

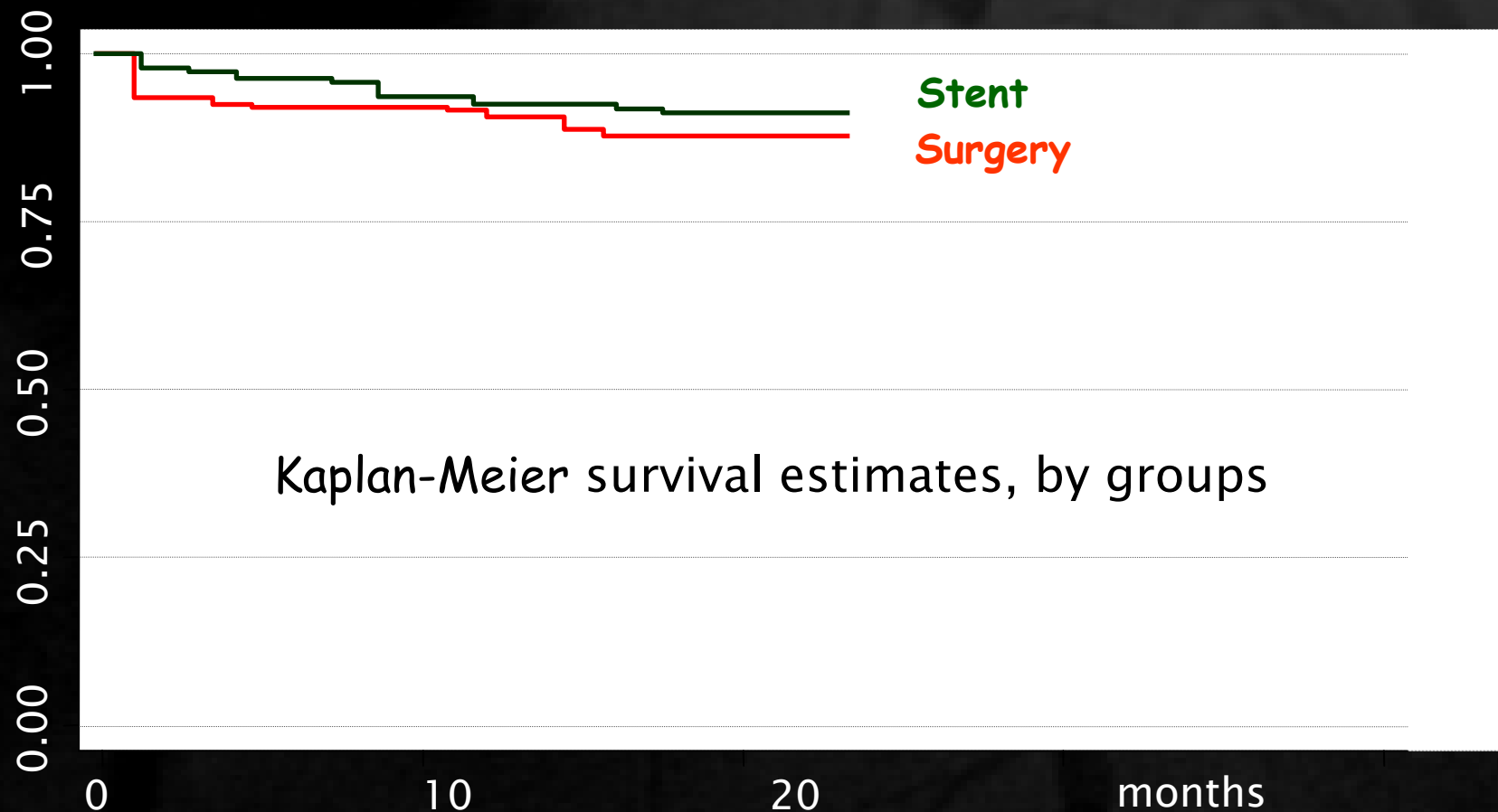
Mid Term Results of the French Multicenter Taxus Left Main Registry

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On Behalf the LM Taxus Study Group



French Registry of LM Coronary Treatment

BMS May 2001 - April 2002



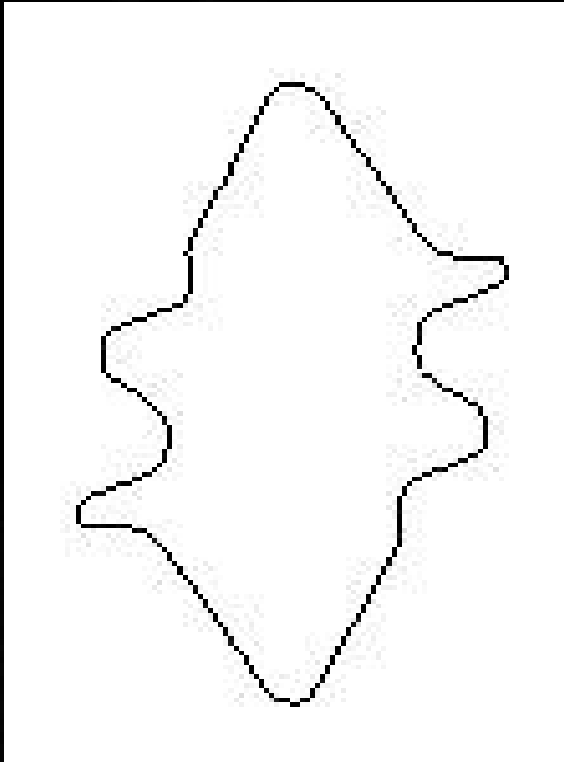
French Registry of LM Coronary Treatment

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



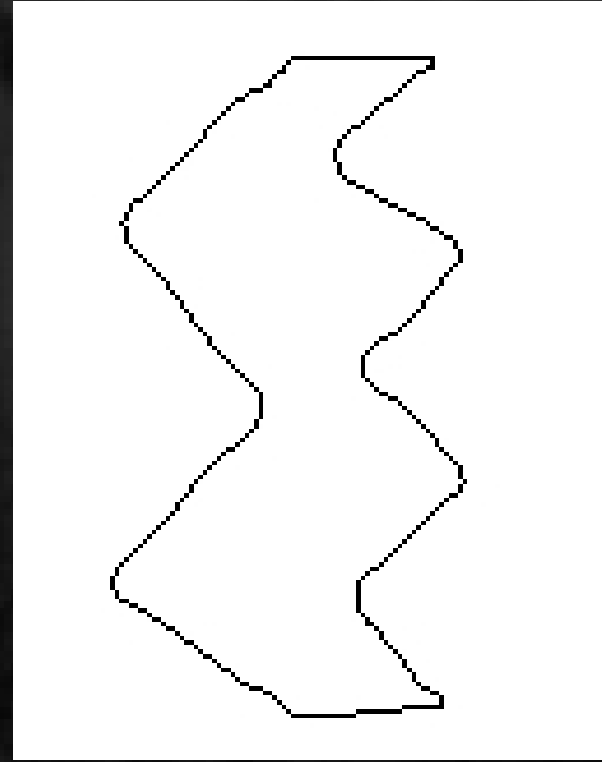
DES for LM Bifurcation Lesions



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

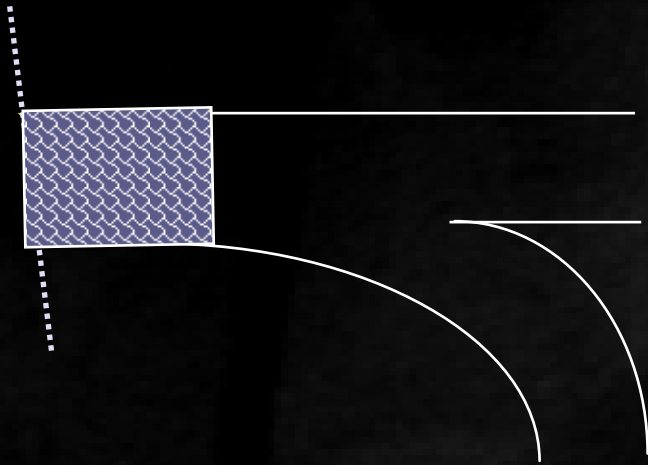
Design of the Study

- ✓ 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

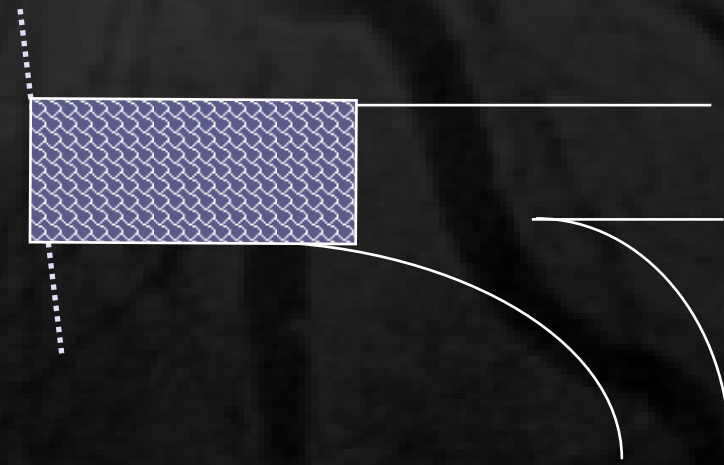


French Left Main Taxus Pilot Study

Strategy and Lesion Type



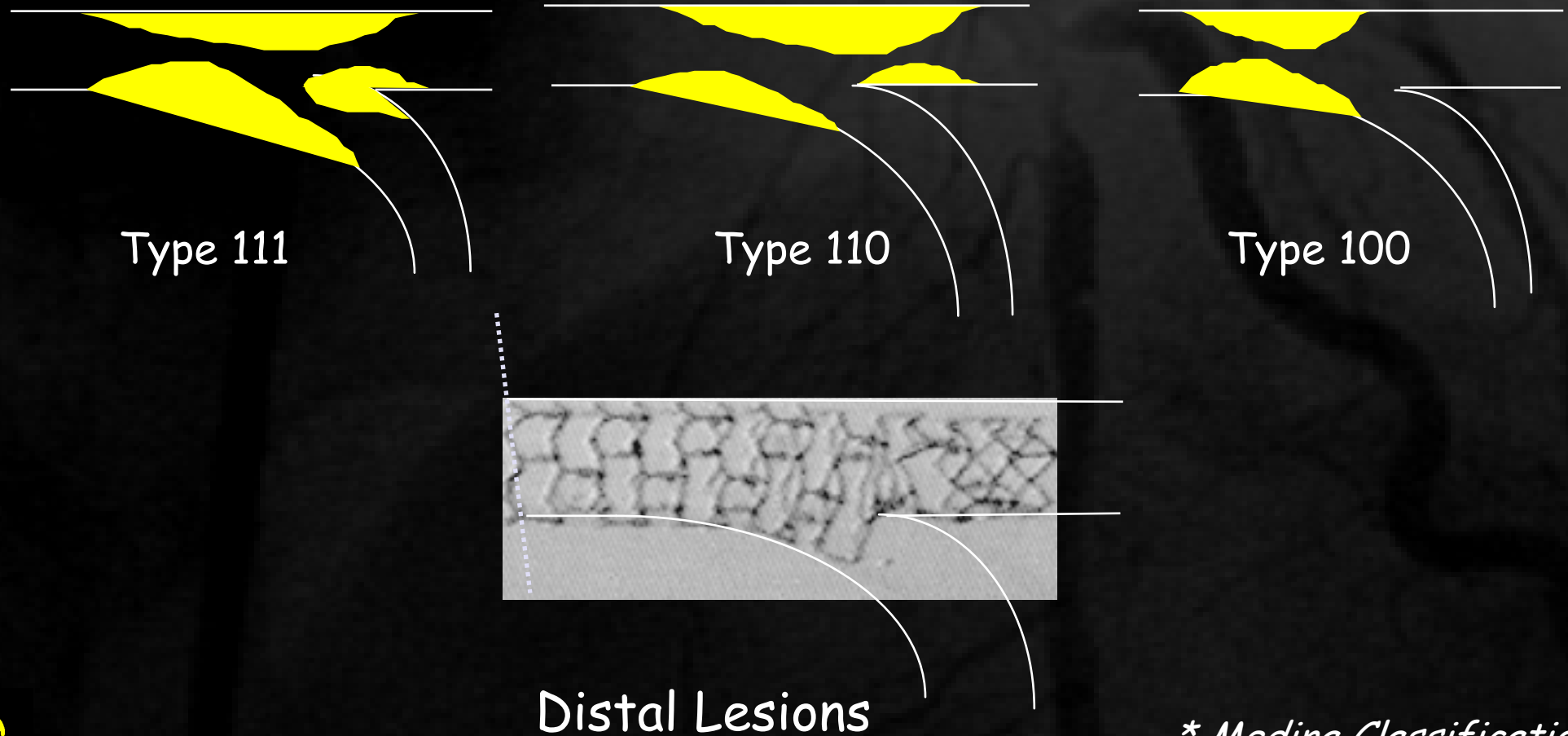
Ostial Lesion



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

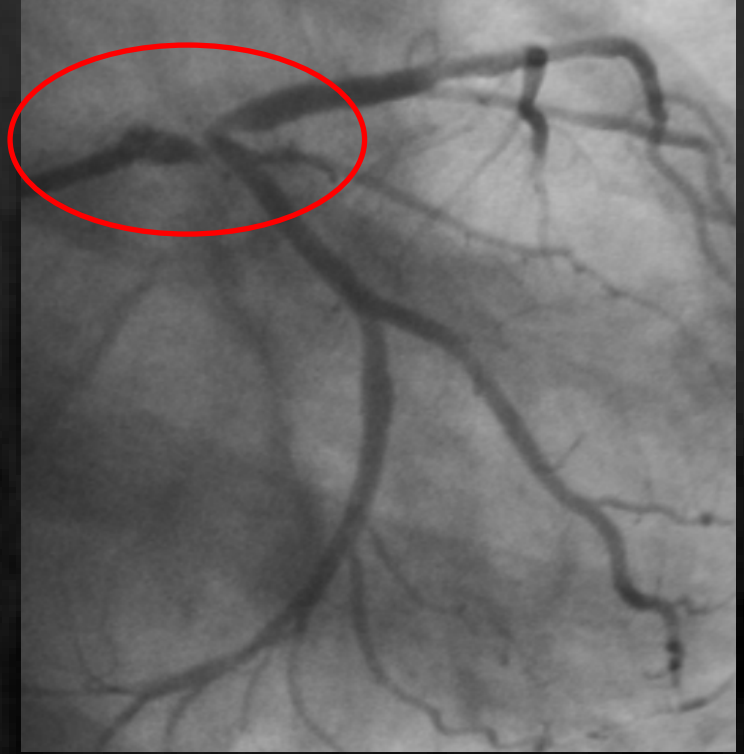
Left Main Lesion Location



Ostial-proximal 16.2 %



Mid-shaft 5.5 %



Distal 78.4 %



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

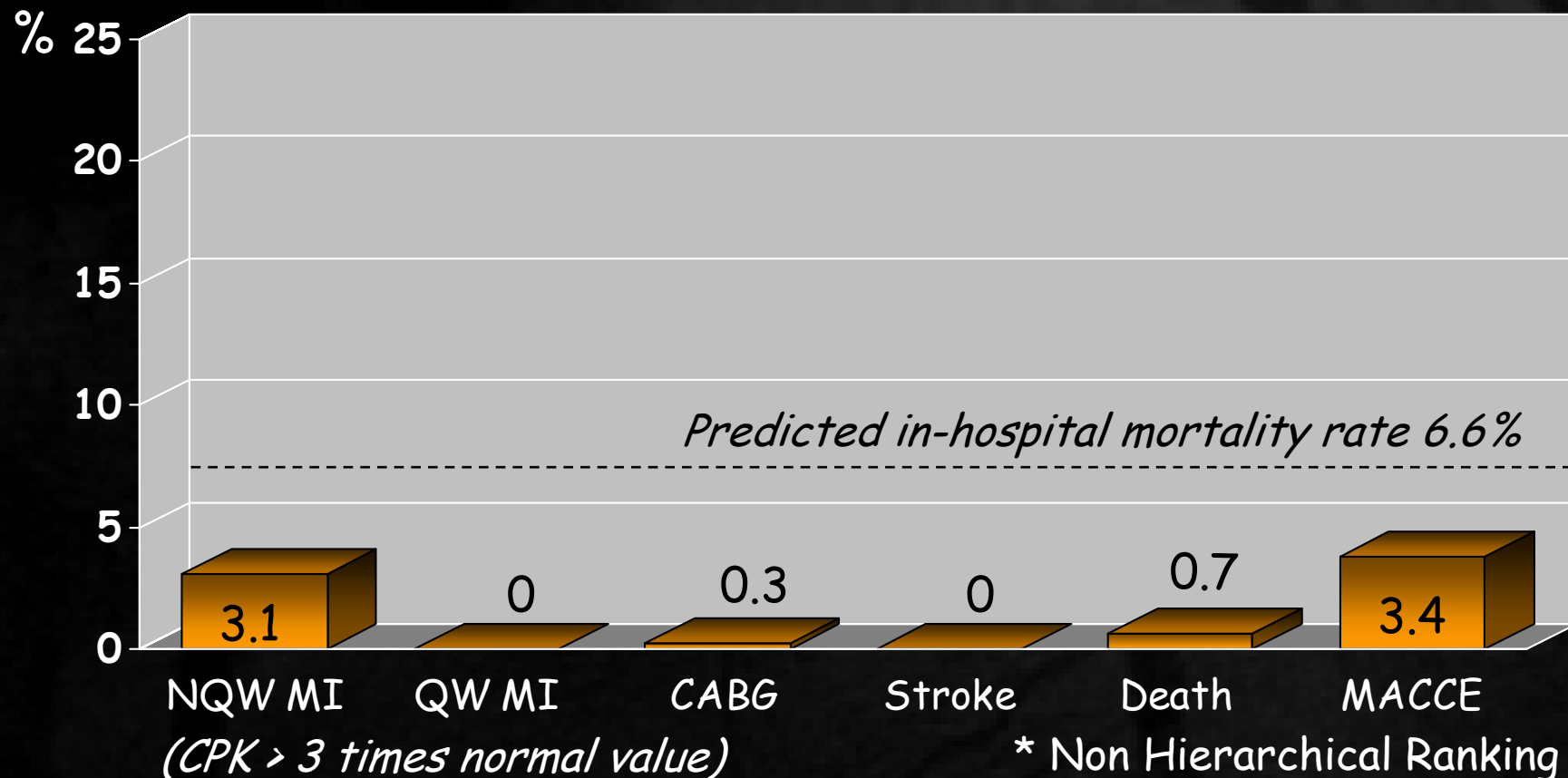
Distal left main in 78.4% of cases

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



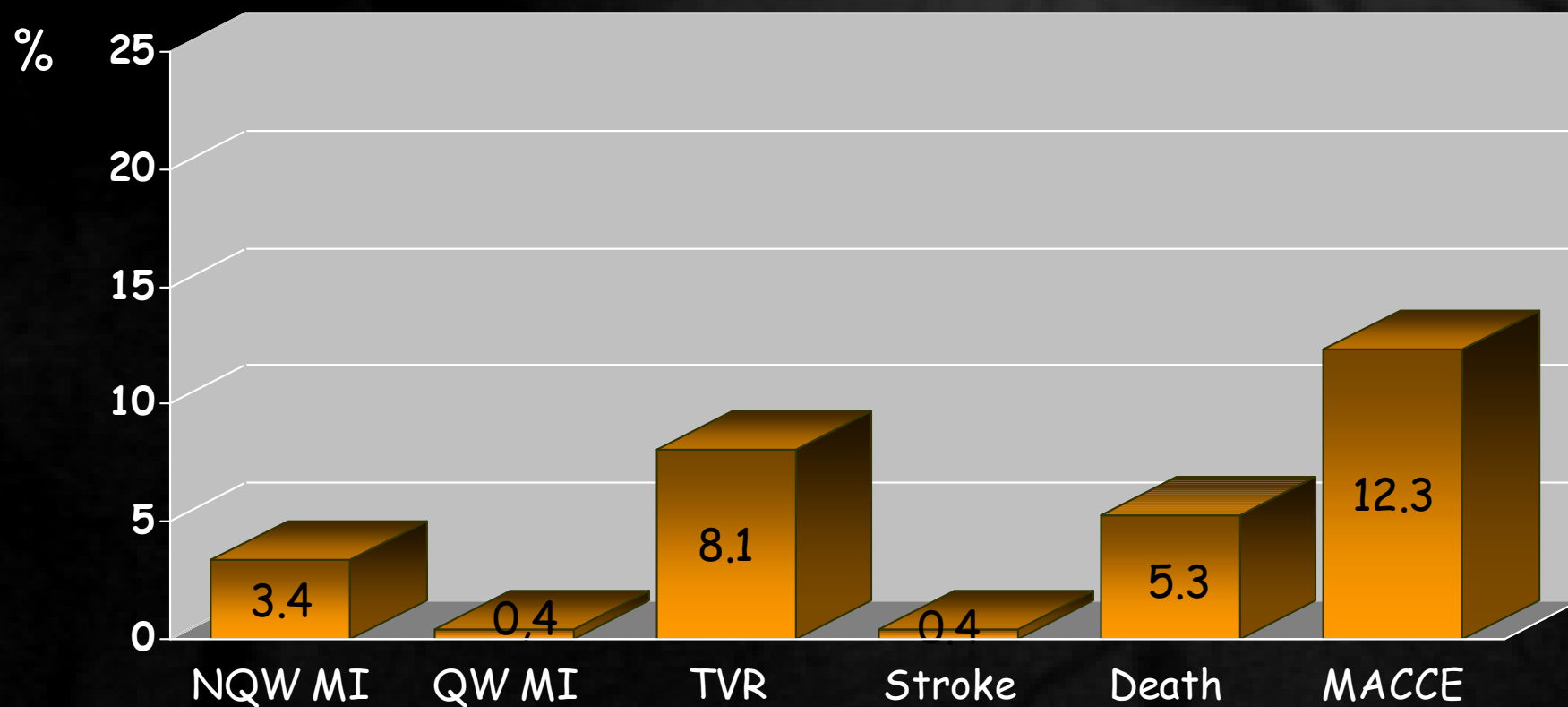
French Left Main Taxus Pilot Study

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



French Left Main Taxus Pilot Study

12 months F-Up (284/291: 97.6%, 14.0_{-3.0} months)

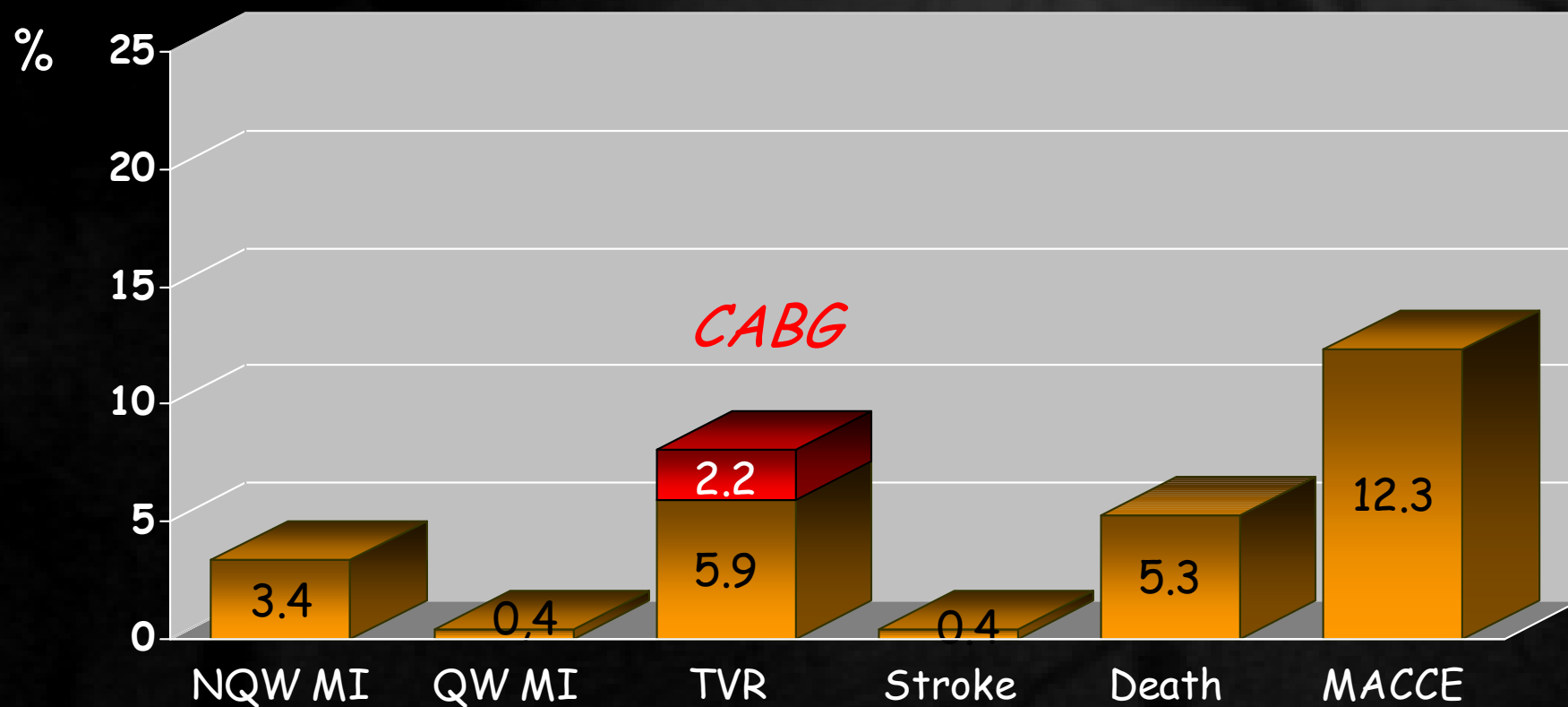


* Non Hierarchical Ranking



French Left Main Taxus Pilot Study

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



* Non Hierarchical Ranking



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

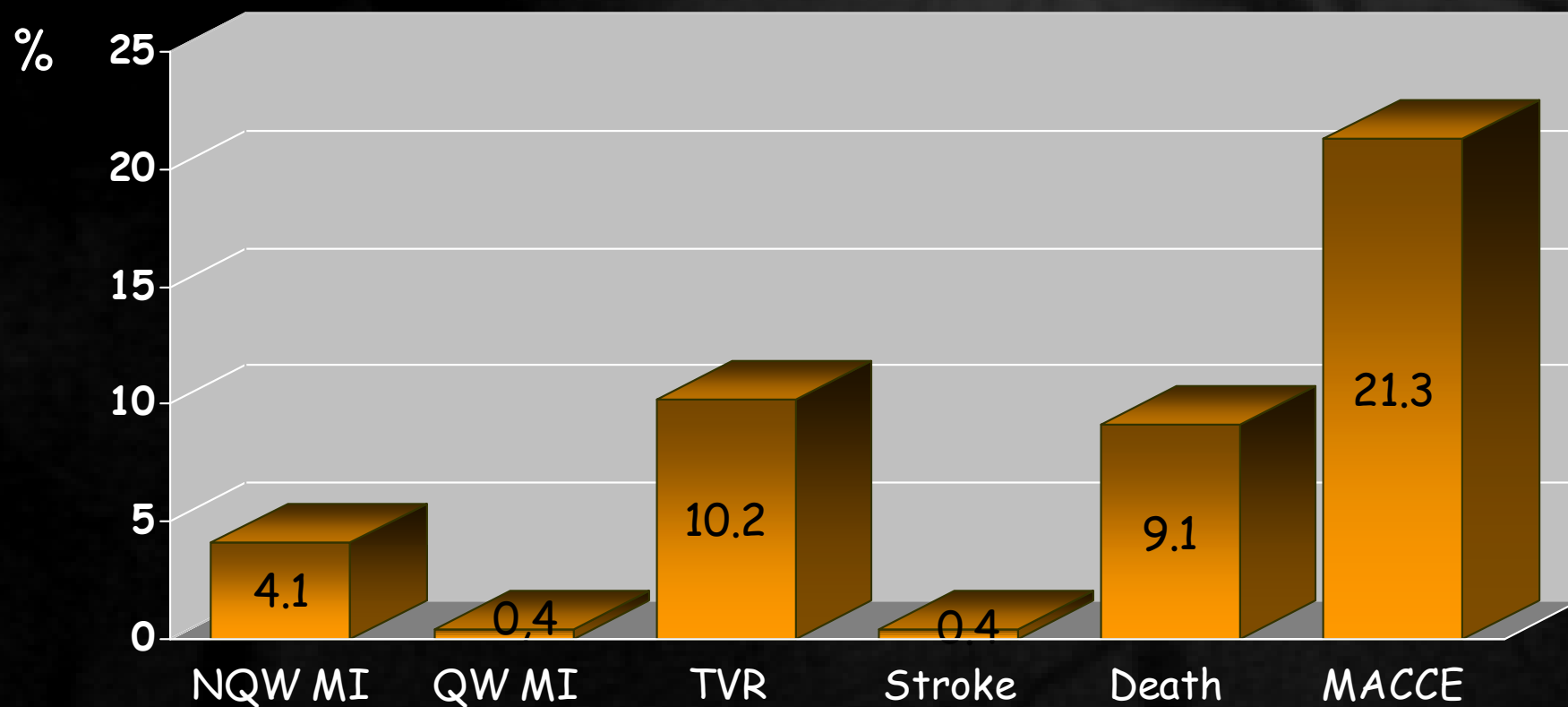
Predictors of Death at 12 months

	Death	No death	p value
Patients (n)	12	272	-
Age (years)	72.6 \pm 12.6	68.6 \pm 11.4	0.25
Euroscore	6.9 \pm 2.9	4.7 \pm 3.4	0.03
Diabetes (%)	72.7	26.8	0.001
Dialysis (%)	27.3	0.8	0.001
Ejection fraction (%)	57 \pm 10	61 \pm 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 (90%)

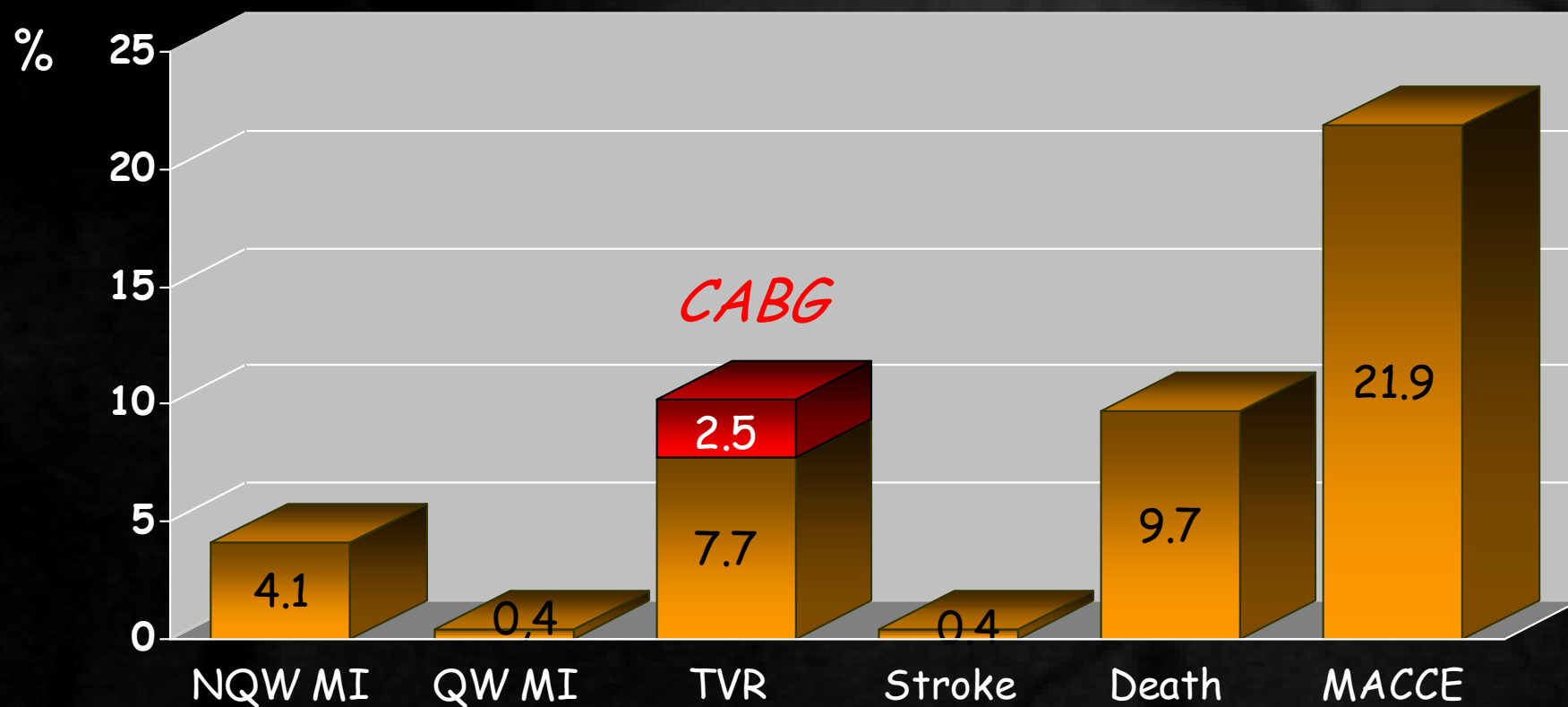


* Non Hierarchical Ranking



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 months | 1 |
| ✓ Unknown, 20 and 21 months | 2 |
| ✓ Acute non-Q-wave MI, 20 months | 1 |

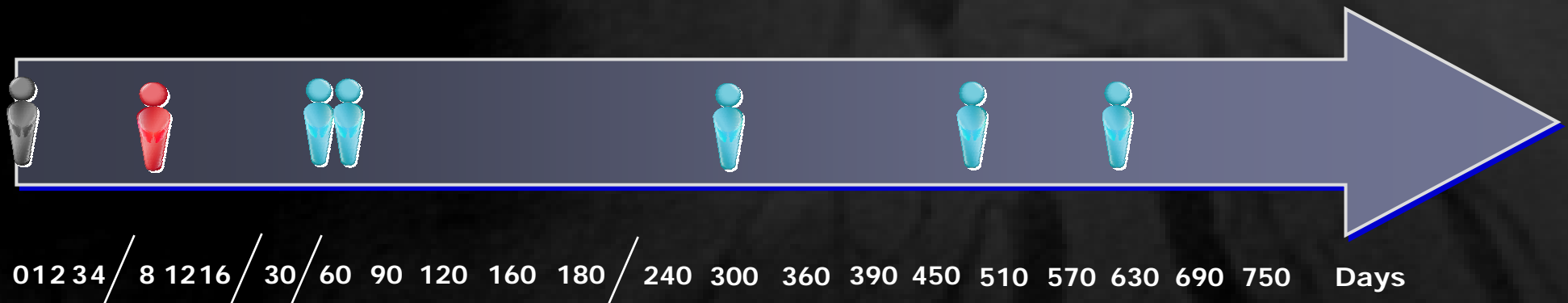
Non cardiac (1.8%)




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



French Left Main Taxus Pilot Study

Safety (n=284)

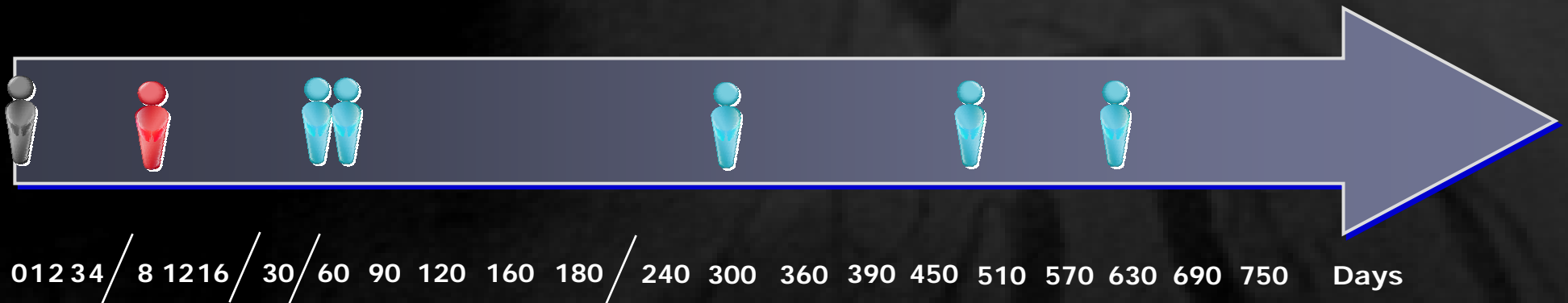


- A**  *Definite stent thrombosis (angiography or autopsy documented)*
- R**  *Probable (unexplained death < 30 days or MI in the treated territory)*
- C**  *Possible (Sudden unexplained death > 30 days)*



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%



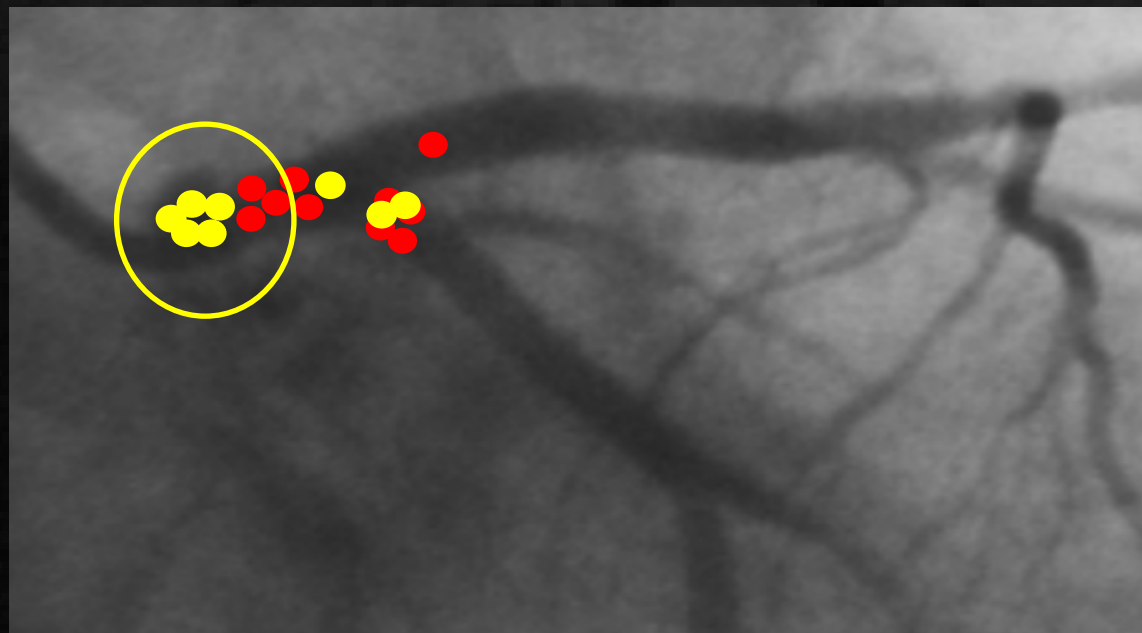
French Left Main Taxus Pilot Study

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

Delay (months) $7.2_{\pm}3.3$

LM restenosis (%) 8.3^*

- In stent
- Not in stent



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

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.

