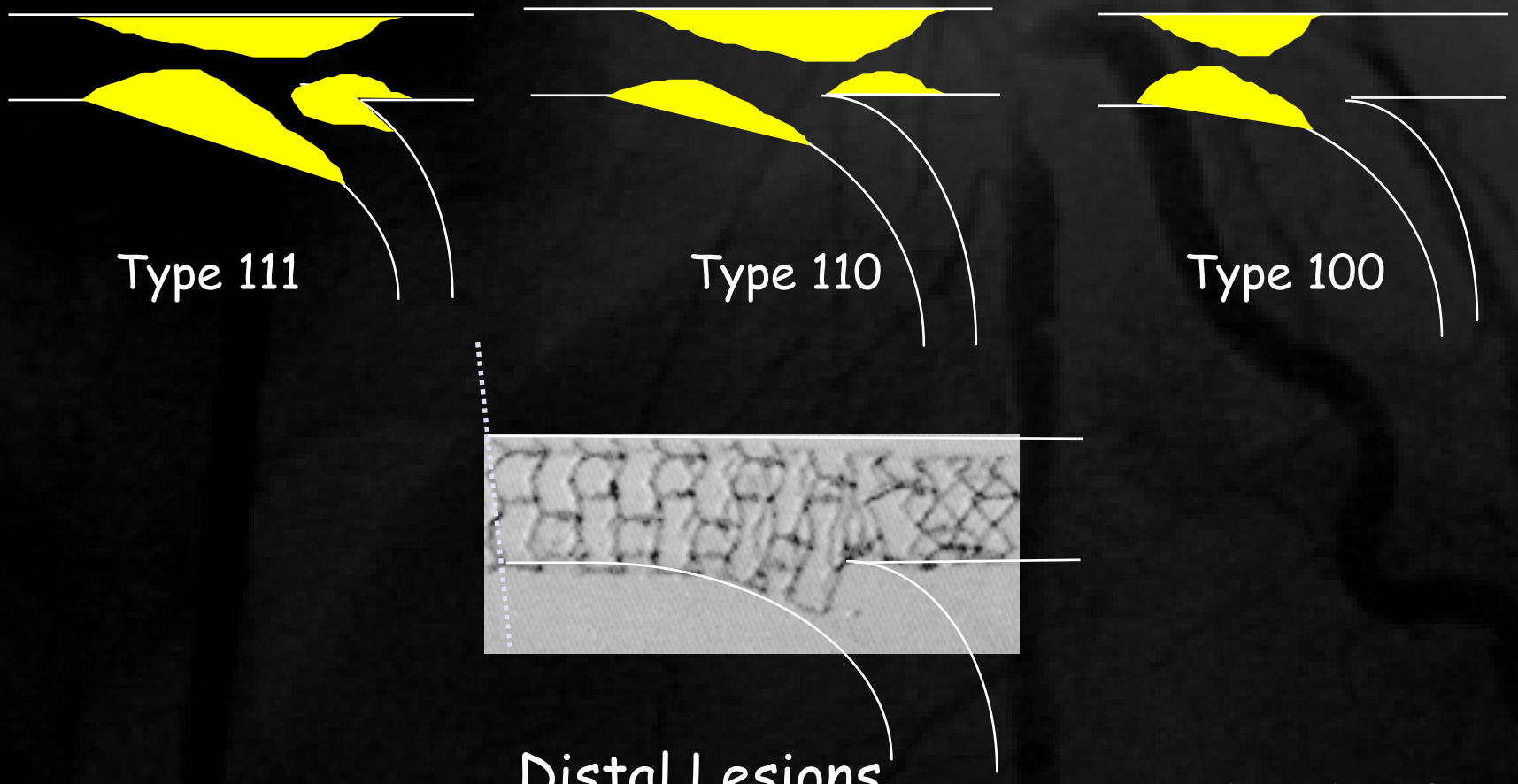
Ostial Lesion



Mid shaft Lesion

French Left Main Taxus Pilot Study

Strategy and Lesion Type*



** Medina Classification*

French Left Main Taxus Pilot Study

Design of the Study (cont.)

Follow-up

- ✓ Angiographic recommended at 6 months
- ✓ Clinical at 1 and 6-8 months, 1, 2, 3 years

Exclusion criteria

- ✓ Acute MI (ST and non ST)
- ✓ Cardiogenic shock

French Left Main Taxus Pilot Study

Clinical Characteristics

Patients (n)	291
Age (years)	68.8±11.4
Male gender (%)	76.6
Risk factors (%)	
Diabetes	28.9
Hypertension	65.5
Hypercholesterolemia	63.2
Smoker	43.0
Family history	19.2
Body Mass Index > 30	19.4
Metabolic syndrome	18.6

French Left Main Taxus Pilot Study

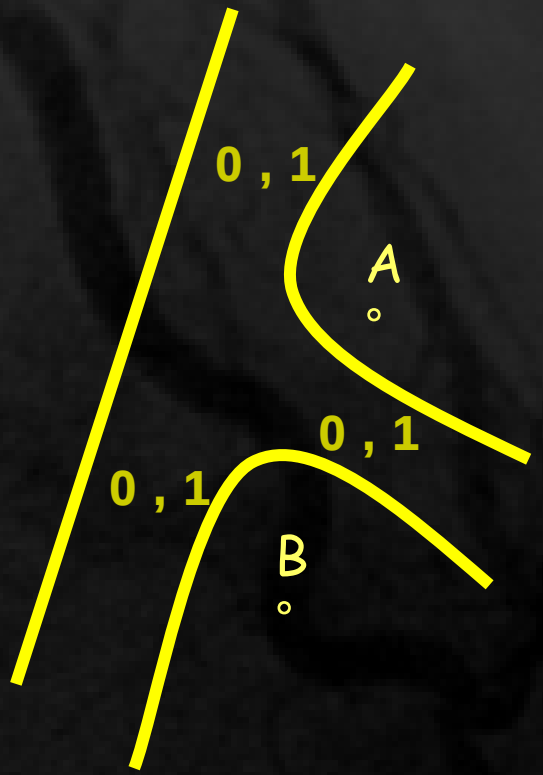
Clinical Characteristics (cont.)

Previous MI (%)	11.3
Previous PCI (%)	19.9
Previous CABG (%)	1.0
Unstable angina (%)	35.9
Recent MI (%)	6.5
3 vessel disease (%)	30.9
EF (%)	61±13
Additive Euroscore	4.8±3.4
Estimated CABG mortality (%)	**6.4±10.5**

French Left Main Taxus Pilot Study

Distal Left Main in 78.4% of cases

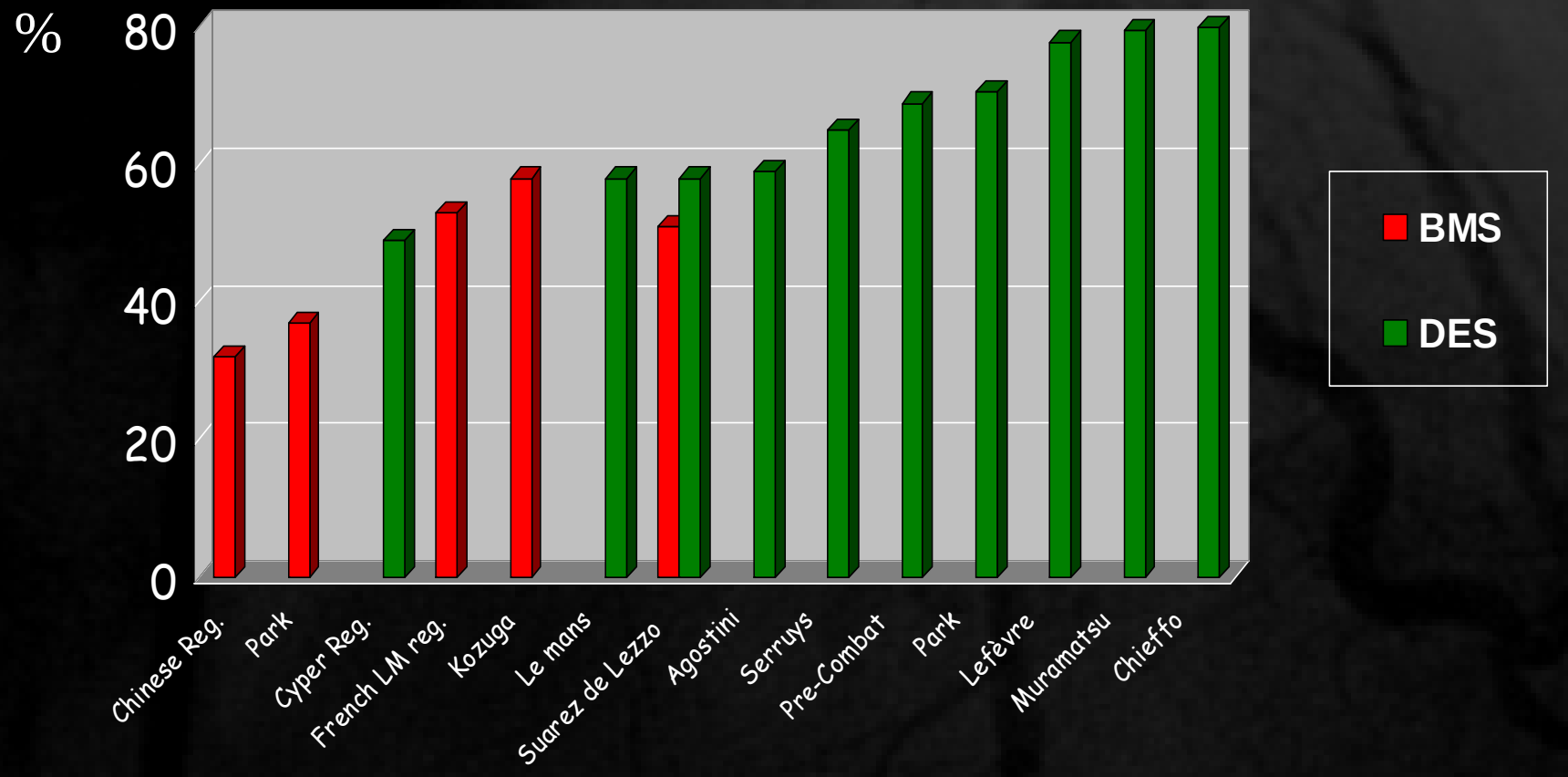
Y shape (%)	62.0
T shape* (%)	38.0
Type 1,1,1 (%)	51
Type 1,1,0 (%)	15
Type 1,0,0 (%)	16
Type 1,0,1 (%)	2
Type 0,1,1 (%)	9
Type 0,1,0 (%)	8
Type 0,0,1 (%)	2



Medina Classification

** T shape= angle B > 70°*

High Frequency of Distal LM Location



French Left Main Taxus Pilot Study

Procedural Data

Gp2b3a inhibitors (%)	4.2
Radial approach (%)	57.0
Guiding size 6 Fr (%)	86.3
7 Fr (%)	12.7
IABP (%)	4.5
Other treated vessel (%)	74.5
Other treated vessels (n)	1.18±0.90
Total stent length (mm)	53±23
Procedure (min.)	58.3±31.2
Contrast medium (ml)	250±138

French Left Main Taxus Pilot Study

QCA analysis pre-PCI and Procedural Data

Left main reference (mm)	3.66±0.50
LAD reference (mm)	3.22±0.57
Circumflex reference (mm)	2.81±0.45
% stenosis left main (%)	69.7±11.9
Left main stent (n)	1.07±0.29
Left main stent length (mm)	18.1±6.3
Left main stent diameter (mm)	3.42±0.19
Final balloon diameter (mm)	3.54±0.32

French Left Main Taxus Pilot Study

QCA Analysis post procedure

Left main reference (mm)	3.82±0.43
Left main MLD (mm)	3.44±0.48
Left main residual stenosis (%)	7.1±7.8
Circ. reference (mm)	3.21±0.54
Circ. MLD (mm)	2.82±0.49
Circ. residual stenosis (%)	8.9±10.7
Angiographic Success (%)	99.6

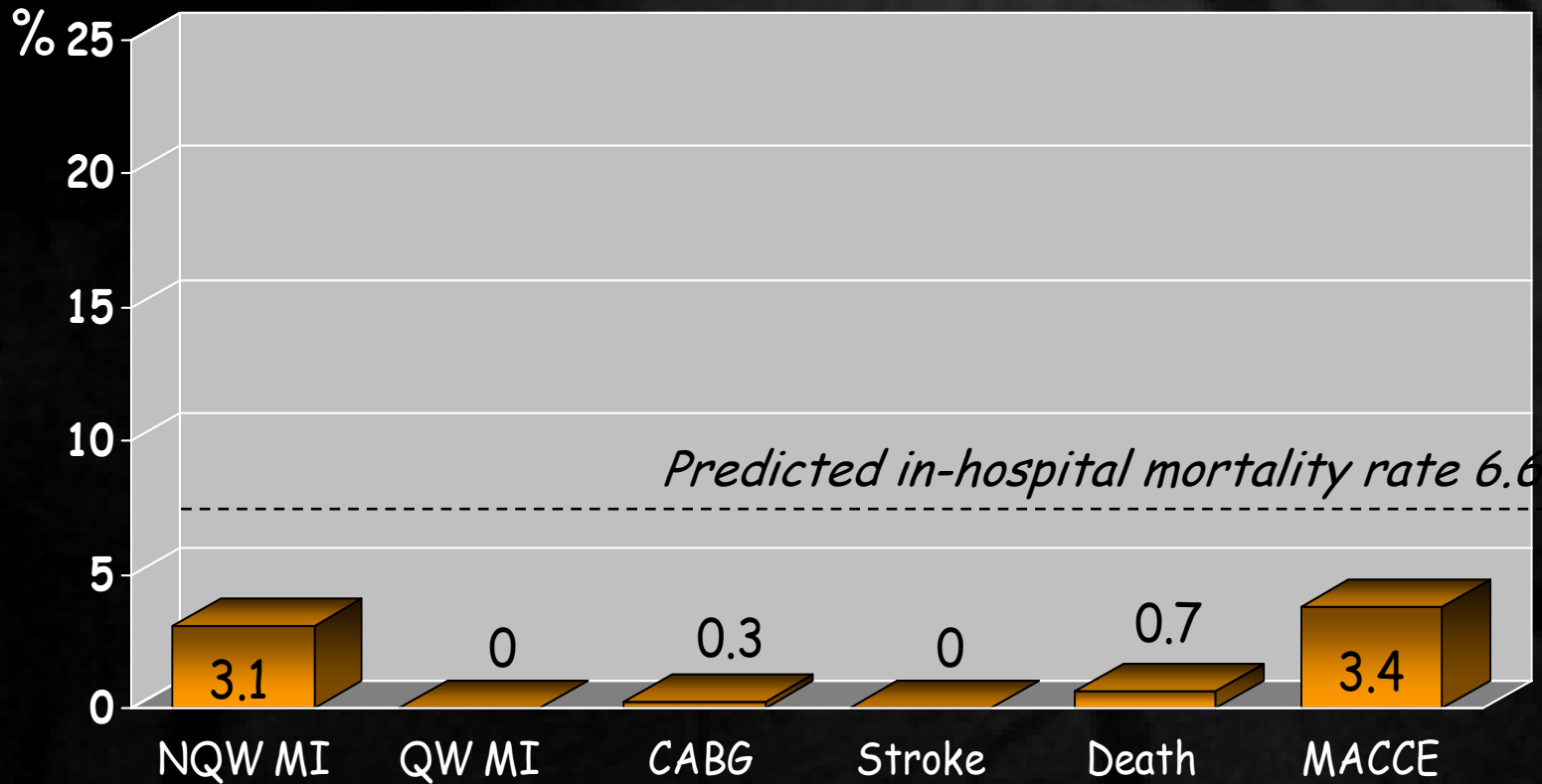
French Left Main Taxus Pilot Study

Distal left main in 77.9% of cases

Provisional SB T-stenting (%)	92.0
Systematic T stenting (%)	7.6
V Stenting (%)	0.4
Side branch stented (%)	42.5
Side branch stent length (mm)	13.8±5.5
Side branch stent diameter (mm)	3.04±0.33
Final Kissing balloon (%)	97.3

French Left Main Taxus Pilot Study

In-hospital Outcome* (n=291/291, 4.6±3.6 days)

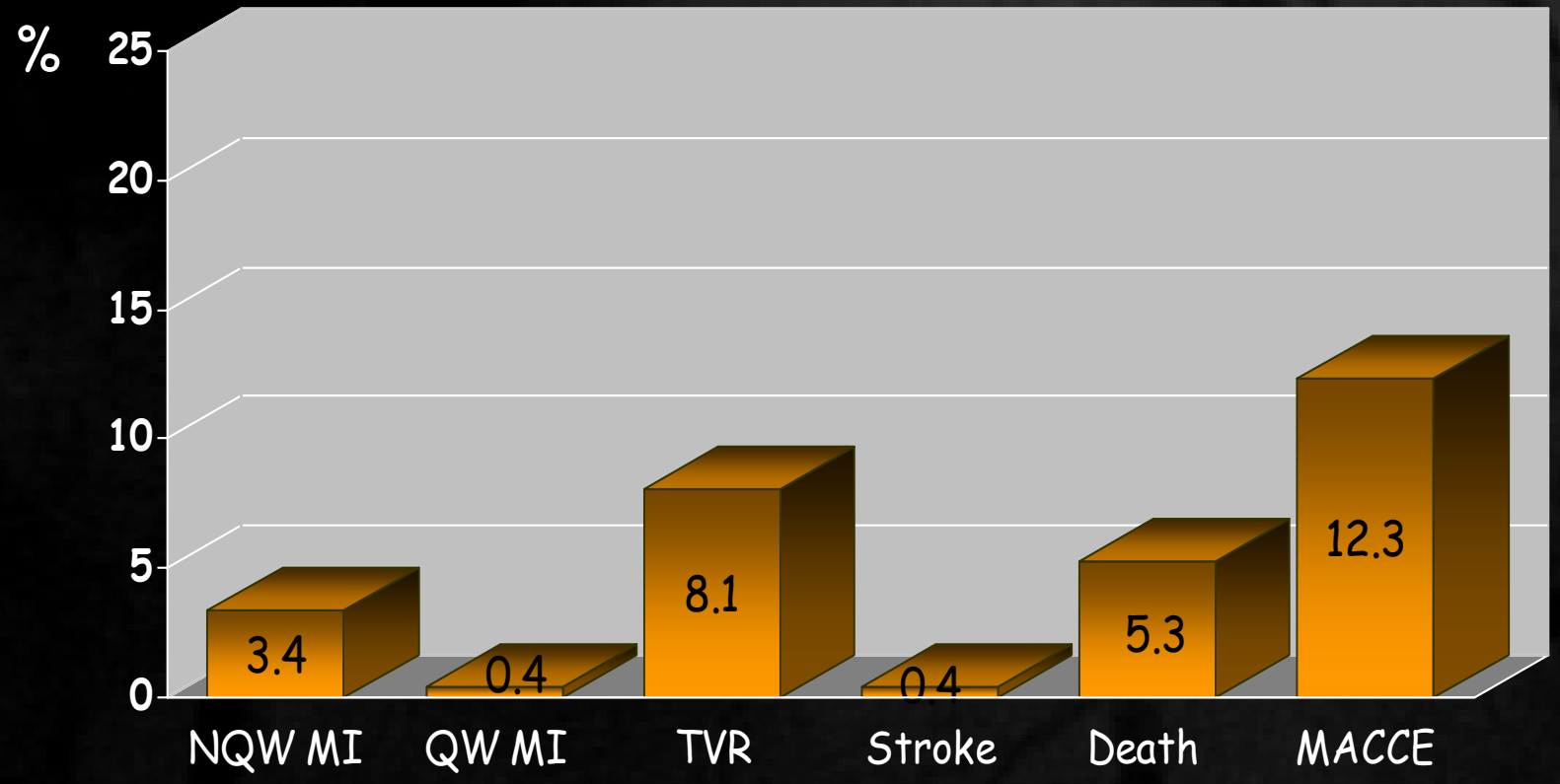


(CPK > 3 times normal value)

* Non Hierarchical Ranking

French Left Main Taxus Pilot Study

12 months' F-Up (284/291: 97.6%, 14.0±3.0 months)



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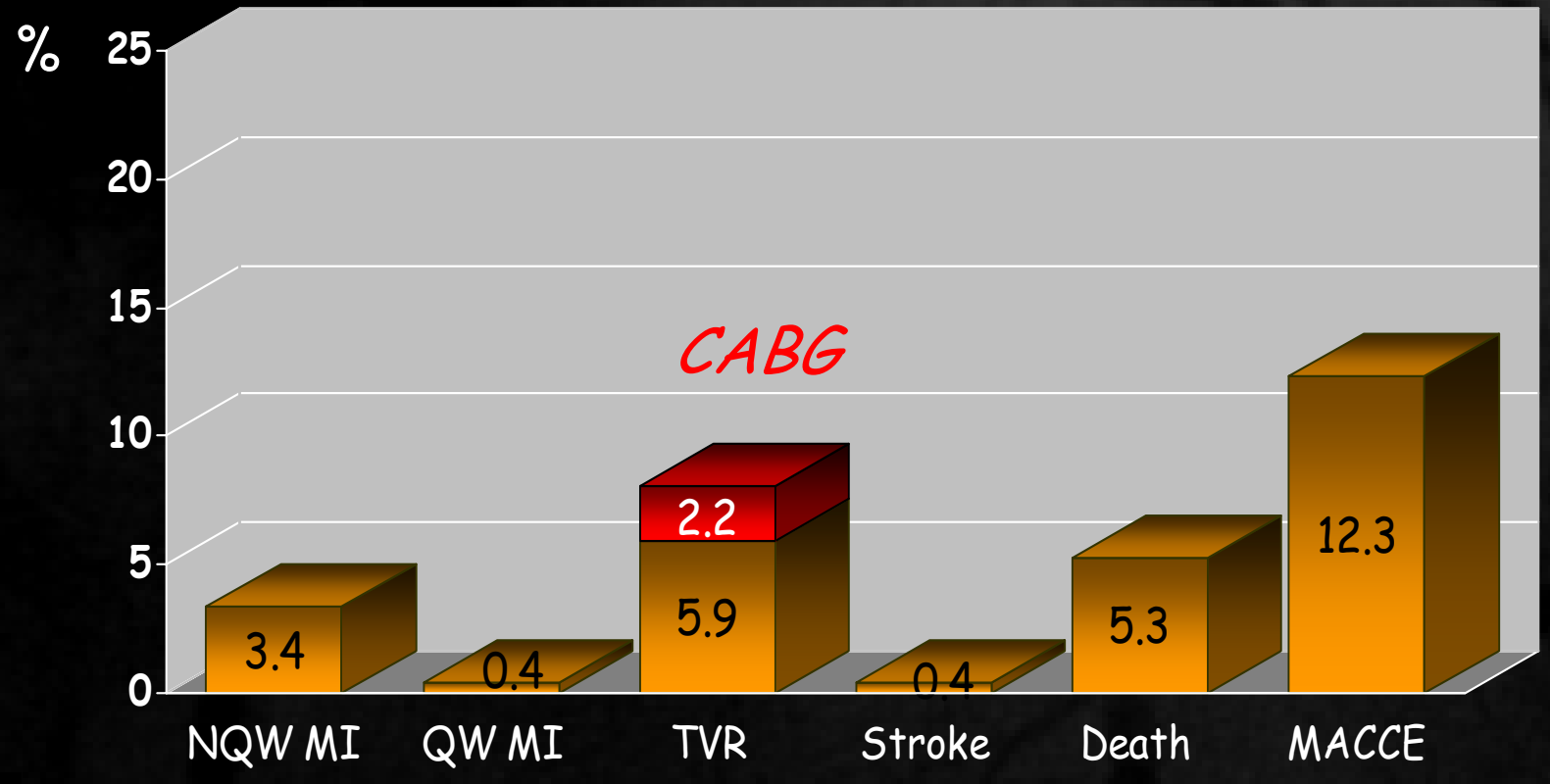
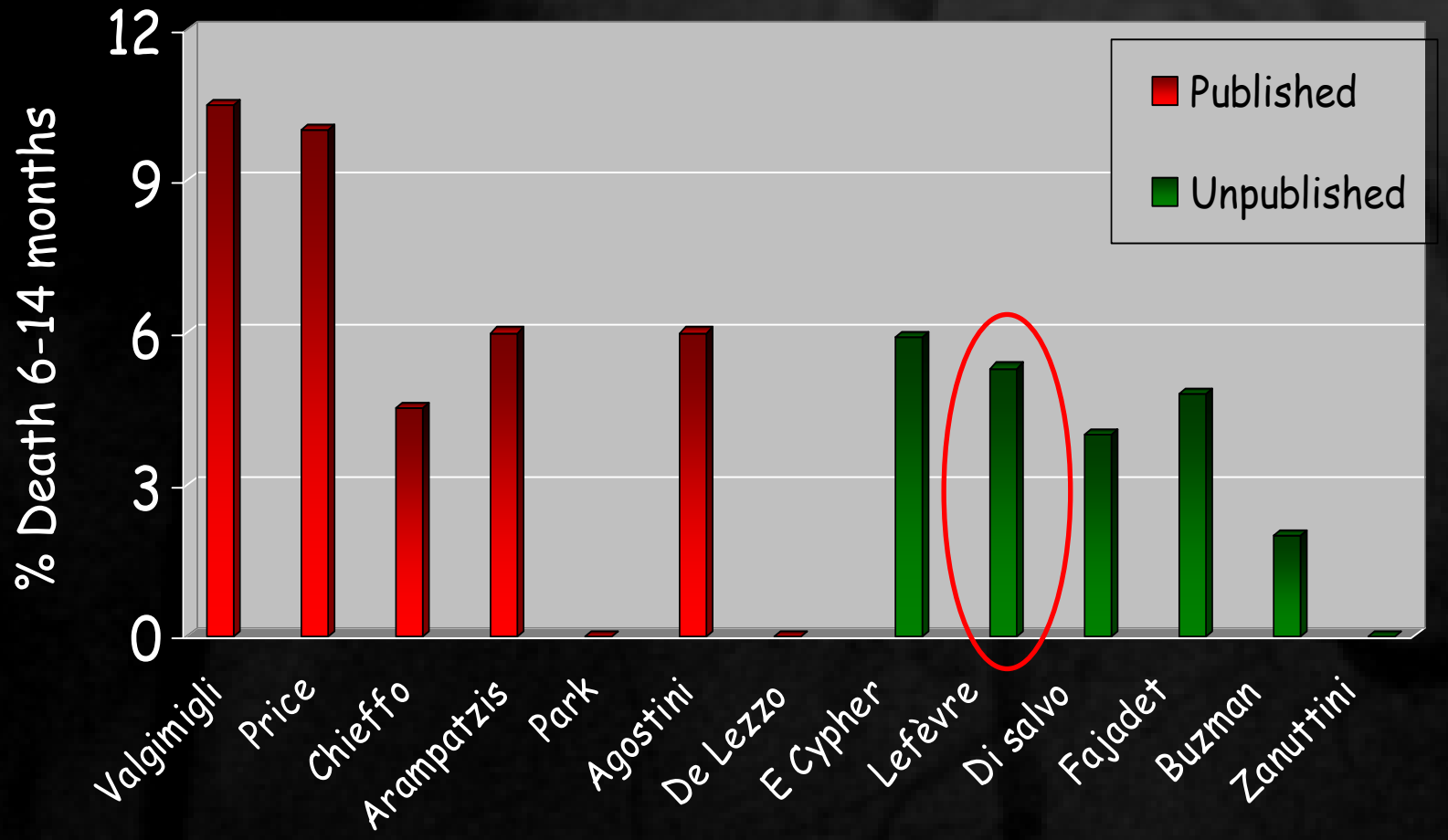
French Left Main Taxus Pilot Study

12 months' F-Up (284/291: 97.6%, 14.0±3.0 months)



* Non Hierarchical Ranking

DES for Left Main Stenting and Death



LM CABG: Mortality at 12 Months

Year	Study	N	CABG	Mortality
2001-02	French LM	230	40% AR	11.4%
2001-03	Buszman	61	47% LIMA	4.9%
1997-03	Lu	1197	On/Off	5%
1999-02	Beauford	234	On Pump	14%
1999-02	Beauford	420	Off Pump	6%

French Left Main Taxus Pilot Study

Cause of death at 12±2 months

Cardiac (3.2%)

✓ AT during the procedure	1
✓ Pulmonary oedema during dialysis, 2 months	1
✓ Sudden death, 8 days, 11 weeks, 2 and 10 months	4
✓ LAD restenosis, 10 months, Embolisation during PCI	1
✓ Mid Circ restenosis, 14 month, death 48 H after PCI	1
✓ Q wave MI, 9 months	1

Non cardiac (2.1%)

✓ Severe groin hematoma, day 2	1
✓ Pulmonary infection, 4 months and 11 months	2
✓ Stroke at 5 months	1
✓ Cancer at 4 and 7 months	2

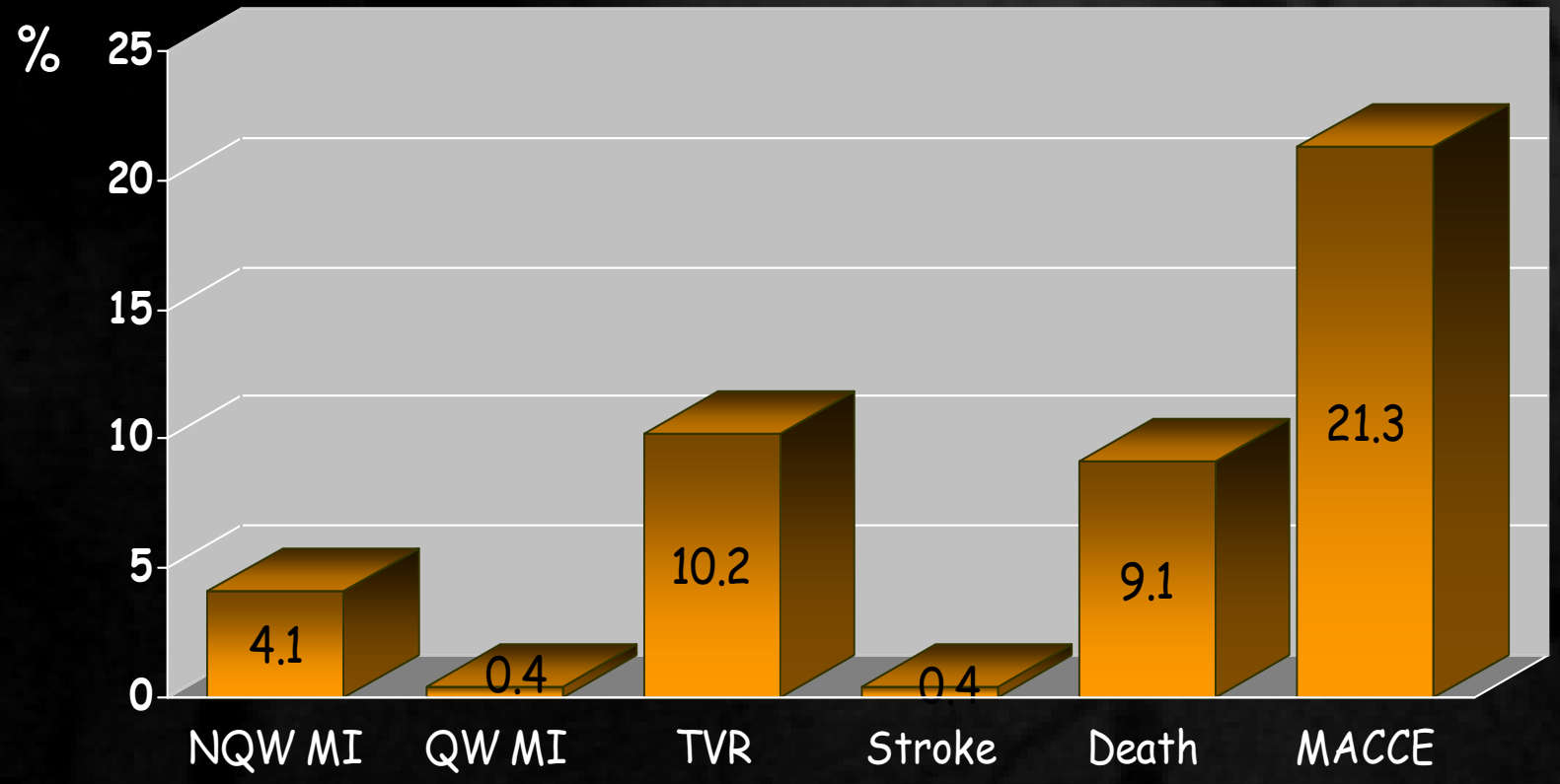
French Left Main Taxus Pilot Study

Predictors of Death at 12 months

	Death	No death	p value
Patients (n)	12	272	-
Age (years)	72.6±12.6	68.6±11.4	0.25
Euroscore	6.9±2.9	4.7±3.4	0.03
Diabetes (%)	72.7	26.8	0.001
Dialysis (%)	27.3	0.8	0.001
Ejection fraction (%)	57±10	61±13	NS
3 vessel disease (%)	44.4	25.5	NS
Bifurcation lesion (%)	90.9	77.5	NS

French Left Main Taxus Pilot Study

24 ± 2 months' F-Up



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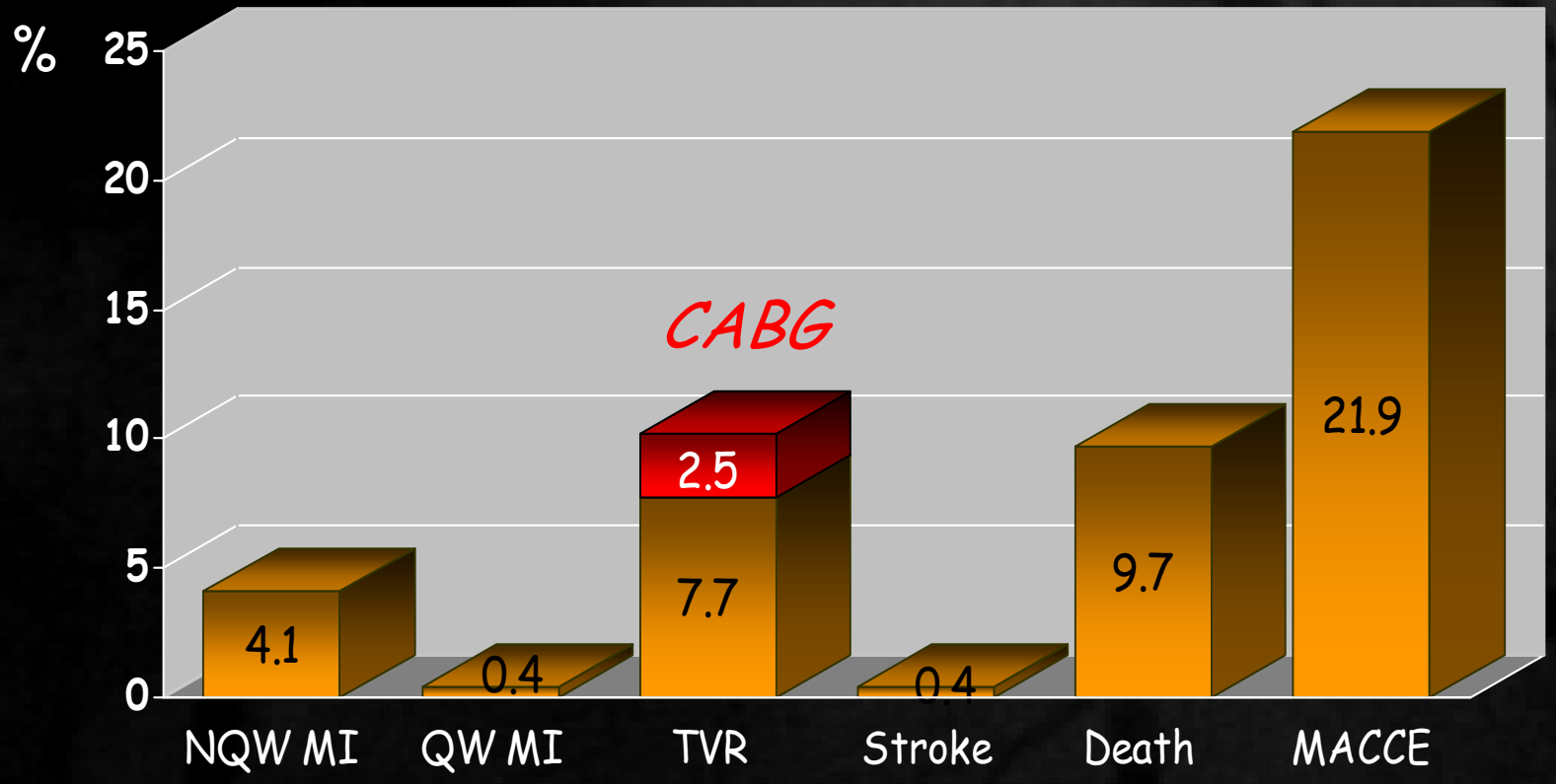
French Left Main Taxus Pilot Study

24 ± 2 months' F-Up



* Non Hierarchical Ranking

French Left Main Taxus Pilot Study

Cause of death between 12 and 24 months

Cardiac (1.8%)

✓ Cardiac failure, 19 months	1
✓ Sudden death, 16	1
✓ Unknown, 20 and 21 months	2
✓ Acute non-Q-wave MI, 20 months	1

Non cardiac (1.8%)

✓ Vascular surgery, 20 and 26 months	2
✓ Cancer at 18 months	1
✓ Othopedic surgery, 19 months	1
✓ Gastric bleeding, 22 months	1

French Left Main Taxus Pilot Study

Safety (n=284)

A *Definite stent thrombosis (angiography or autopsy documented)*

R *Probable (unexplained death < 30 days or MI in the treated territory)*

C *Possible (Sudden unexplained death > 30 days)*

French Left Main Taxus Pilot Study

Safety (n=284)

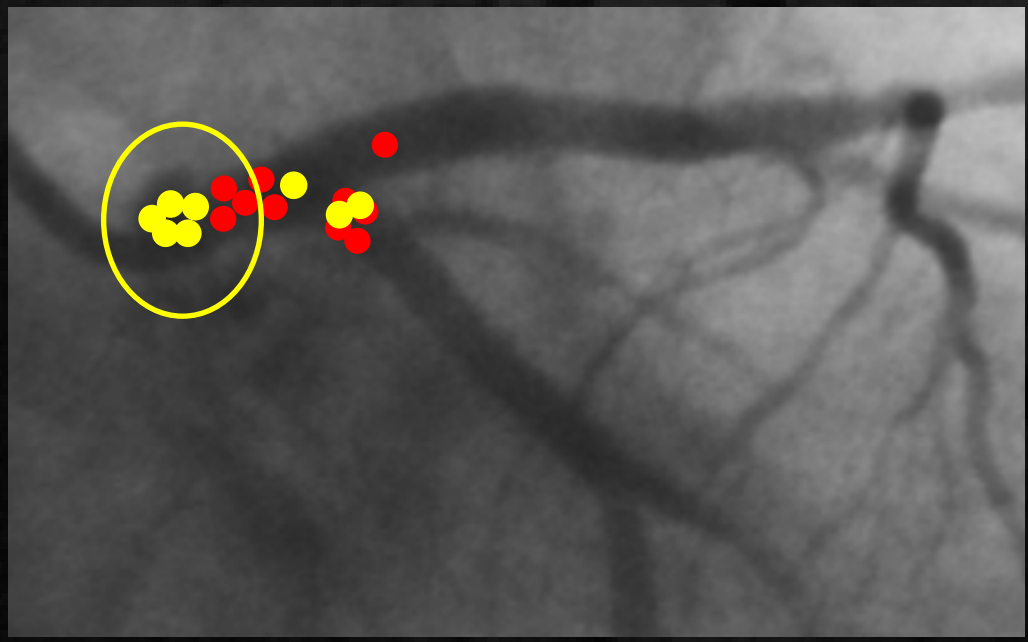
		1 Year	2 years
A	Definite	0.4%	0%
R	*Probable*	0.4%	0%
C	*Possible*	1.1%	0.7%

French Left Main Taxus Pilot Study

Angiographic F-Up (178/277: 64.7%)

Delay (months)	7.2±3.3
LM restenosis (%)	8.3*

- In stent
- Not in stent



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** % of patients with angiographic follow-up*

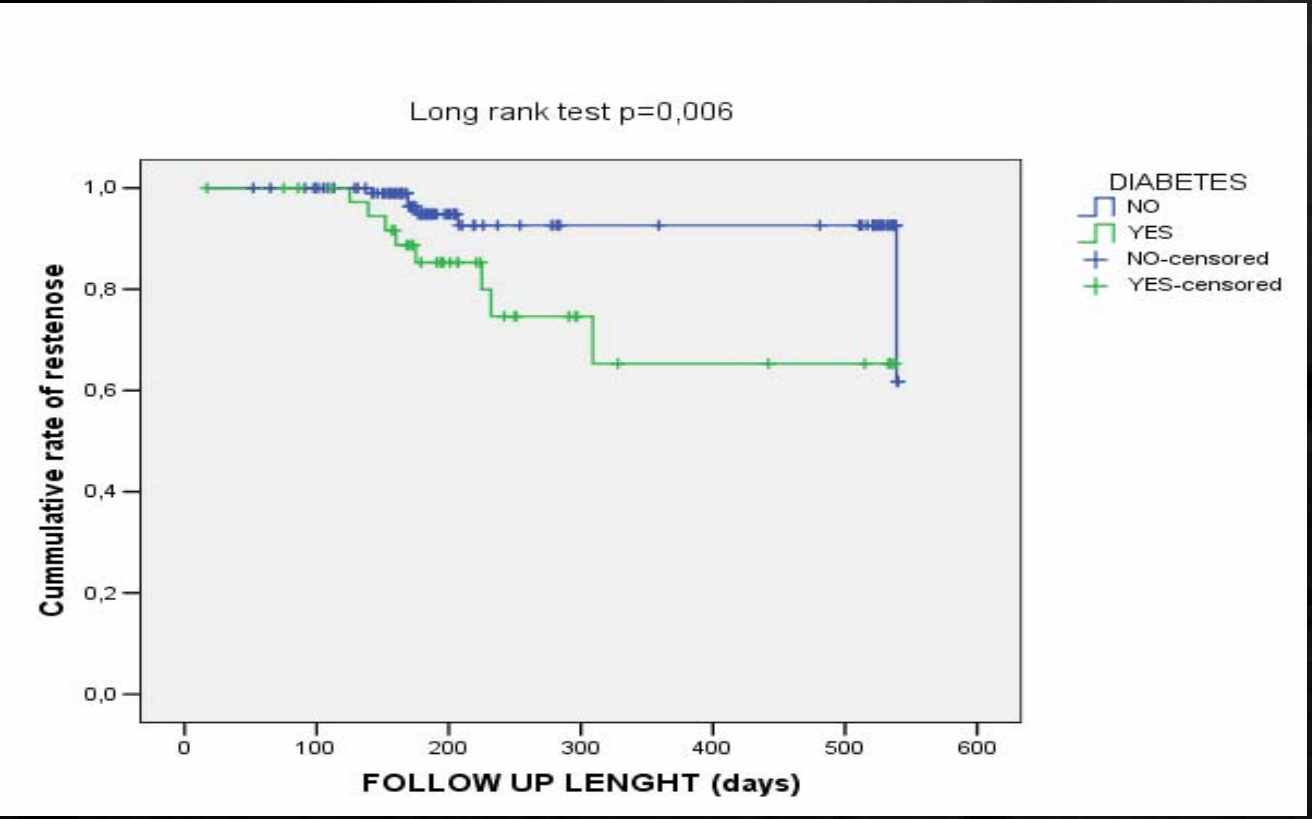
French Left Main Taxus Pilot Study

Predictors of Restenosis

Variable	No restenosis	Restenosis	P	OR
3-vessel-disease (%)	14.4	33.3	0.07	2.96
EF < 40% (%)	6.5	23.1	0.07	3.07
Hypertension (%)	62.9	82.7	0.06	3.89
SB stent < 3 mm (%)	17.1	50.0	0.06	3.62
Diabetes (%)	25.6	53.5	0.03	4.67
SB MLD post PCI <3 mm (%)	21.2	63.6	<0.01	7.92

French Left Main Taxus Pilot Study

Diabetes and Restenosis



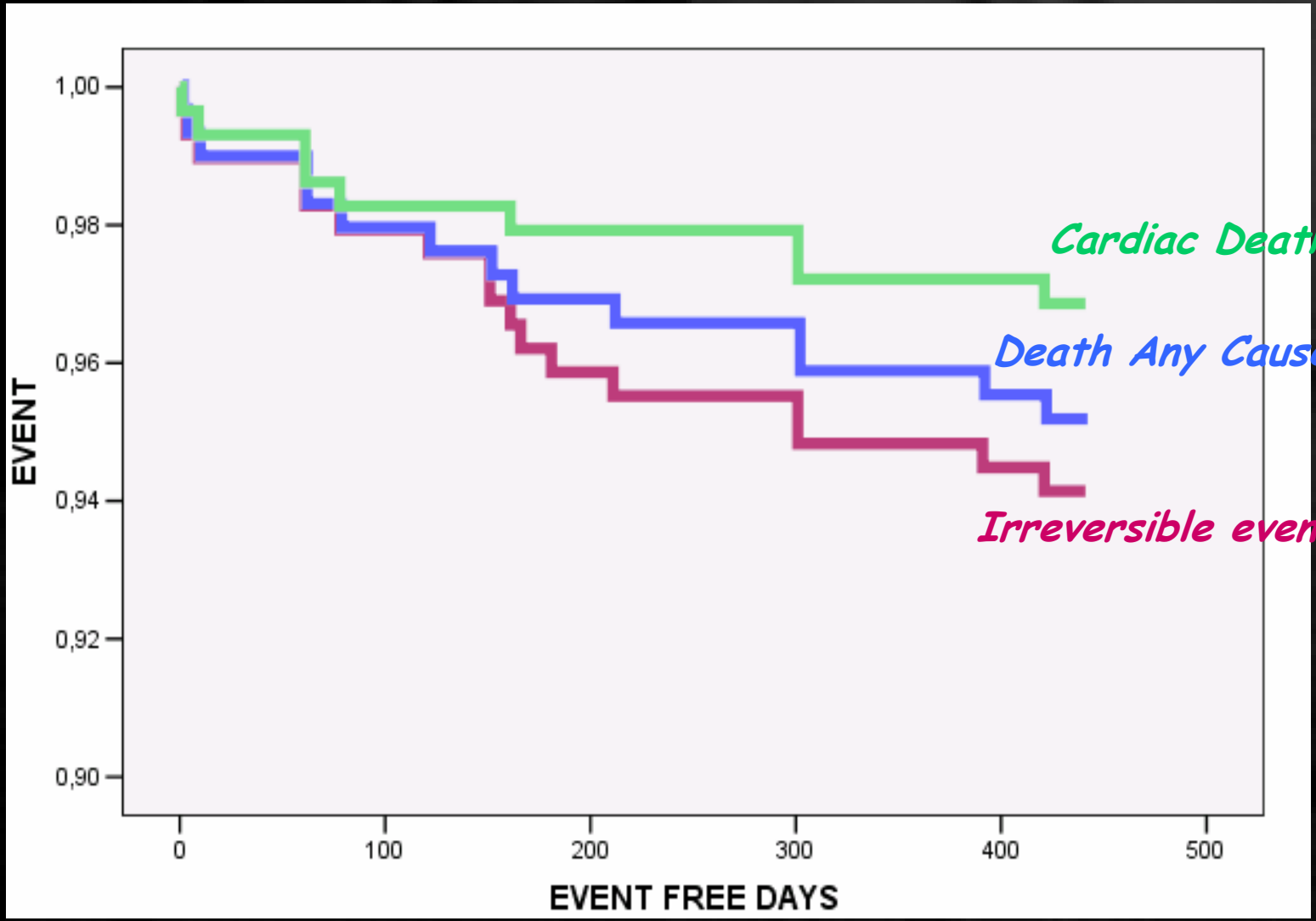
French Left Main Taxus Pilot Study

Predictors of Irreversible Events at 12 month F-up

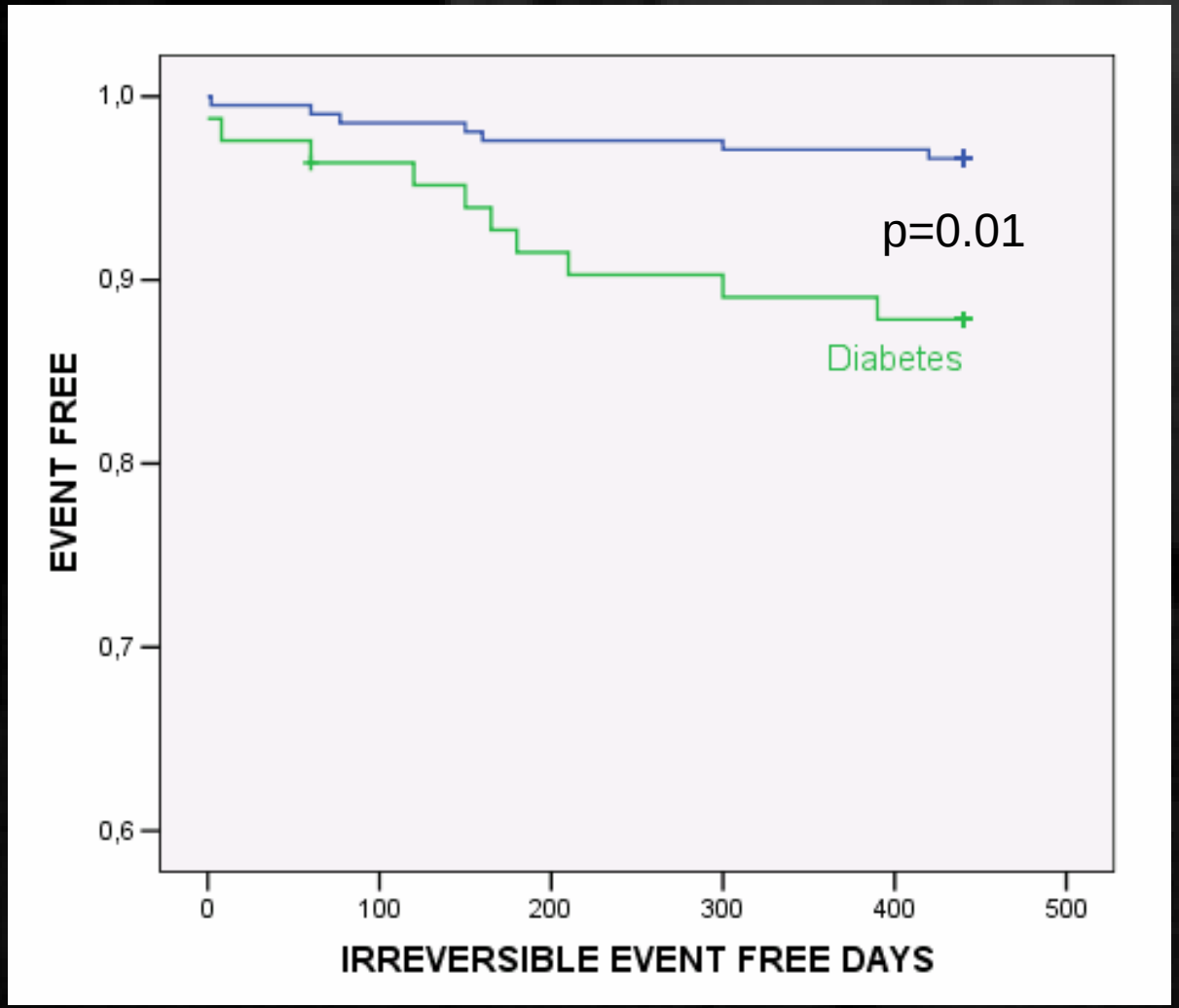
Irreversible events: 17/291 patients (5.8%)
CABG 1.0%, Q-wave MI 0%, stroke 0.3% and death 4.8%.

Diabetes	(OR 3.32, 95%CI 1.07-10.24, p=0.037)
No dyslipidemia	(OR 3.32, 95% CI 0.08-0.82, p=0.022)

Death Curves and Irreversible events



Kaplan-Meier curves at 1 year Diabetic vs non-Diabetic patients



French Left Main Taxus Pilot Study

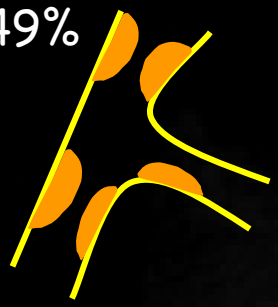
Conclusion

Left main PCI using the TAXUS stent with a strategy of provisional side branch T stenting, in the presence of distal LM disease, provides excellent acute angiographic results and good mid-term outcome in experienced centers compared to surgery.

Back Up Slides

Lesion Type and 8 month Outcome

Type 1,1,1
49%

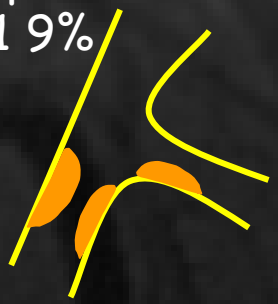


2 stents 51%
TVR 7.6%

Type
1,0,1 2%

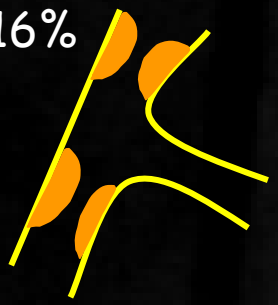
2 stents 33%
TVR 0%

Type
0,1,1 9%



2 stents 50%
TVR 0%

Type 1,1,0
16%

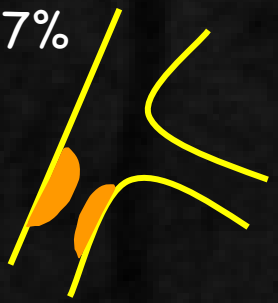


2 stents 26%
TVR 3.4%

Type 1,0,0
15%

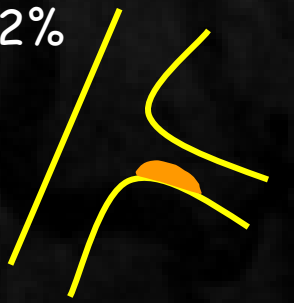
2 stents 21%
TVR 0%

Type 0,1,0
7%



2 stents 14%
TVR 14%

Type 0,0,1
2%



2 stents 25%
TVR 0%

French Left Main Taxus Pilot Study

Clinical Characteristics

	Distal	Not distal	P value
Patients (n)	227	64	NS
Age (years)	69±12	68±10	NS
Diabetes (%)	29.5	25.4	NS
Previous MI (%)	10.6	14.3	NS
Previous PCI (%)	20.3	19.0	NS
Unstable angina (%)	36.6	30.2	NS
Recent MI (%)	6.6	6.3	NS
3 vessel disease (%)	28.0	15.8	0.063
EF < 40% (%)	10.1	8.3	NS
Additive Euroscore	4.7±3.3	5.1±3.6	NS
Estimated mortality (%)	6.2±10.2	7.0±11.5	NS

French Left Main Taxus Pilot Study

12 months Follow-up (cumulative)

	Distal	Not distal	P value
Follow-up obtained (%)	97	98	NS
Coronary angiogram (%)	64.4	64.9	NS
Q wave MI (%)	0	0	NS
Stroke (%)	0.5	0	NS
TVR (%)	7.8	3.2	NS
Death (%)	5.9	1.6	NS
Cardiac death (%)	2.6	1.7	NS
MACCE (%)	15.4	5.3	0.057
Irreversible events (%)	7.5	1.8	NS

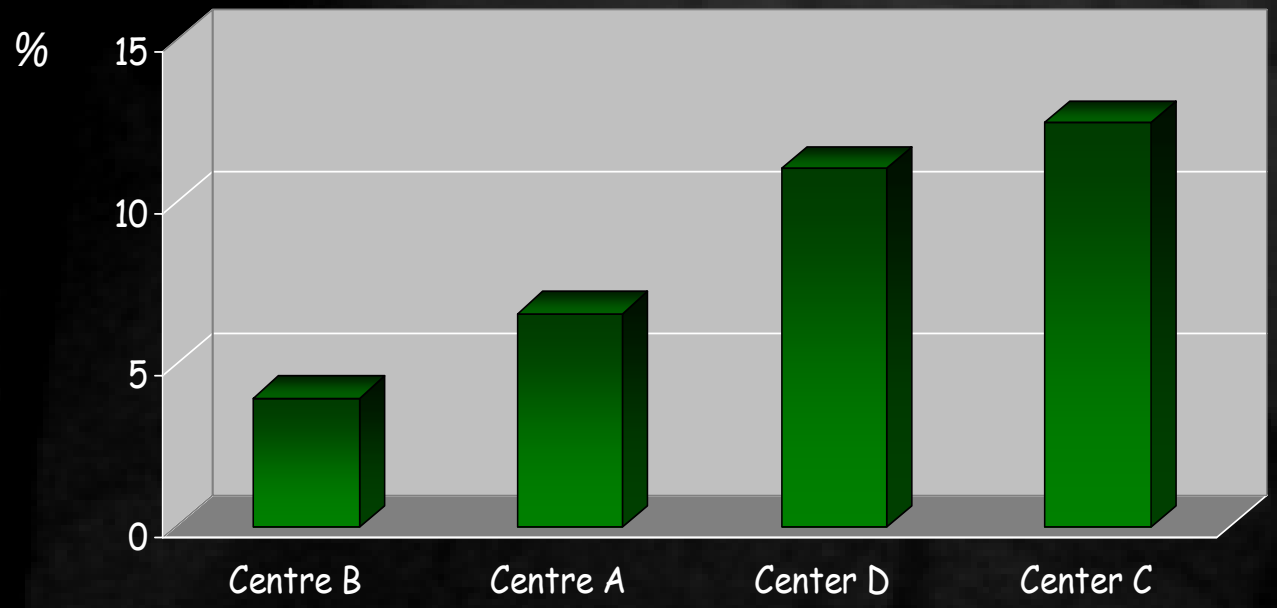
French Left Main Taxus Pilot Study

Procedural Data

	Distal	Not Distal	P value
Gp2b3a inhibitors (%)	3.5	4.8	NS
IABP (%)	4.9	3.2	NS
Other treated vessels (n)	1.4±0.9	1.2±1.0	NS
Left Main Proximal ref. (mm)	3.63±0.47	3.82±0.70	NS
Stenosis left main (%)	70±12	68±11	N
Left Main stent (n)	1.08±0.31	1.03±0.18	NS
Left Main stent length (mm)	19.8±5.7	12.3±4.8	NS
Left Main stent diameter (mm)	3.43±0.18	3.46±0.14	NS
Total stent length (mm)	57±25	49±18	NS
Procedure (min.)	62±31	47±28	<0.0001
Contrast medium (ml)	261±140	201±130	0.002

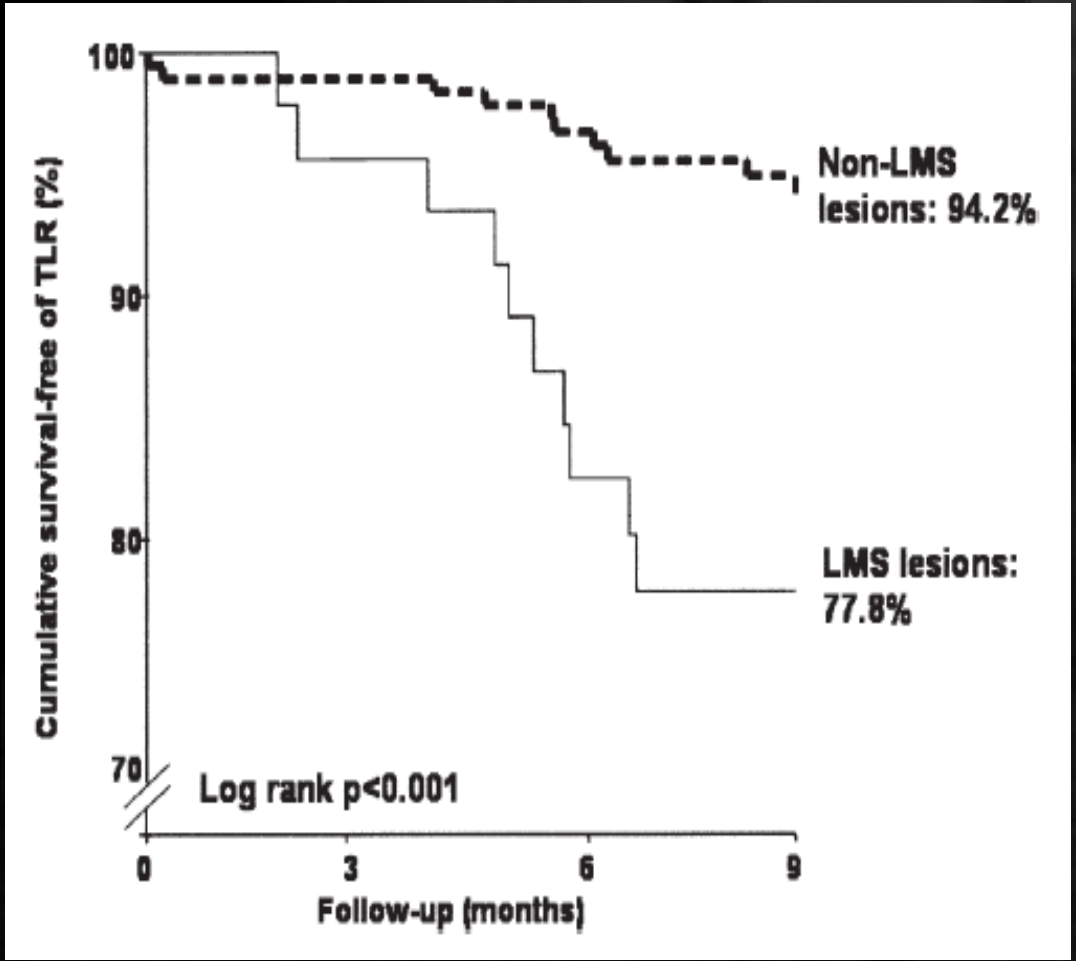
French Left Main Taxus Registry

Reintervention at 12 Months



Diabete (%)	*29*	*26*	*36*	*25*
Distal LM (%)	*81*	*83*	*71*	*82*
2 stents dis. LM (%)	*31*	*38*	*67*	*71*
Final kiss. (%)	*99*	*100*	*85*	*90*

Long-Term Outcome After Stenting of Bifurcation Lesions With the « Crush » Technique



Hoye et al. JACC 2006;47;1949-1958