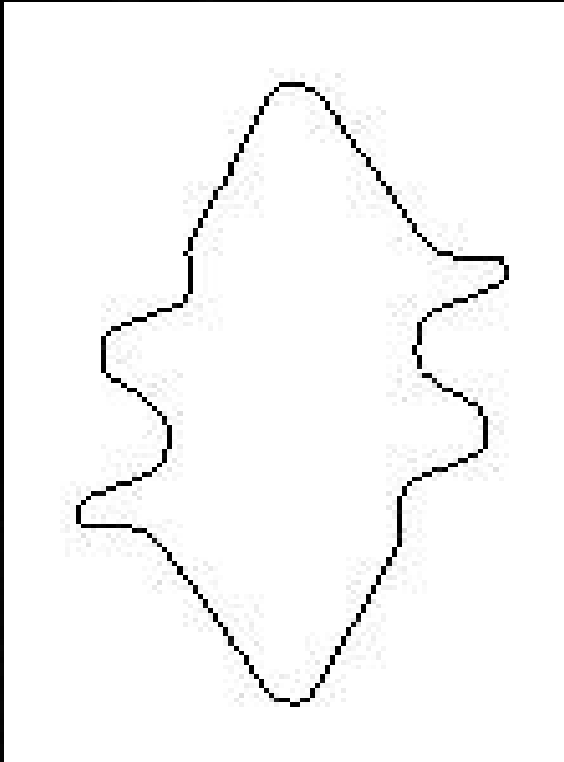


# Mid Term Results of the French Multicenter Taxus Left Main Registry

T. Lefèvre, M. Silvestri, O. Darremont  
*On Behalf the LM Taxus Study Group*



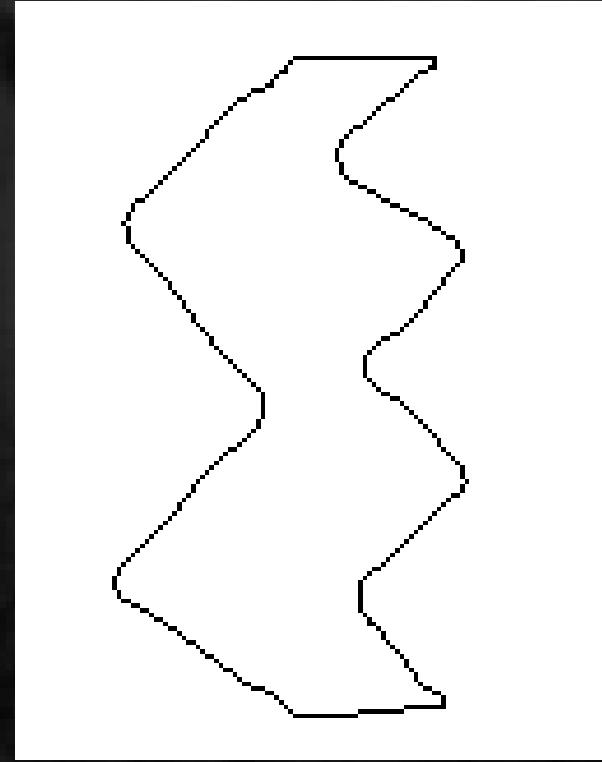
# DES for LM Bifurcation Lesions



**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

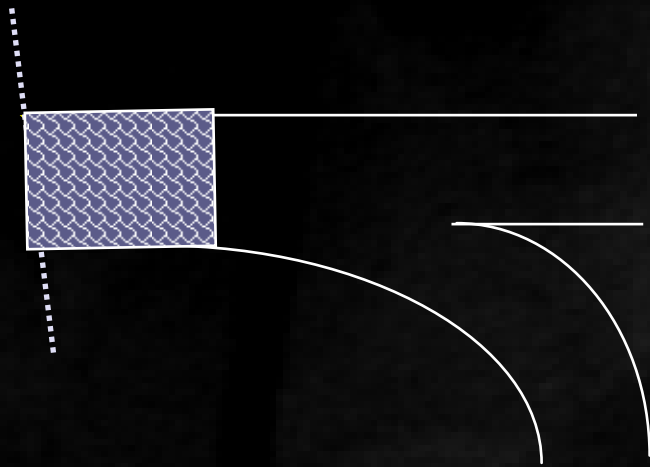
## Design of the Study

- ✓ 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

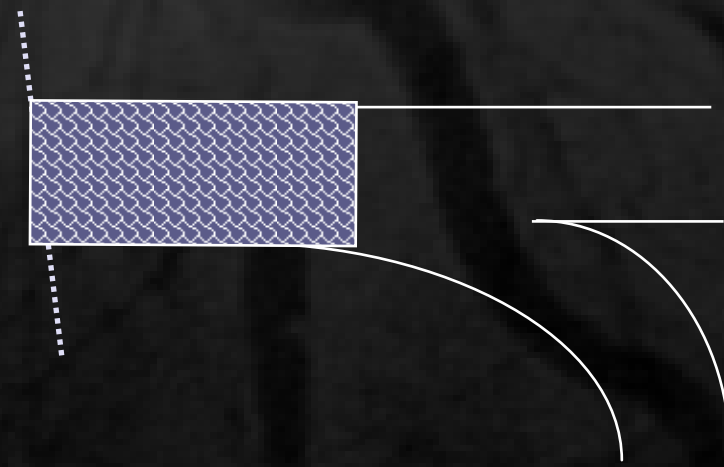


# French Left Main Taxus Pilot Study

## Strategy and Lesion Type



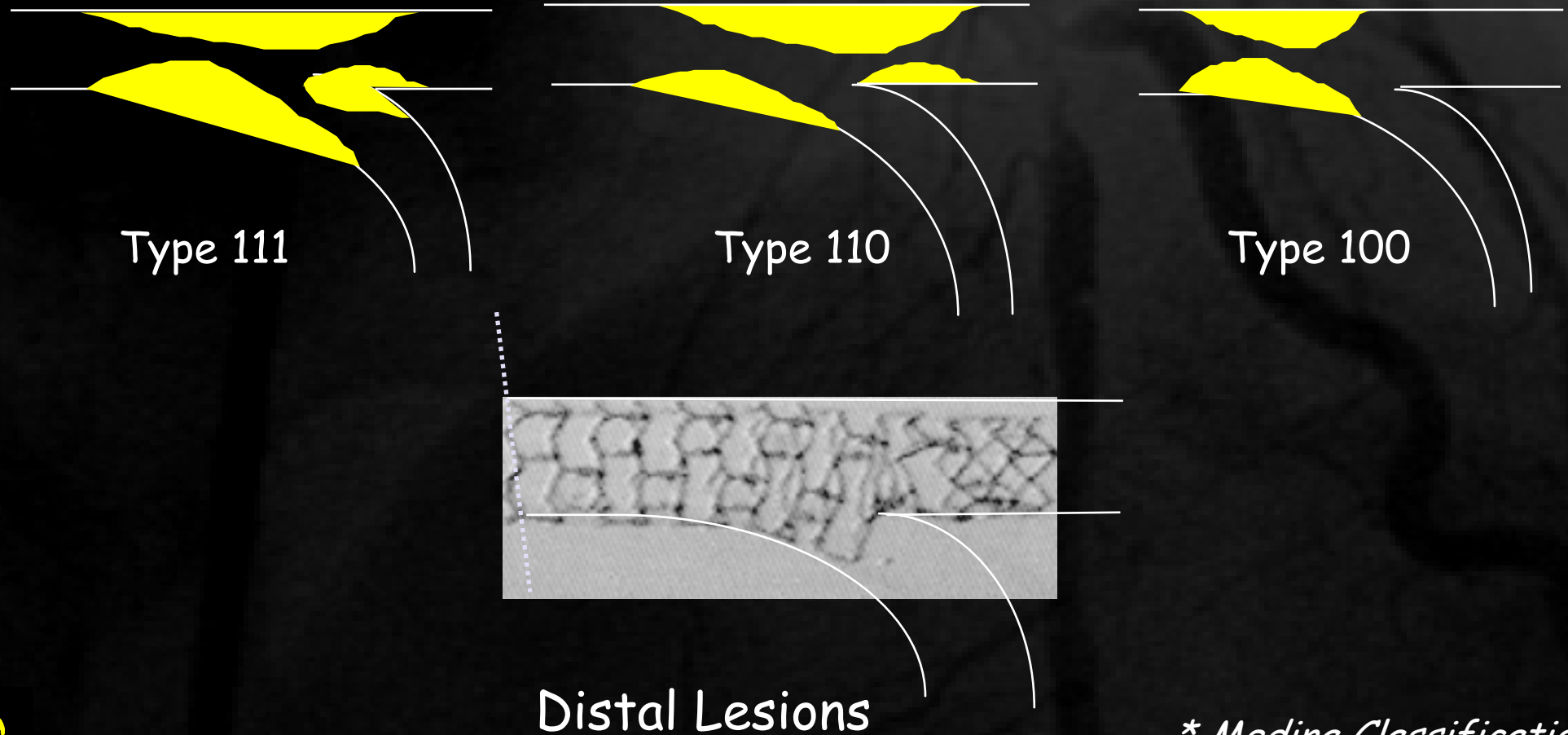
Ostial Lesion



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 <sub>±</sub> 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 <sub>±</sub> 13
Additive Euroscore	4.8 <sub>±</sub> 3.4
Estimated CABG mortality (%)	6.4 <sub>±</sub> 10.5





# 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 <sub>-0.90</sub>
Total stent length (mm)	53 <sub>-23</sub>
Procedure (min.)	58.3 <sub>-31.2</sub>
Contrast medium (ml)	250 <sub>-138</sub>



# 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 <sub>-</sub> 0.43
Left main MLD (mm)	3.44 <sub>-</sub> 0.48
Left main residual stenosis (%)	7.1 <sub>-</sub> 7.8
Circ. reference (mm)	3.21 <sub>-</sub> 0.54
Circ. MLD (mm)	2.82 <sub>-</sub> 0.49
Circ. residual stenosis (%)	8.9 <sub>-</sub> 10.7
<b>Angiographic Success (%)</b>	<b>99.6</b>



# French Left Main Taxus Pilot Study

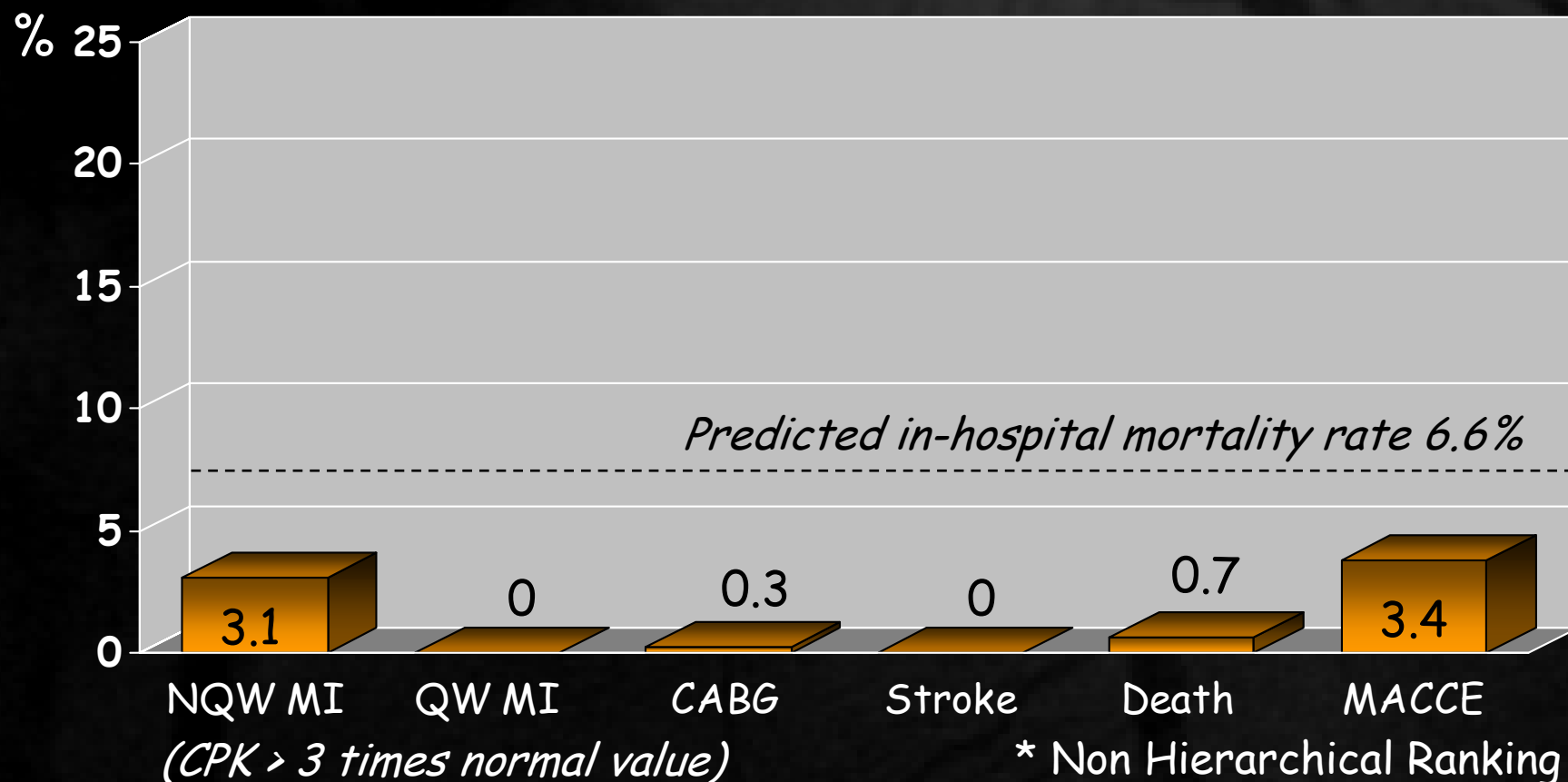
Distal left main in 77.9% of cases

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 <sub>-</sub> 5.5
Side branch stent diameter (mm)	3.04 <sub>-</sub> 0.33
Final Kissing balloon (%)	97.3



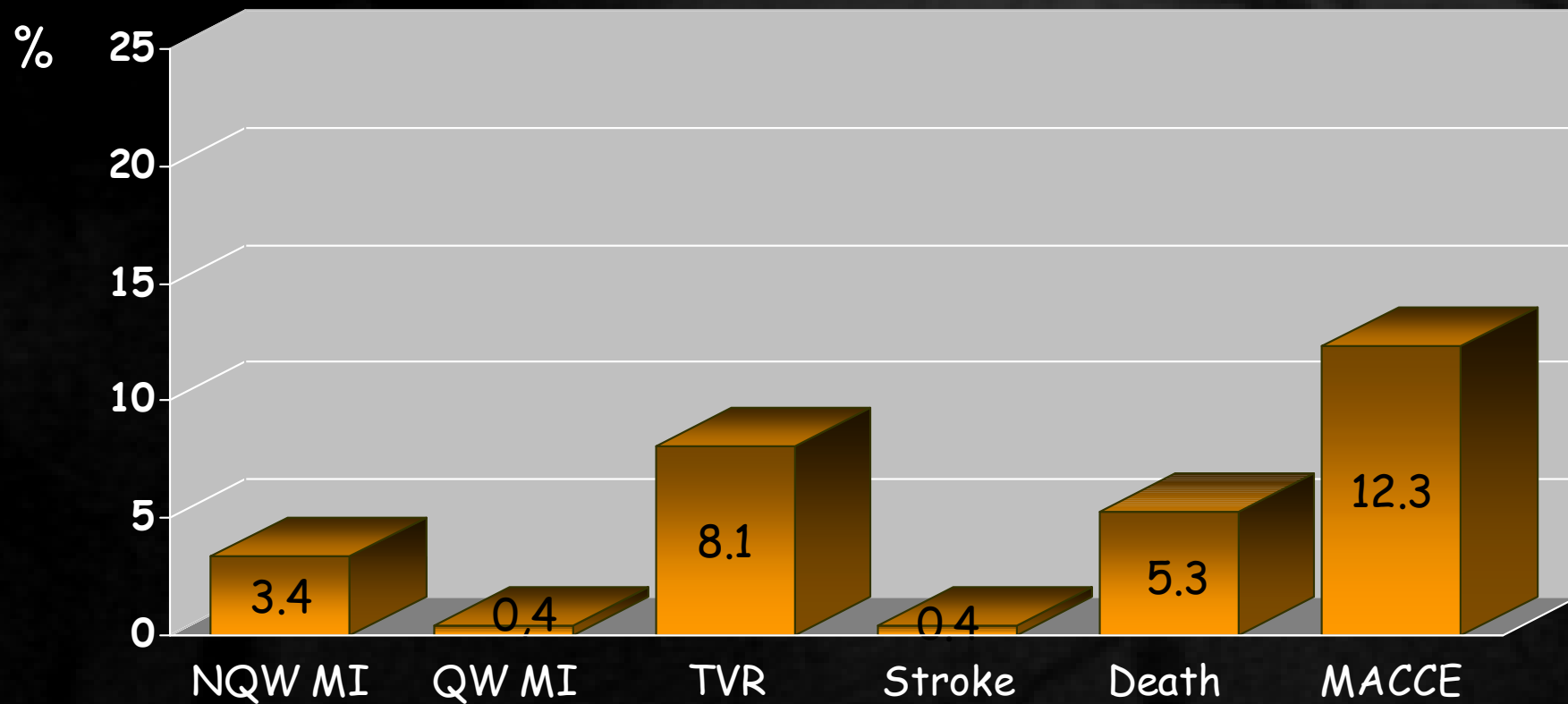
# French Left Main Taxus Pilot Study

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<sub>-3.0</sub> months)

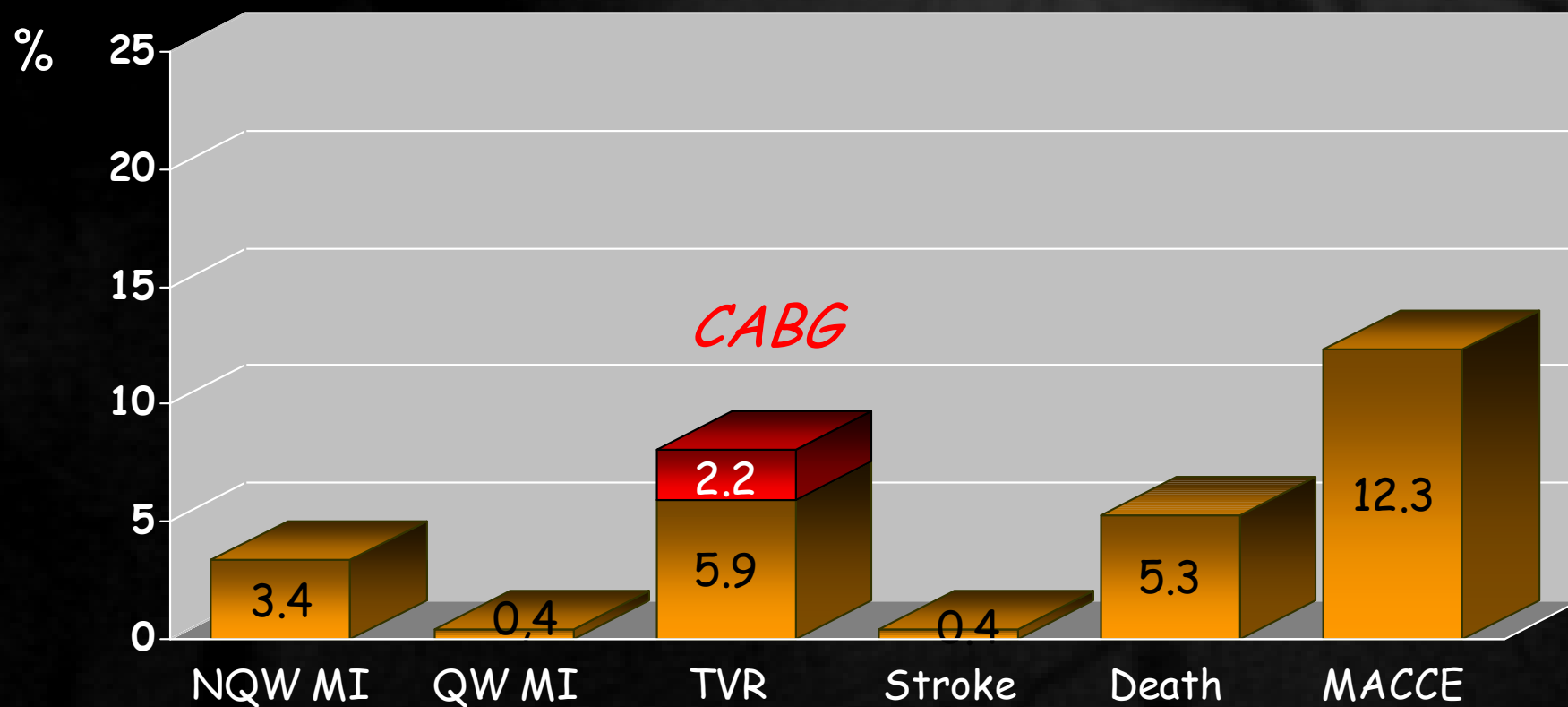


\* Non Hierarchical Ranking



# French Left Main Taxus Pilot Study

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



\* Non Hierarchical Ranking



# French Left Main Taxus Pilot Study

## Cause of death at 12<sub>+</sub>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%)

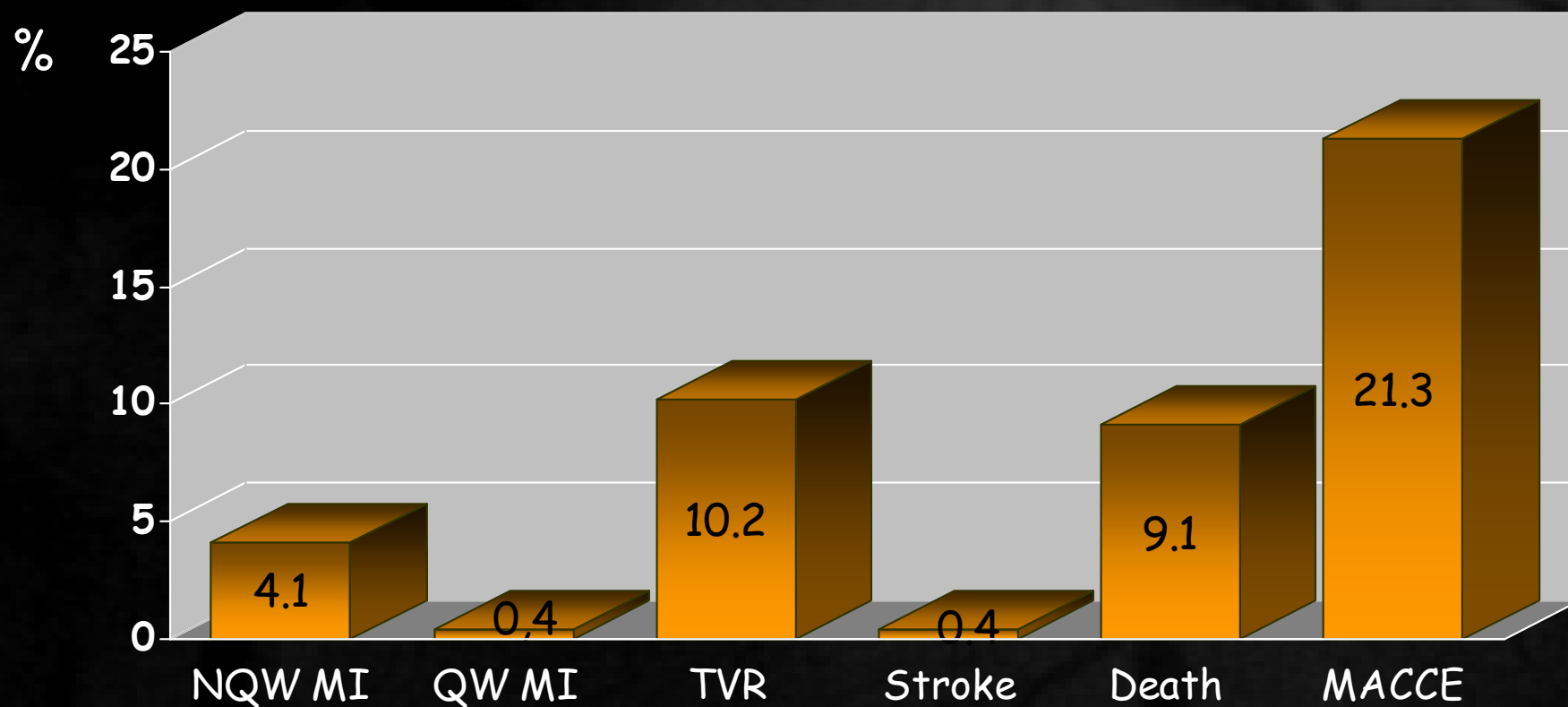
- |   |   |
|---|---|
| ✓ Severe groin hematoma, day 2                | 1 |
| ✓ Pulmonary infection, 4 months and 11 months | 2 |
| ✓ Stroke at 5 months                          | 1 |
| ✓ Cancer at 4 and 7 months                    | 2 |





# French Left Main Taxus Pilot Study

24 ± 2 months' F-Up

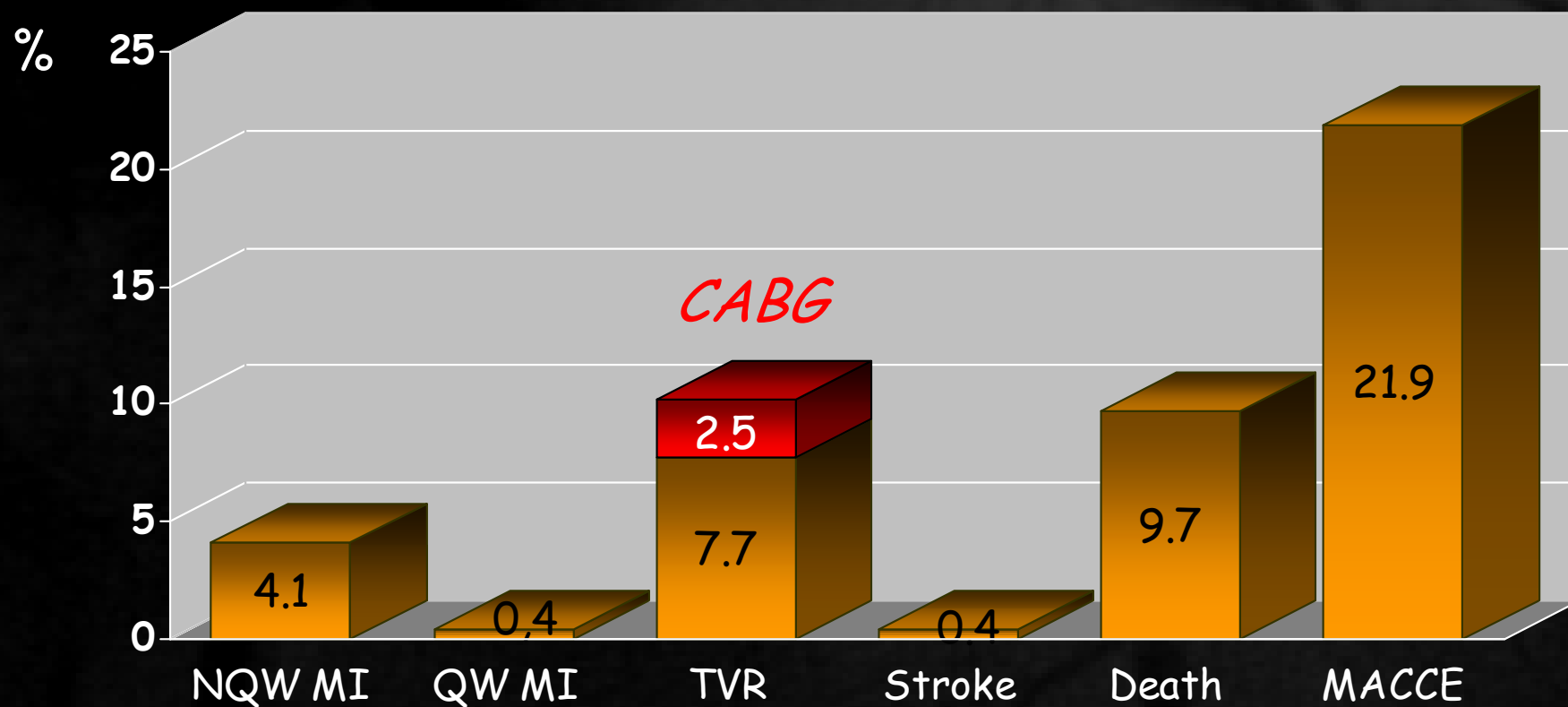


\* Non Hierarchical Ranking



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

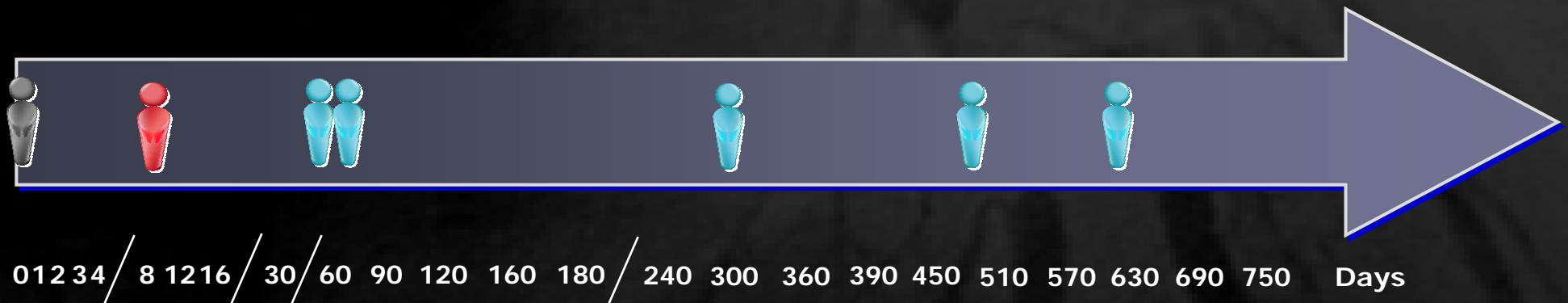
### Non cardiac (1.8%)




- |                                      |   |
|--------------------------------------|---|
| ✓ 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)

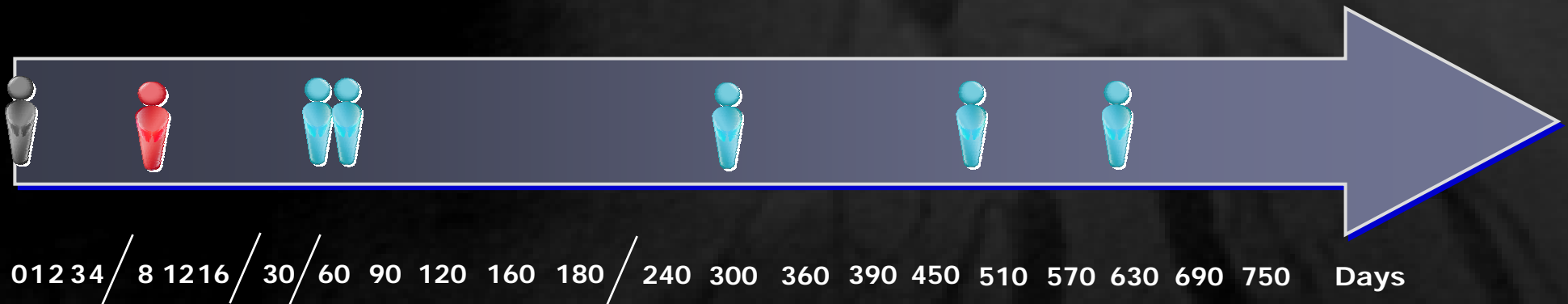


- A**  *Definite stent thrombosis (angiography or autopsy documented)*
- R**  *Probable (unexplained death < 30 days or MI in the treated territory)*
- C**  *Possible (Sudden unexplained death > 30 days)*






# French Left Main Taxus Pilot Study

## Safety (n=284)



1 Year      1- 2 years

<b>A</b>		Definite	0.4%	0%
<b>R</b>		Probable	0.4%	0%
<b>C</b>		Possible	1.1%	0.7%



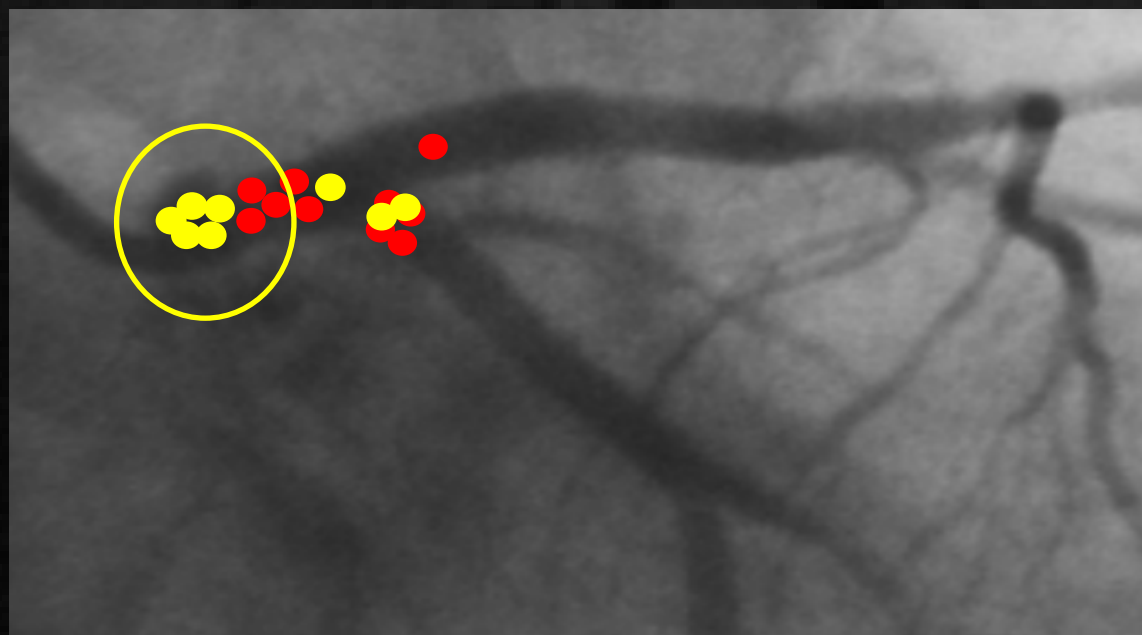
# French Left Main Taxus Pilot Study

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

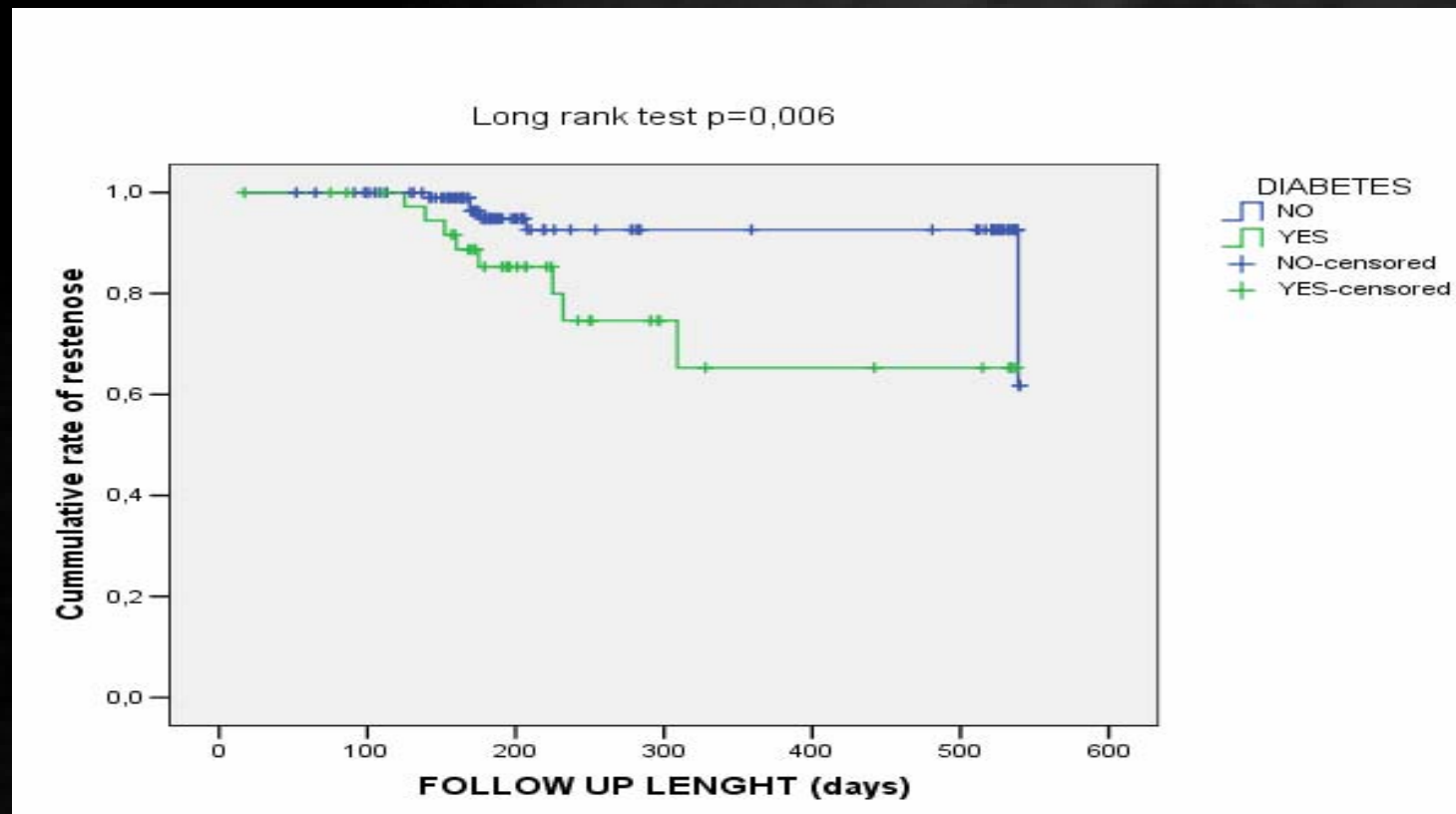
## Predictors of Restenosis

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

## Diabetes and Restenosis





# French Left Main Taxus Pilot Study

## Conclusion

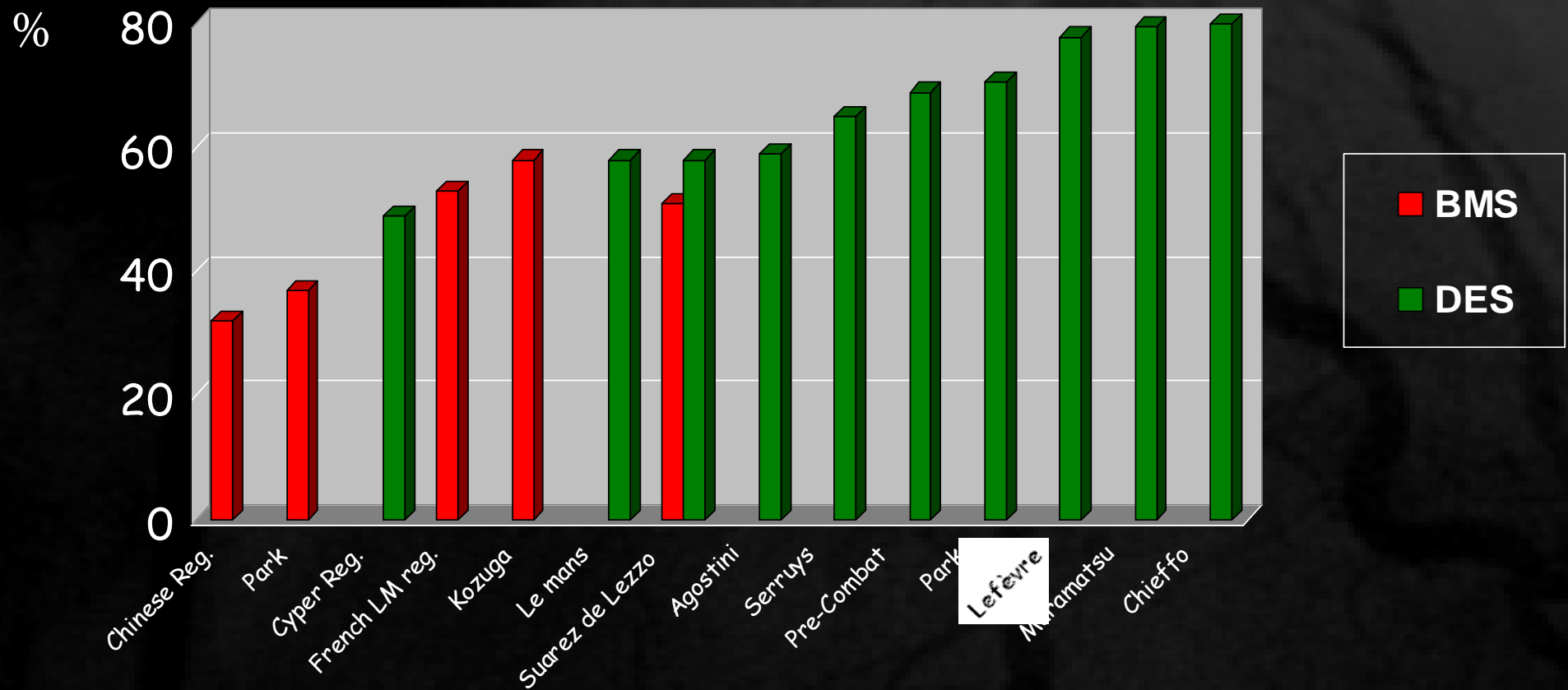
Left main PCI using the TAXUS stent with a strategy of provisional side branch T stenting, in the presence of distal LM disease, provides excellent acute angiographic results and good mid-term outcome in experienced centers compared to surgery.



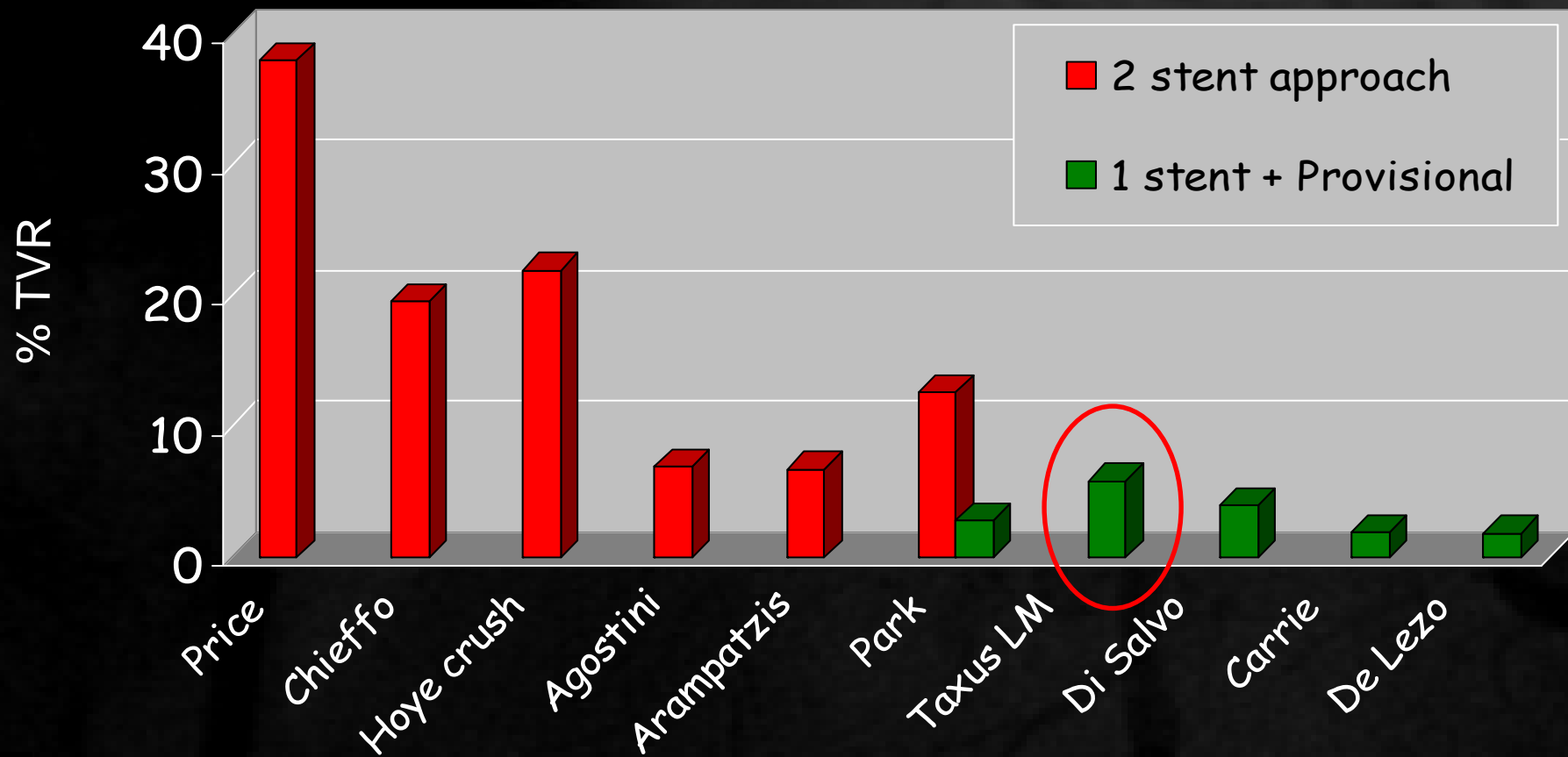
# Back Up Slides



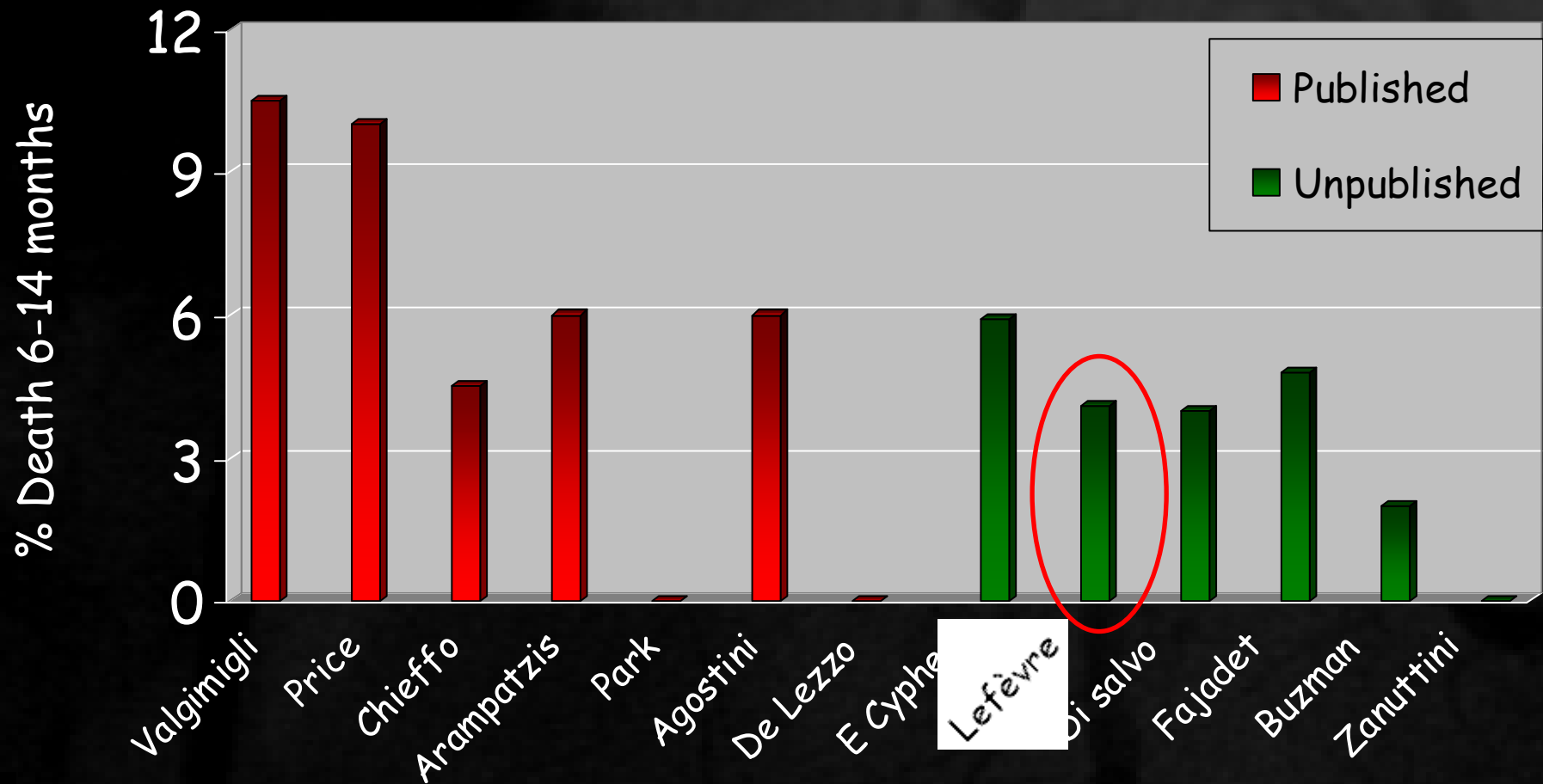
# High Frequency of Distal LM Location



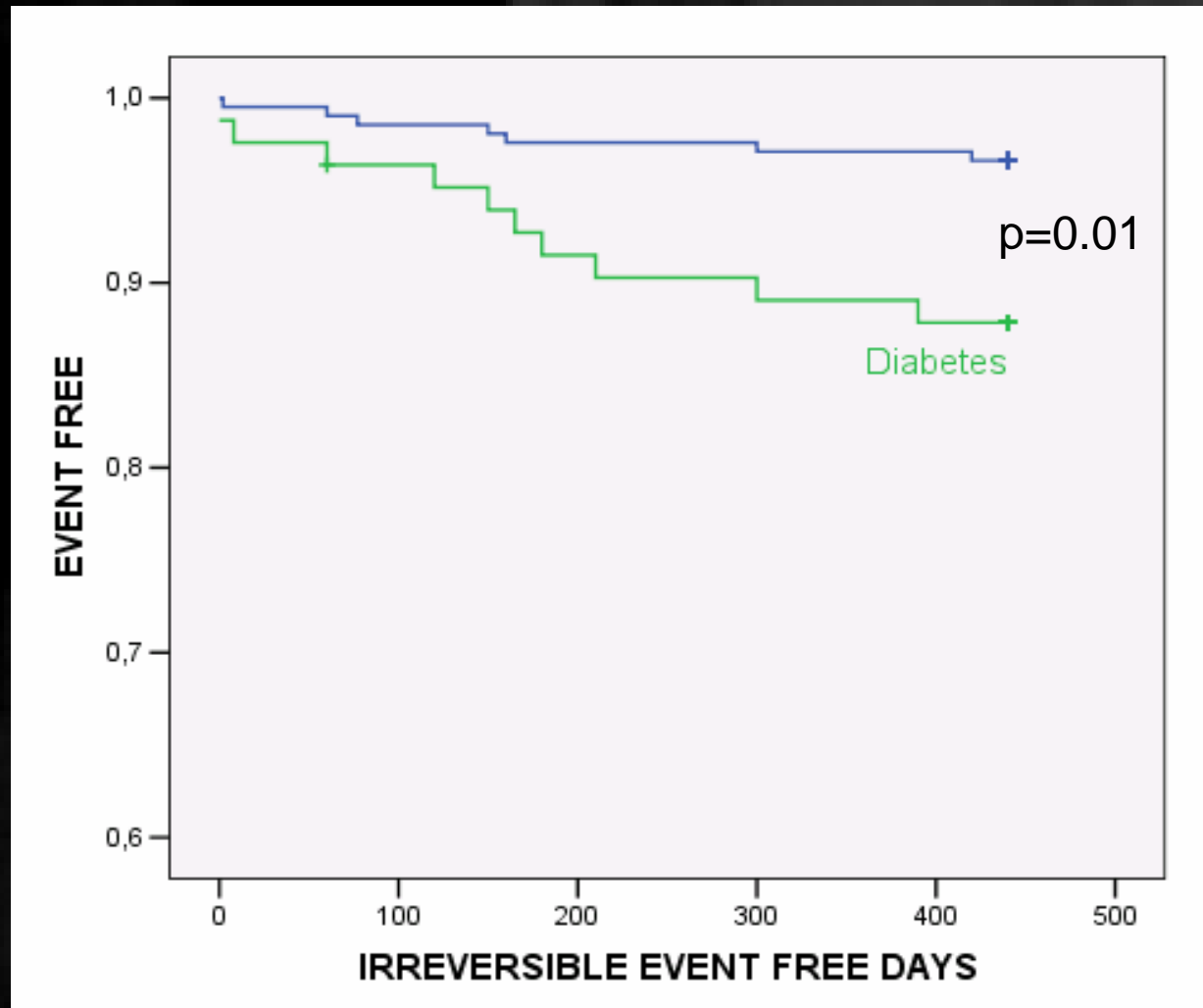
# Single Digit TVR After LM SB Provisional Stenting



# DES for Left Main Stenting and Death



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



# 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

## Clinical Characteristics

	Distal	Not distal	P value
Patients (n)	227	64	NS
Age (years)	69 <sub>+12</sub>	68 <sub>+10</sub>	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 <sub>+3.3</sub>	5.1 <sub>+3.6</sub>	NS
Estimated mortality (%)	6.2 <sub>+10.2</sub>	7.0 <sub>+11.5</sub>	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

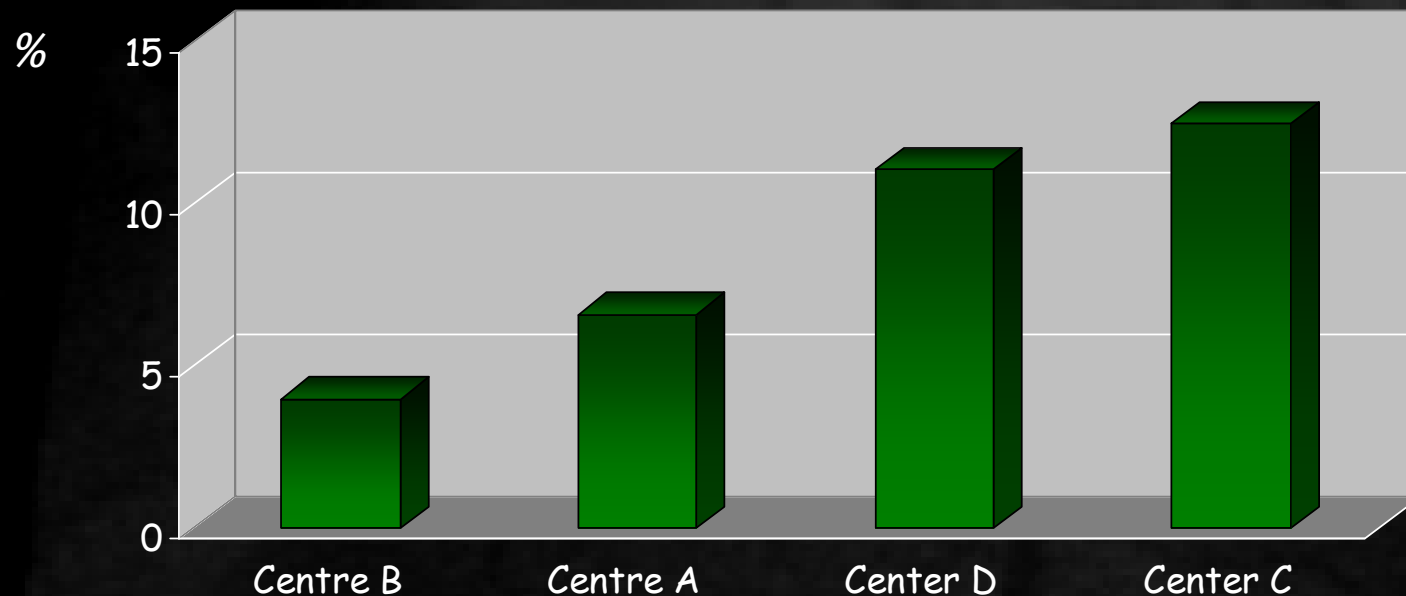
## Procedural Data

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



# French Left Main Taxus Registry

## Reintervention at 12 Months



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



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

