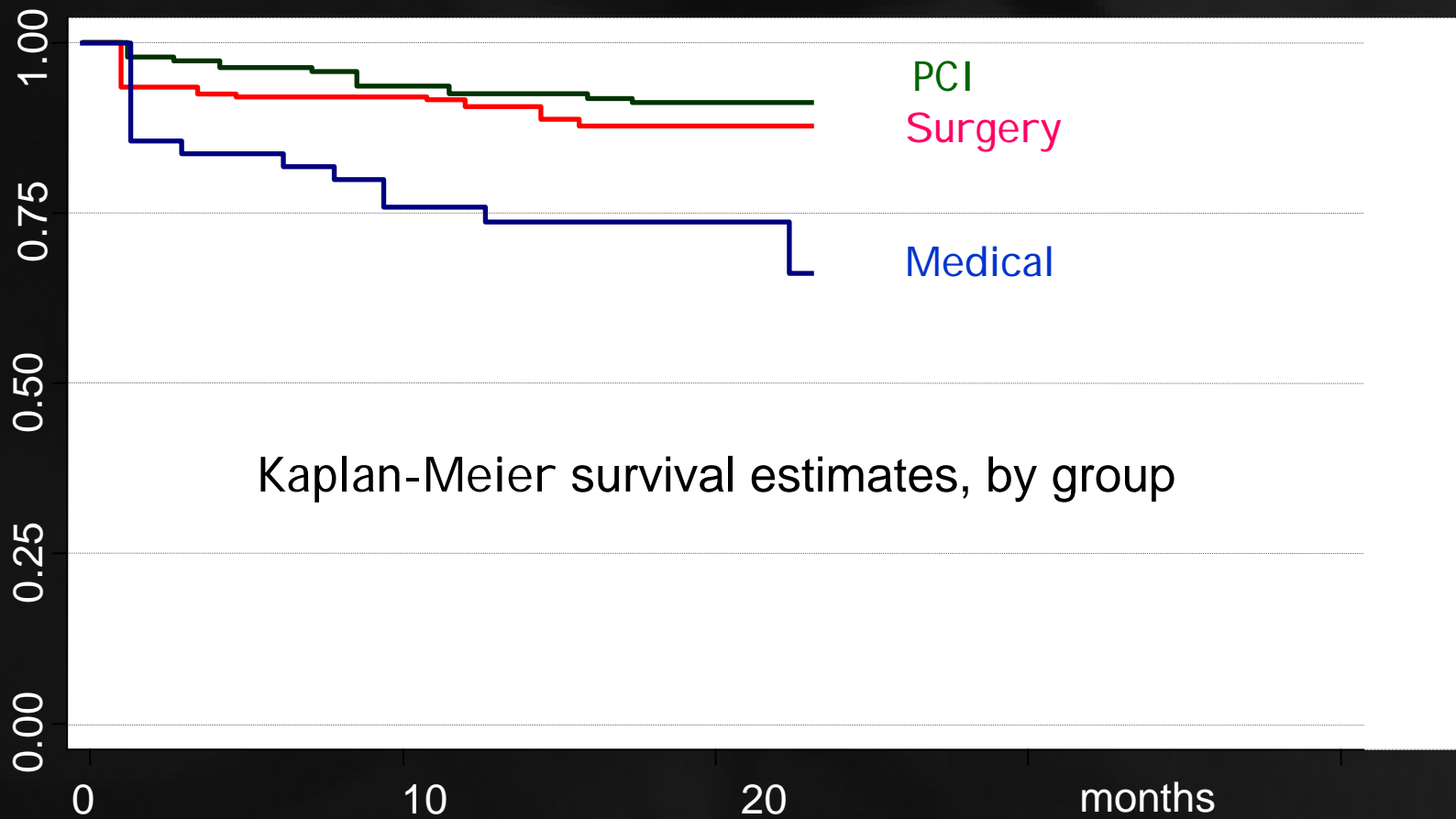


# Left Main TAXUS Pilot Study. Mid-term follow-up

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*On behalf the Left Main TAXUS Pilot Study Investigators.*

# Final results of the French Registry of Left Main Coronary Treatment



# Final results of the French Registry of Left Main 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
<b>TVR left main (%)</b>	<b>13.4</b>	<b>3.7</b>	<b>0.001</b>
<b>Total Reintervention (%)</b>	<b>28.5</b>	<b>3.7</b>	<b>&lt;0.001</b>

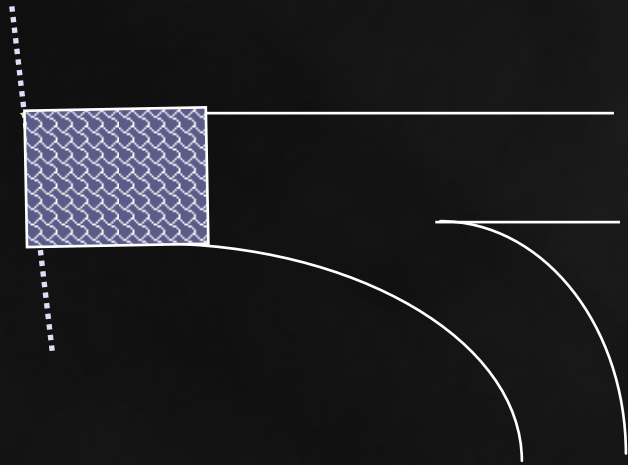
# French Left Main Taxus Pilot Study

## Design of the Study

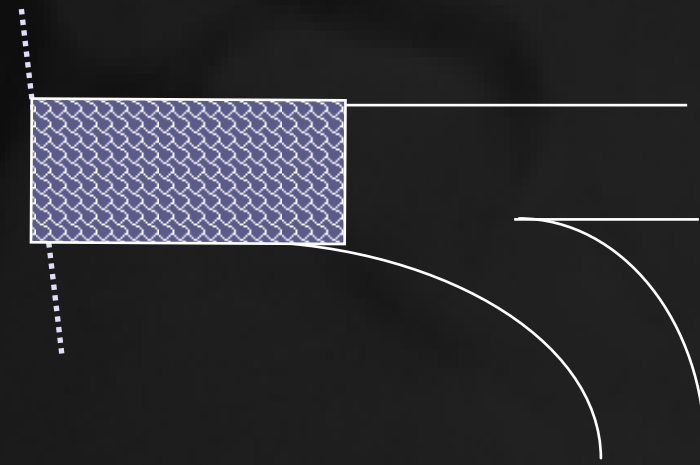
- ✓ May 2003-June 2005
- ✓ Feasibility and Safety Study
- ✓ 4 experienced centers
- ✓ Consecutive patients with de novo lesions
- ✓ Informed consent
- ✓ Standardized approach
- ✓ Plavix + Aspirin  $\geq$  6 months

# French Left Main Taxus Pilot Study

## Strategy and Lesion Type



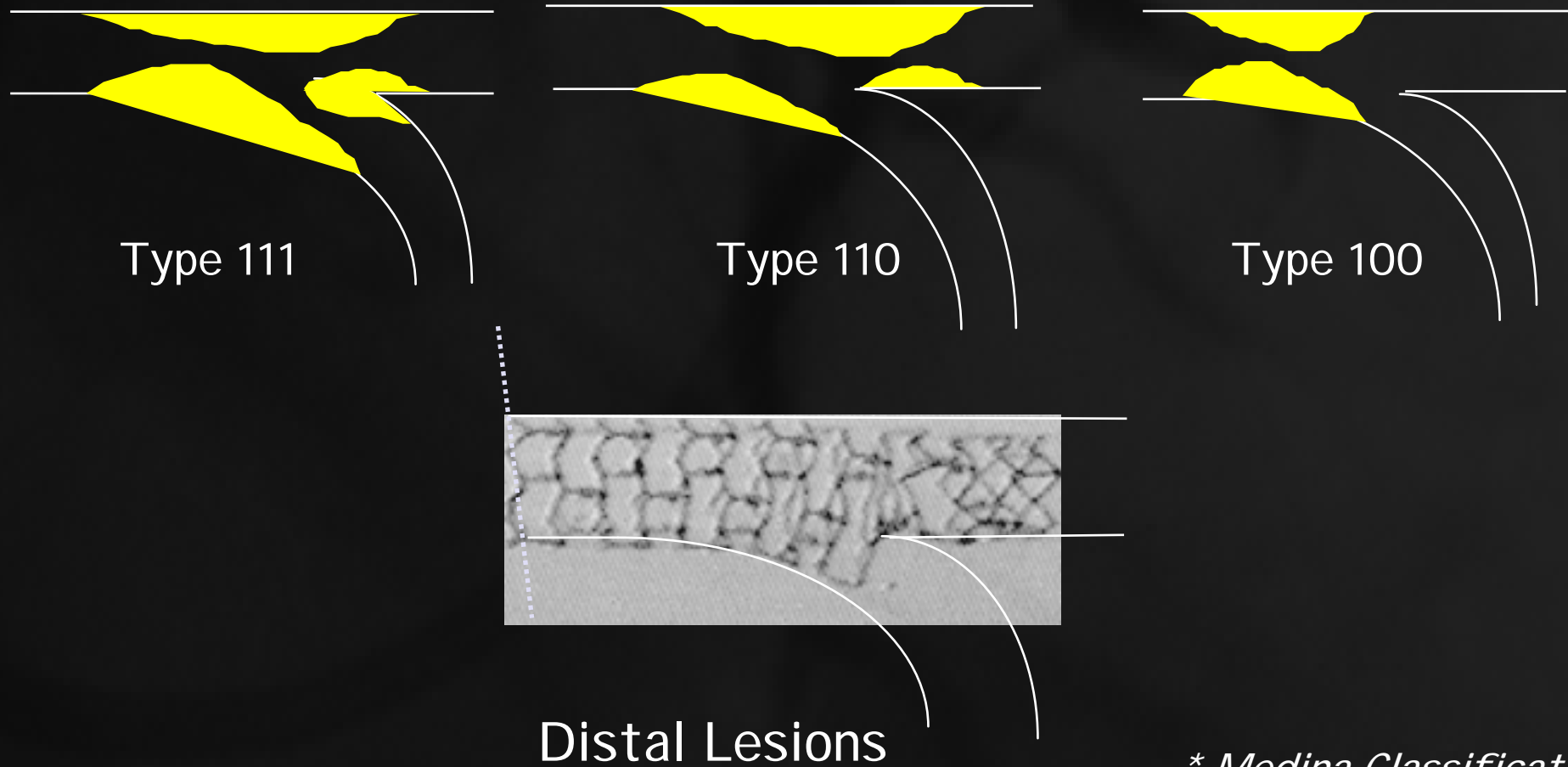
Ostial Lesion



Mid shaft Lesion

# French Left Main Taxus Pilot Study

## Strategy and Lesion Type\*



# 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

May 2003 - June 2005: 291 Patients included



# French Left Main Taxus Pilot Study

## Clinical Characteristics

Patients (n)	291
Age (years)	68.8 $\pm$ 11.4
Male gender (%)	76.5
Risk factors (%)	
Diabetes	28.7
Hypertension	63.9
Hypercholesterolemia	62.6
Smoker	43.3
Family history	19.4

# French Left Main Taxus Pilot Study

## Clinical Characteristics (cont. )

Previous MI (%)	11.5
Previous PCI (%)	20.1
Previous CABG (%)	1.0
Unstable angina (%)	37.4
Recent MI (%)	6.6
3 vessel disease (%)	25.8
EF (%)	60 <sub>±</sub> 13
Additive Euroscore	4.8 <sub>±</sub> 3.4
<b>Estimated mortality (%)</b>	<b>6.6<sub>±</sub>10.8</b>

# French Left Main Taxus Pilot Study

## Left Main Lesion Location



Ostial-proximal 29.4 %



Mid-shaft 11.4 %



Distal 77.9 %

# French Left Main Taxus Pilot Study

## Procedural Data

Gp2b3a inhibitors (%)	4.2
Radial approach (%)	57.4
Guiding size 6 Fr (%)	85.8
7 Fr (%)	12.8
I ABP (%)	4.5
Other treated vessel (%)	78.4
Other treated vessels (n)	1.35 $\pm$ 0.93
Total stent length (mm)	53 $\pm$ 23
Procedure (min.)	58.3 $\pm$ 31.2
Contrast media (ml)	250 $\pm$ 140

# French Left Main Taxus Pilot Study

## QCA analysis pre-PCI and Procedural Data

Left main reference (mm)	3.64 $\pm$ 0.50
LAD reference (mm)	3.23 $\pm$ 0.56
Circumflex reference (mm)	2.89 $\pm$ 0.44
% stenosis left main (%)	69.8 $\pm$ 11.9
Left main stent (n)	1.08 $\pm$ 0.30
Left main stent length (mm)	18.1 $\pm$ 6.3
Left main stent diameter (mm)	3.43 $\pm$ 0.17
Final balloon diameter (mm)	3.63 $\pm$ 0.32

# French Left Main Taxus Pilot Study

## QCA Analysis post procedure

Left main reference (mm)	3.83 $\pm$ 0.43
Left main MLD (mm)	3.46 $\pm$ 0.47
Left main residual stenosis (%)	6.7 $\pm$ 7.5
Circ. reference (mm)	3.22 $\pm$ 0.55
Circ. MLD (mm)	2.83 $\pm$ 0.50
Circ. residual stenosis (%)	8.4 $\pm$ 10.6
<b>Angiographic Success (%)</b>	<b>99.6</b>

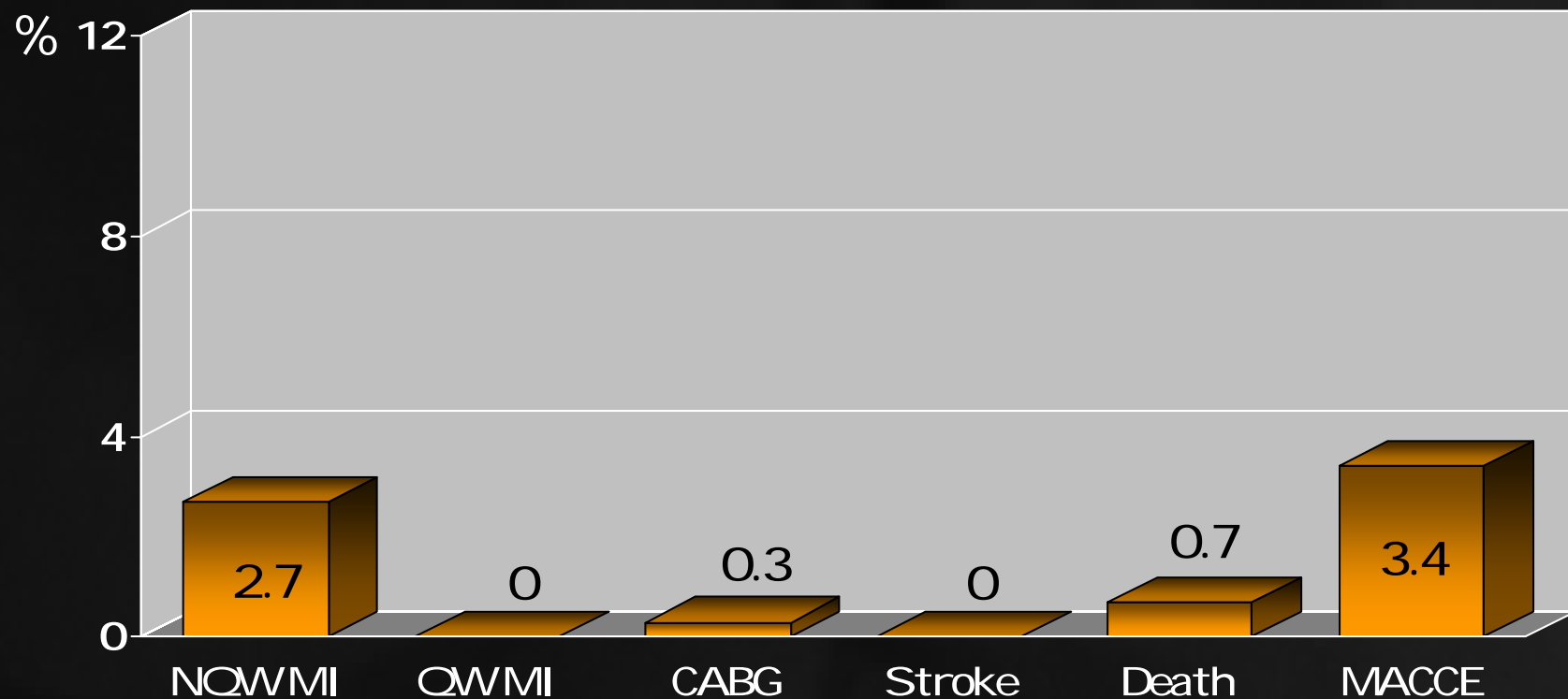
# French Left Main Taxus Pilot Study

Distal left main in 77.9% of cases

Provisional SB T-stenting (%)	91.5
Systematic T stenting (%)	8.0
V Stenting (%)	0.5
Side branch stented (%)	40.6
Side branch stent length (mm)	13.8 $\pm$ 5.5
Side branch stent diameter (mm)	3.04 $\pm$ 0.34
Final Kissing balloon (%)	96.8

# French Left Main Taxus Pilot Study

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

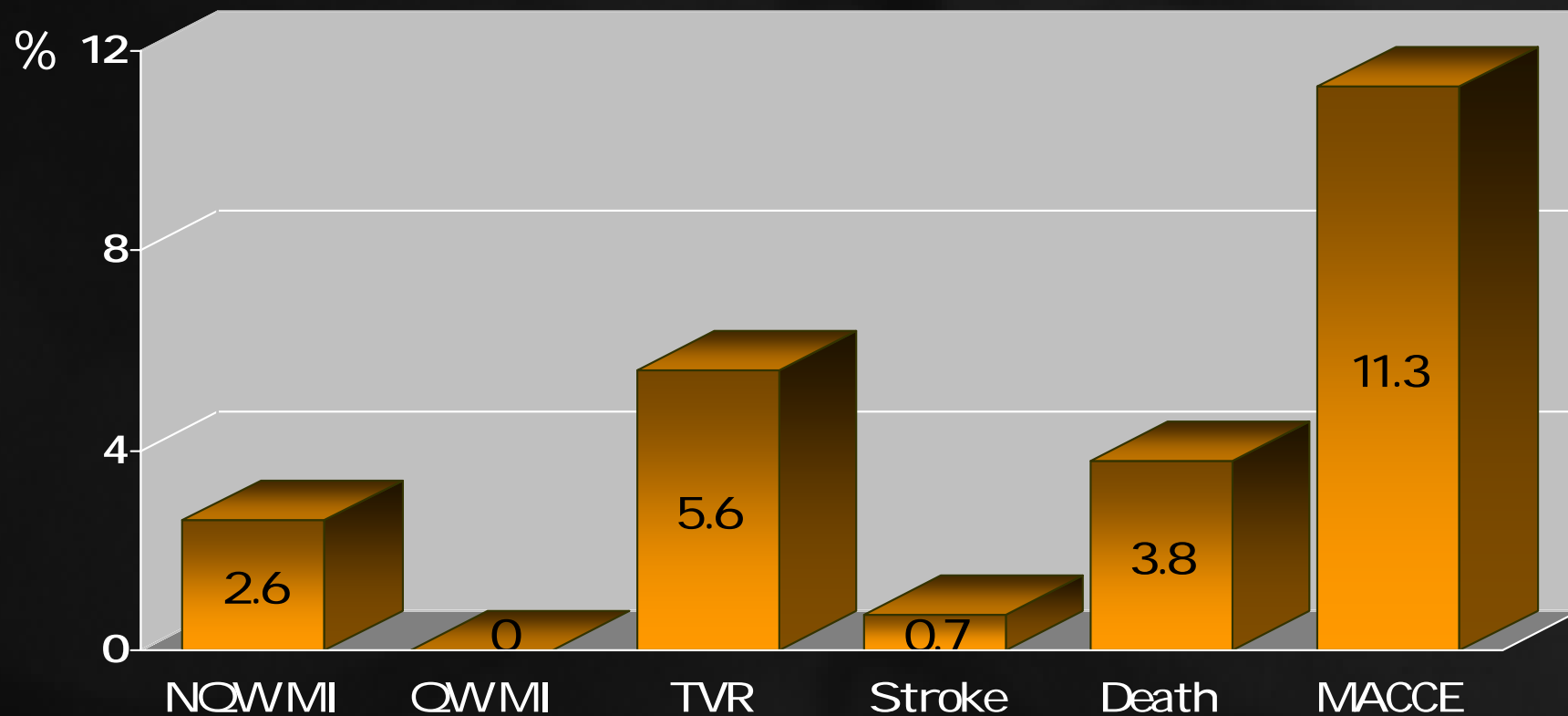


\* Non Hierarchical Ranking



# French Left Main Taxus Pilot Study

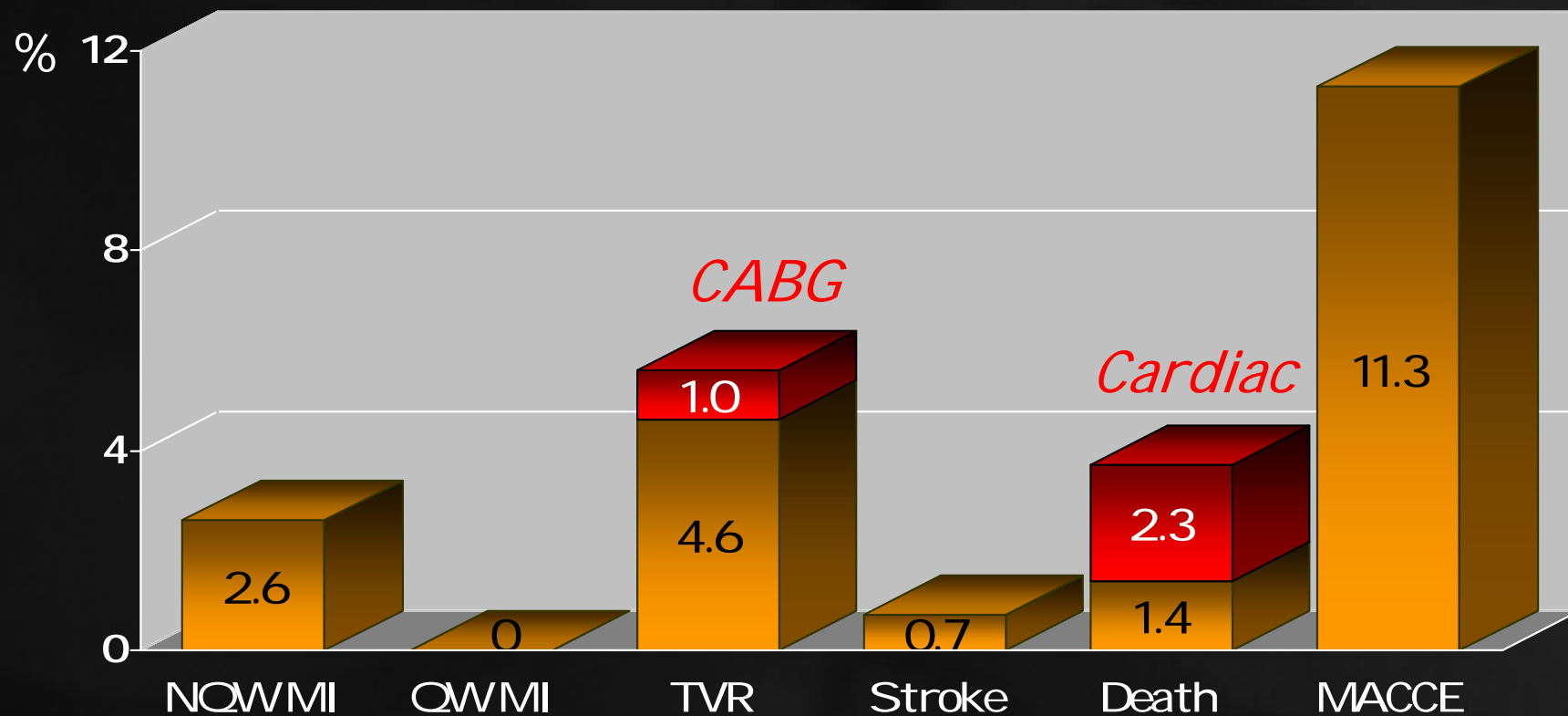
6-12 months F-Up (287/291: 98%, 9.1±1.9 months)



\* Non Hierarchical Ranking

# French Left Main Taxus Pilot Study

6-12 months F-Up (287/291: 98%, 9.1±1.9 months)



\* Non Hierarchical Ranking

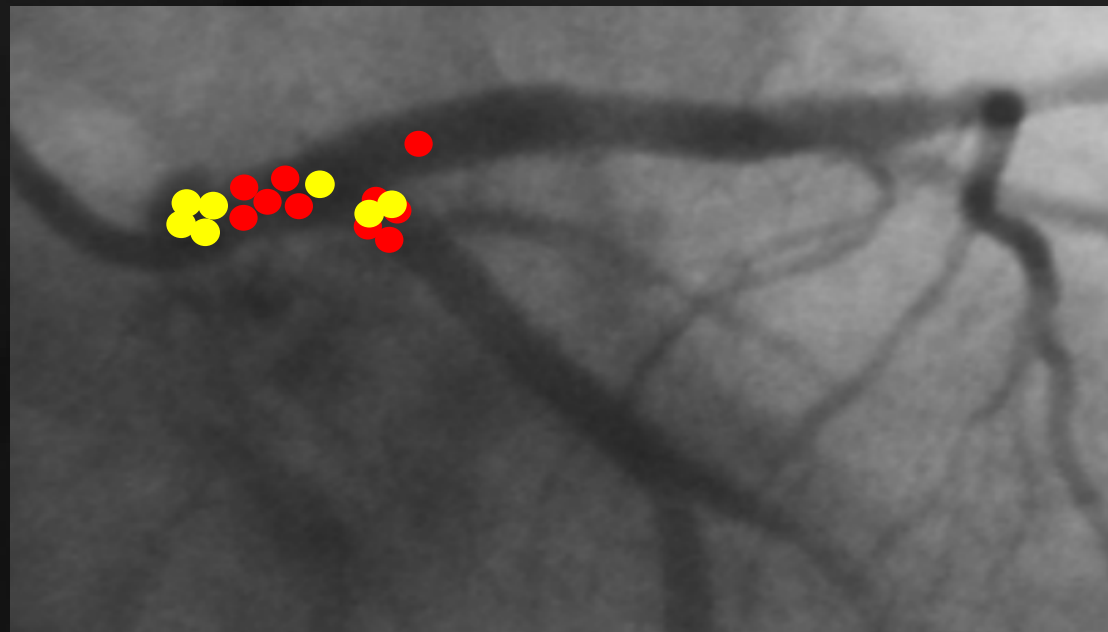
# French Left Main Taxus Pilot Study

Angiographic F-Up (178/277: 64.3%)

Delay (months)  $6.9 \pm 2.6$

LM restenosis (%)  $9.6^*$

- In stent
- Not in stent



# French Left Main Taxus Pilot Study

Cause of death (n=11/287: 3.8%)

## Cardiac

- ✓ AT during the procedure 1
- ✓ Severe groin hematoma, day 2 1
- ✓ Sudden death, day 8 1
- ✓ Pulmonary oedema during dialysis, 2 months 1
- ✓ Sudden death, 8 weeks and 11 weeks 2
- ✓ LAD restenosis, reintervention 1

## Non cardiac

- ✓ Pulmonary infection, 4 months 1
- ✓ Hemorrhage during dialysis, 2 months 1
- ✓ Stroke at 5 months 1
- ✓ Cancer at 7 months 1

# French Left Main Taxus Pilot Study

## Predictors of Death at 6-12 Months

	Death	No death	p value
Patients (n)	11	280	-
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
Two stents in distal LM (%)	50.0	40.6	NS

# French Left Main Taxus Pilot Study

## Conclusion

Mid term results of this “real world” multicenter pilot study with the TAXUS stent for LM PCI using a standardized technical approach are encouraging and certainly challenging CABG.

However there is still a room for improvement in stent design and drug delivery approach.