Left Main Session:
Focus on Technique and Late Outcome

French Taxus LM Registry at 5 years

European Bifurcation Club

Thierry Lefèvre,
on Behalf the French Registry

French Left Main Taxus Pilot Study

Design of the Study

- ✓ Unprotected LM
- ✓ May 2003-June 2005
- ✓ « All comers » (Only AMI and Shock excluded)
- ✓ Feasibility and Safety Study
- ✓ Taxus Express stent
- ✓ 4 experienced French centers
- ✓ Informed consent

French Left Main Taxus Pilot Study

Design of the Study (Cont')

- ✓ Provisional side branch T stenting for Bifurcations
- ✓ Aspirin ≥75 mg/d indefinitely
- ✓ Clopidogrel 75 mg/d for at least 6 months
- ✓ Angiographic F-up recommended at 6 months

French Left Main Taxus Pilot Study

Main Clinical Characteristics

Patients (n)	291
Age (years)	68.8±11.4
Diabetes (%)	28.9
Renal failure (%)*	27.6
Previous MI (%)	11.3
Previous PCI (%)	20.1
ACS (%)	41.9
3 vessel disease (%)	30.9
EF (%)	60±13
Logistic Euroscore (%)	6.4±10.5

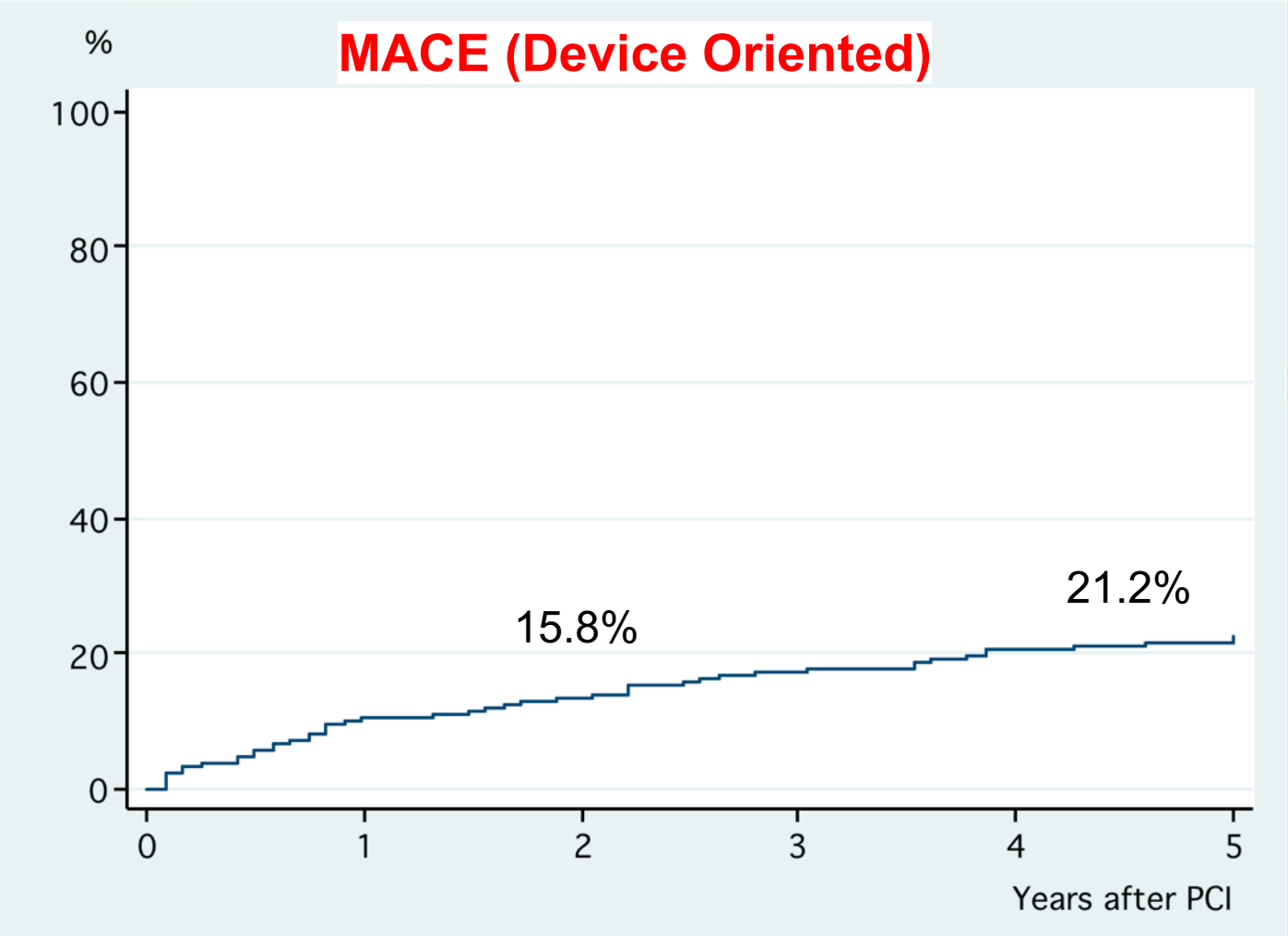
** Creatinine clearance < 90ml/min/1.73m^2*

French Left Main Taxus Pilot Study

Main Procedural Data

Gp2b3a inhibitors (%)	4.2
IABP (%)	4.5
Left main reference (mm)	3.66±0.50
Other treated vessel (%)	78.4
Total stent length (mm)	53±23
LM angiographic success (%)	99.6
Distal LM (%)	78.4
T shape bifurcation (%)	38.0
Side branch stented (%)	42.5
Final Kissing balloon (%)	97.4

French Left Main Taxus Pilot Study

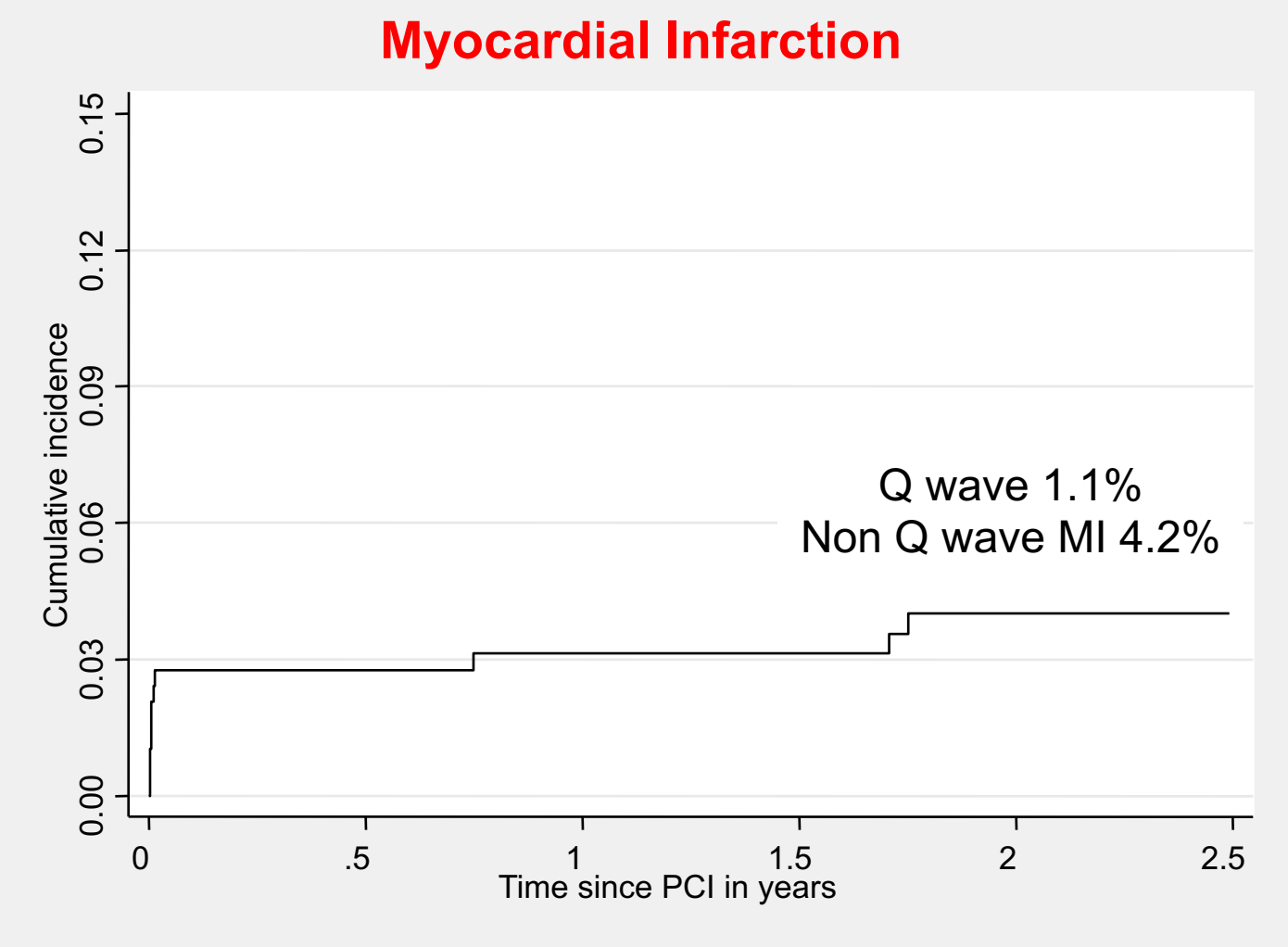


French Left Main Taxus Pilot Study

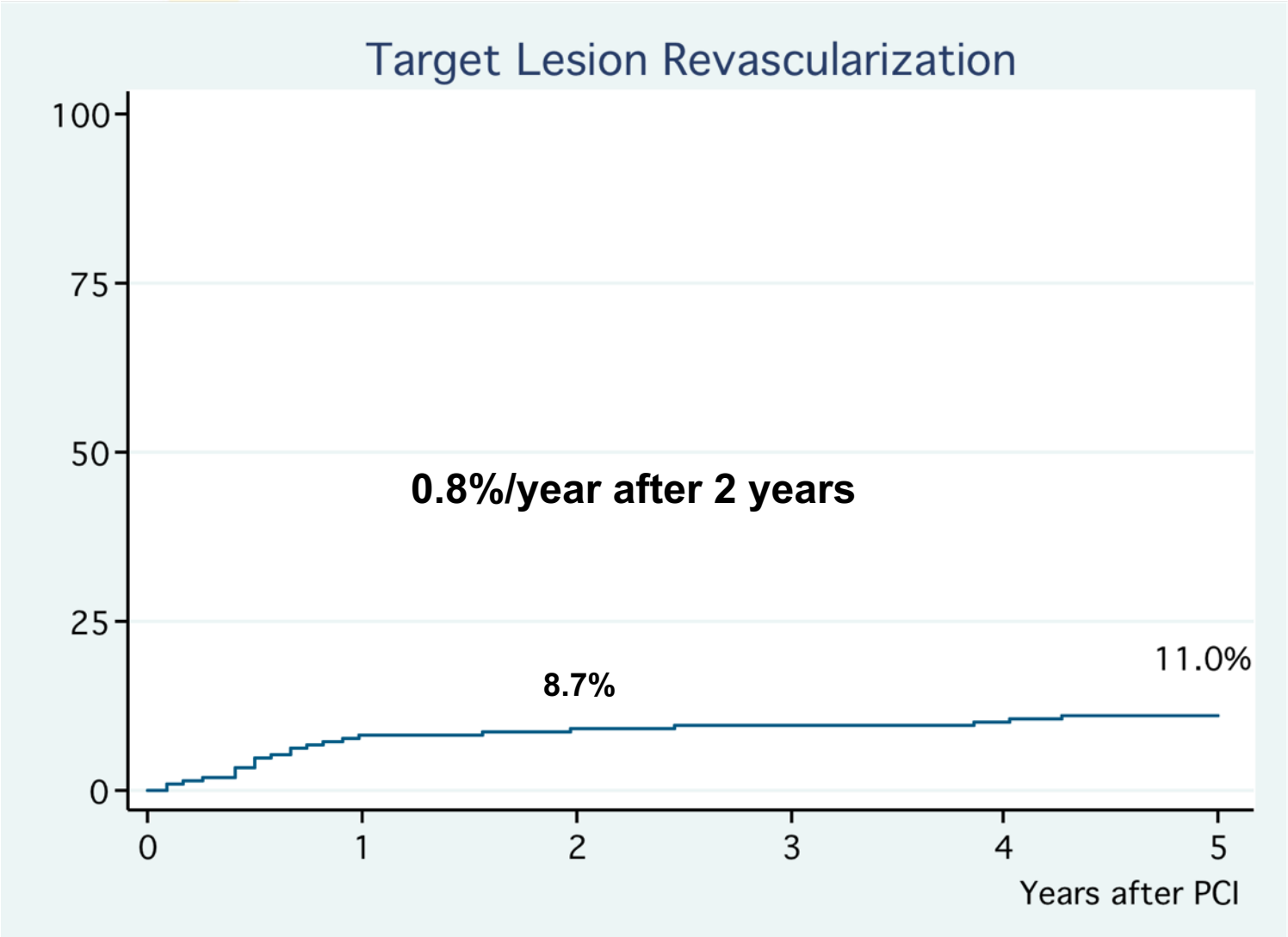
Predictors of device oriented MACE at 5 years
(Cardiac death, TLR and MI) (all Pts, n= 291)

Variables	Univariate p value	Multivariate p value	Odds ratio	95%CI
Age	0.024			
Euroscore	0.059			
Hypertension	0.003	0.043	4.827	1.054 – 22.104
Diabetes	0.022			
Creatinine clearance	0.004			
LVEF	0.004	0.009	0.944	0.905 – 0.986
2 stents	0.011			

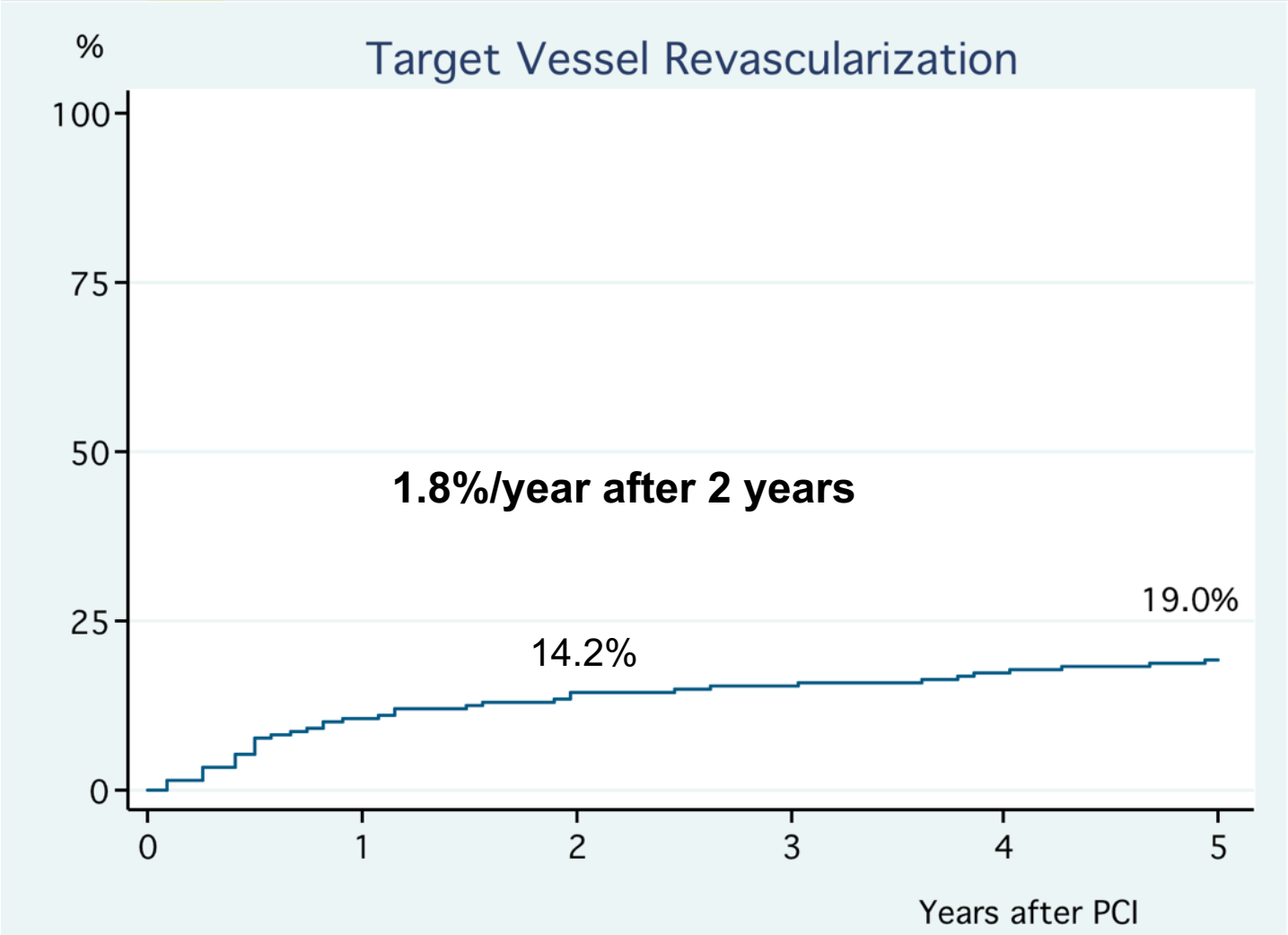
French Left Main Taxus Pilot Study



French Left Main Taxus Pilot Study



French Left Main Taxus Pilot Study

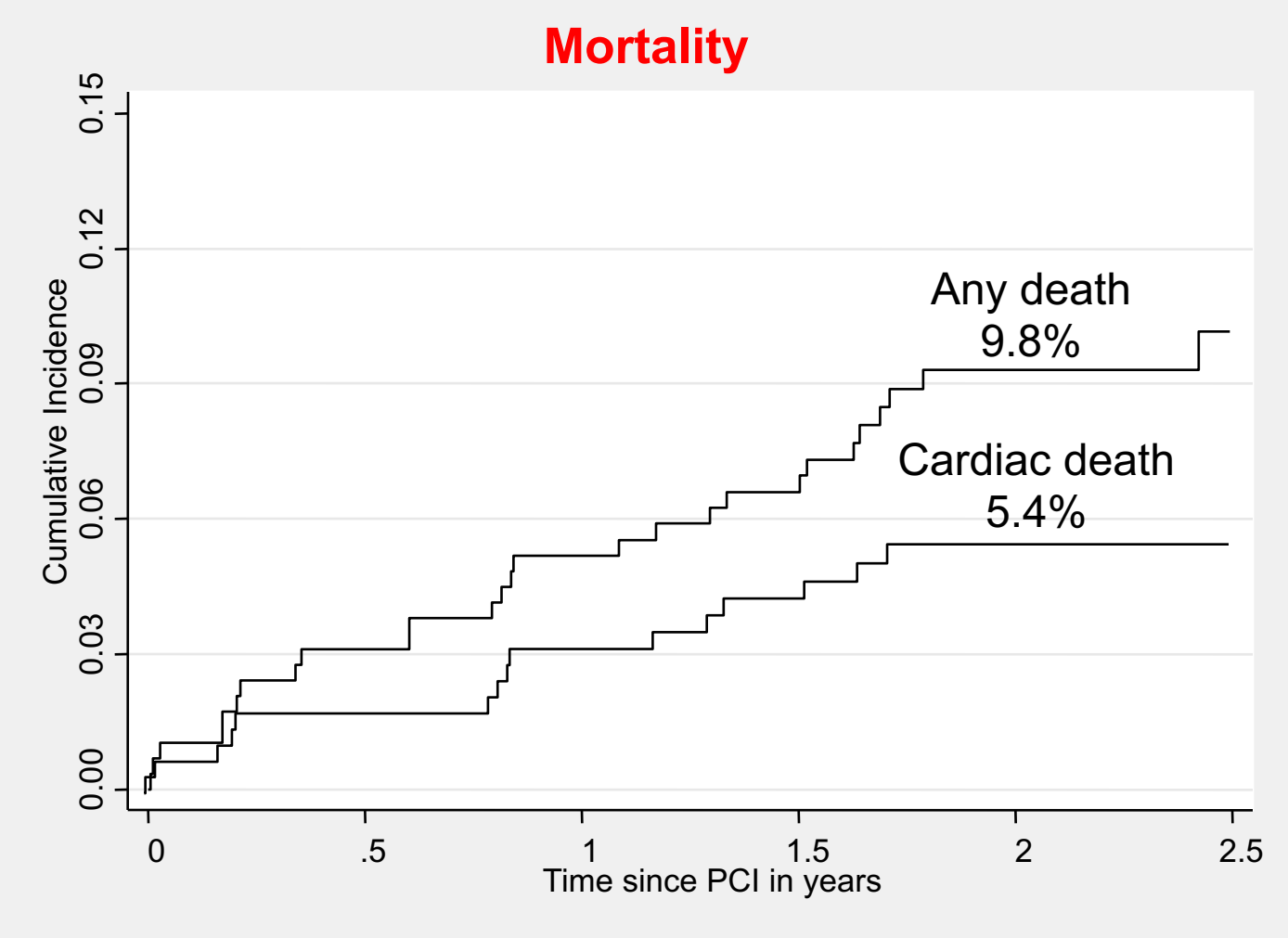


French Left Main Taxus Pilot Study

Predictors of TLR at 5 years (all Pts, n= 291)

Variables	Univariate p value	Multivariate p value	Odds ratio	95%CI
Diabetes	0.014			
Metabolic syndrome	**0.030**	**0.012**	**3.612**	**1.325 – 9.851**

French Left Main Taxus Pilot Study



French Left Main Taxus Pilot Study

Predictors of cardiac death at 2 years (all Pts, n= 291)

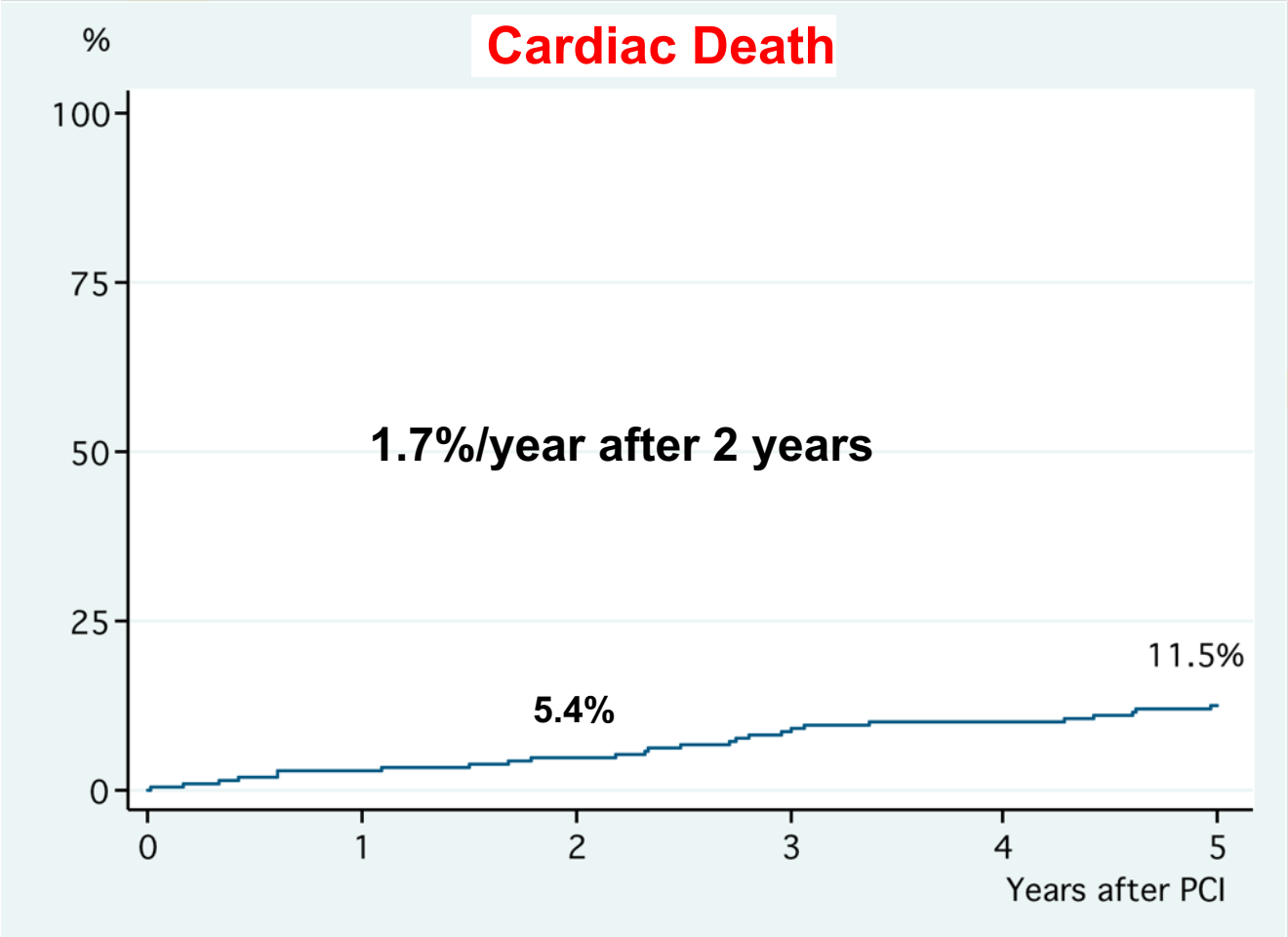
	Univariate		Multivariate	
	HR 95% CI	*P*	HR 95% CI	*P*
Additive EuroSCORE	1.149 (1.029-1.282)	0.013	1.170 (1.042-1.314)	0.008
LVEF, %	0.953 (0.920-0.986)	0.006		
Creatinine clearance	0.972 (0.956-0.988)	0.001		
SB MLD, mm	0.414 (0.170-1.004)	0.051		
SB diameter stenosis, %	1.025 (1.003-1.048)	0.022		

French Left Main Taxus Pilot Study

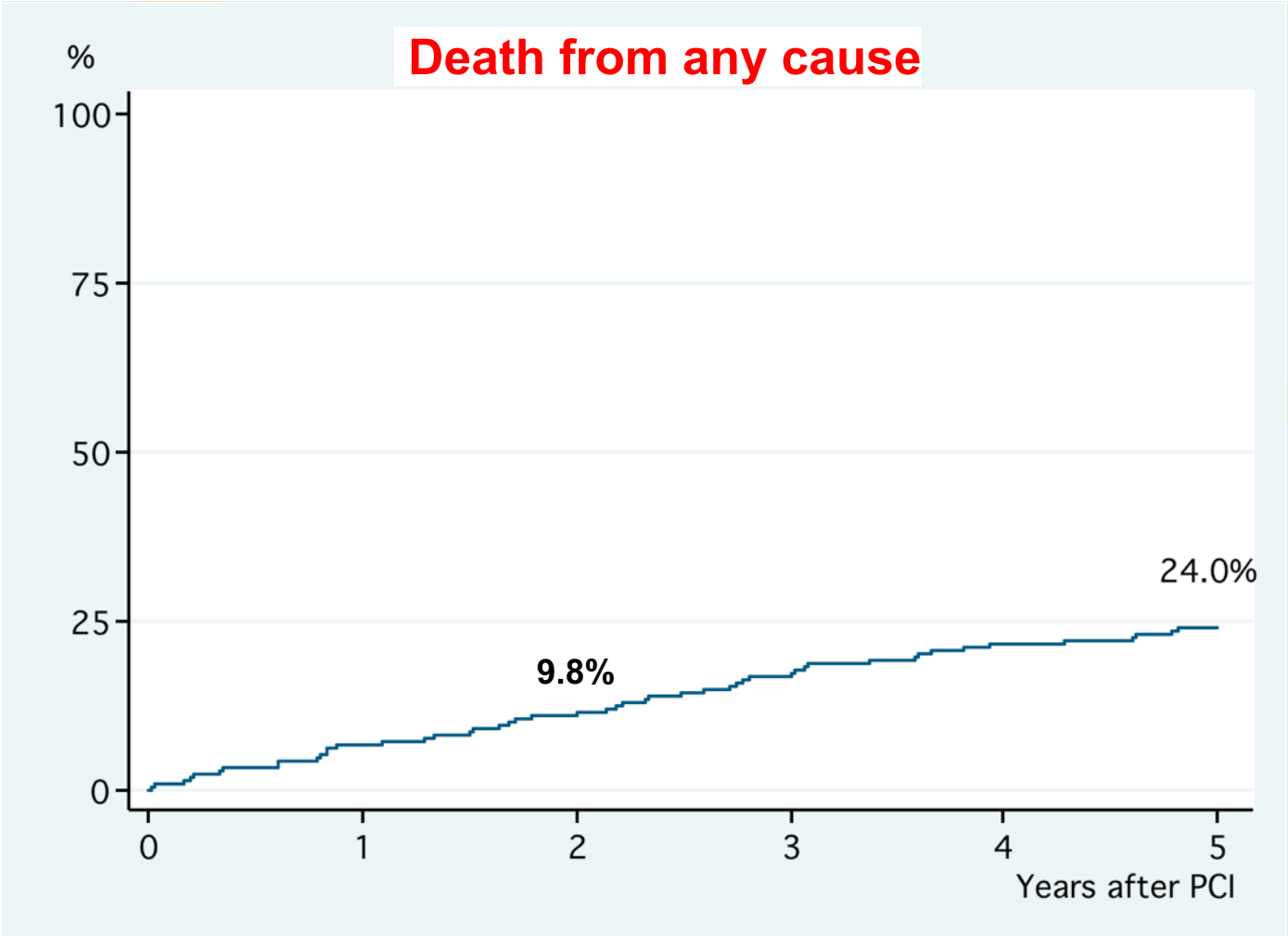
Predictors of cardiac death (Pts with bifurcation, n= 228)

	Univariate		Multivariate	
	HR 95%IC	*P*	HR 95%IC	*P*
Additive EuroSCORE	1.187 (1.057-1.334)	0.004	1.191 (1.049-1.353)	0.007
LVEF, %	0.954 (0.916-0.994)	0.026		
Creatinine clearance	0.980 (0.962-0.998)	0.032		
SB MLD, mm	0.418 (0.172-1.016)	0.054		
SB diameter stenosis, %	1.024 (1.002-1.047)	0.030		
T-shaped bifurcation lesion	3.487 (1.049-11.85)	0.041		

French Left Main Taxus Pilot Study



French Left Main Taxus Pilot Study

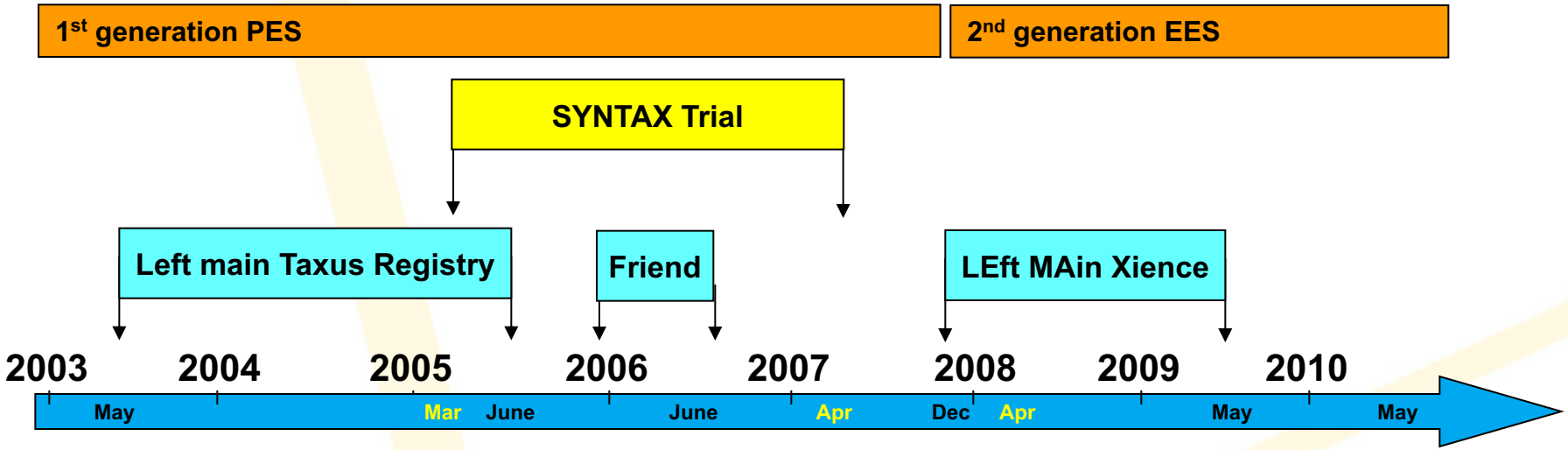


French Left Main Taxus Pilot Study

Predictors of Cardiac death at 5 years (all Pts, n= 291)

Variables	Univariate p value	Multivariate p value	Odds ratio	95%CI
Age	0.001			
Euroscore	<0.001			
Hyperlipidemia	0.038			
Creatinine clearance	0.001			
LVEF	**<0.001**	**0.009**	**0.912**	**0.852 – 0.978**
SB % stenosis post procedure	0.041			

French Left Main Taxus Pilot Study vs LEMAX



- 2 consecutive registries
- 4 french institutions
- Same operators
- Same technique for Left Main stenting (Provisional T stenting strategy)

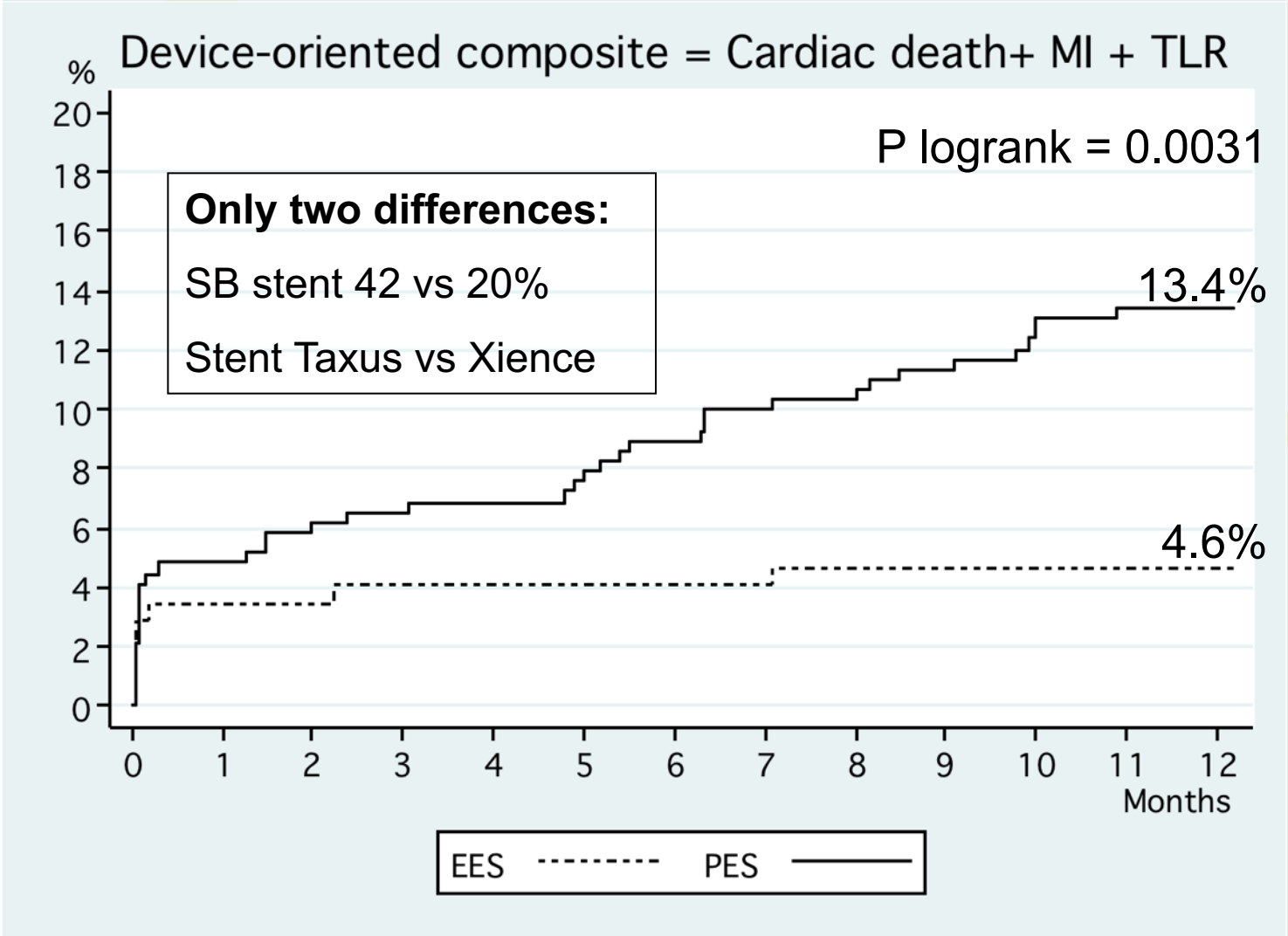
Vaquerizo et al. Unprotected left main stenting in the real world: two-year outcomes of the french left main Taxus registry. *Circulation* 2009;119:2349-2356.

Carrié et al. Eurointervention 2008.

Salvatella et al. Unprotected left main stenting with a second-generation drug-eluting stent. One-year outcomes of the LEMAX Pilot study. *Submitted*.

Garot et al. TCT 2010

French Left Main Taxus Pilot Study vs LEMAX



Garot et al. TCT 2010

French Left Main Taxus Pilot Study vs LEMAX

Predictors of Device-oriented MACE *(Cardiac death+MI+TLR)*

Variable	Odds Ratio	p	95% Conf. Interval
Paclitaxel-Eluting Stent	3.37	0.006	[1.41-8.08]
Syntax score	1.05	0.015	[1.01-1.10]
Euro score	1.05	0.359	[0.95-1.17]
Diabetes	1.63	0.226	[0.74-3.62]
Previous MI	0.58	0.422	[0.16-2.18]
Nb stents in LM	2.21	0.011	[1.20-4.08]

Garot et al. TCT 2010

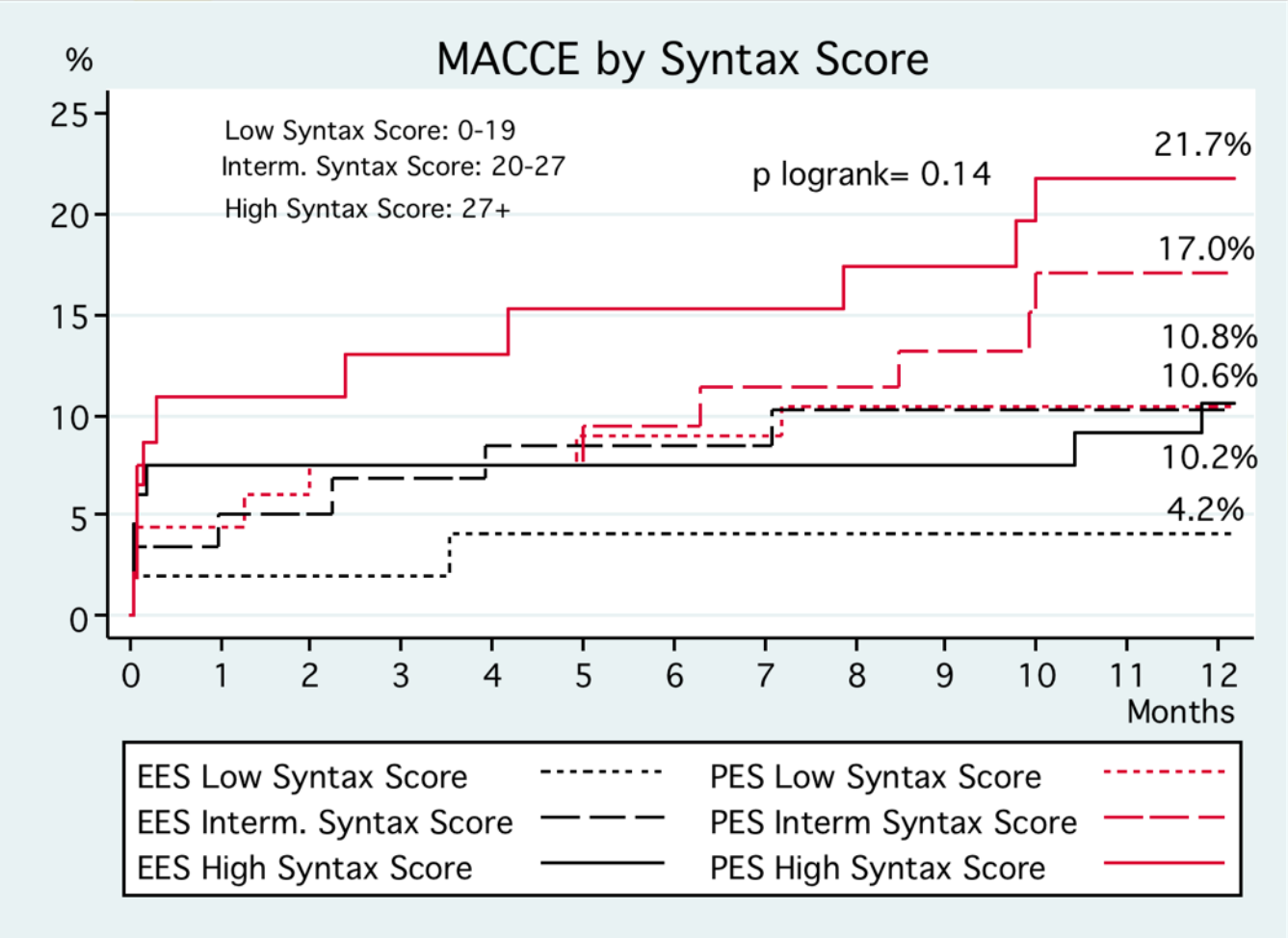
French Left Main Taxus Pilot Study vs LEMAX

Predictors of MACCE *(Death,MI,Clinically-driven TLR,CABG,Stroke)*

Variable	Odds Ratio	p	95% Conf. Interval
Paclitaxel-Eluting Stent	2.11	0.043	[1.02-4.34]
Syntax score	1.05	0.009	[1.01-1.09]
Euro score	1.13	0.007	[1.03-1.24]
Diabetes	1.98	0.061	[0.97-3.99]
Previous MI	0.38	0.148	[0.10-1.42]
Nb stents in LM	1.54	0.148	[0.86-2.78]

Garot et al. TCT 2010

French Left Main Taxus Pilot Study vs LEMAX



Garot et al. TCT 2010

French Left Main Taxus Pilot Study

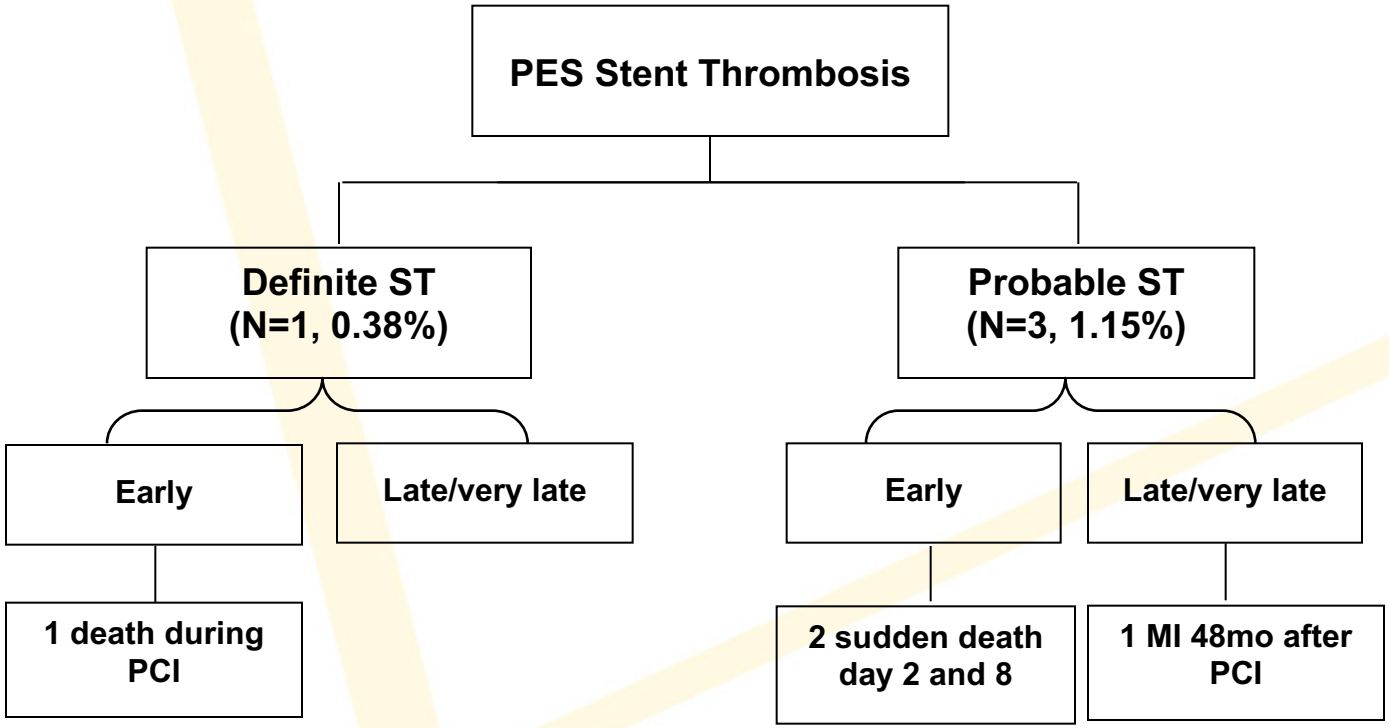
Conclusion

Unprotected LM PCI using PES with a strategy of Provisional SB stenting provides good long term outcome in real world patients. Annual cardiac mortality is 1.7% and all-cause mortality 4.4% after 2 years.

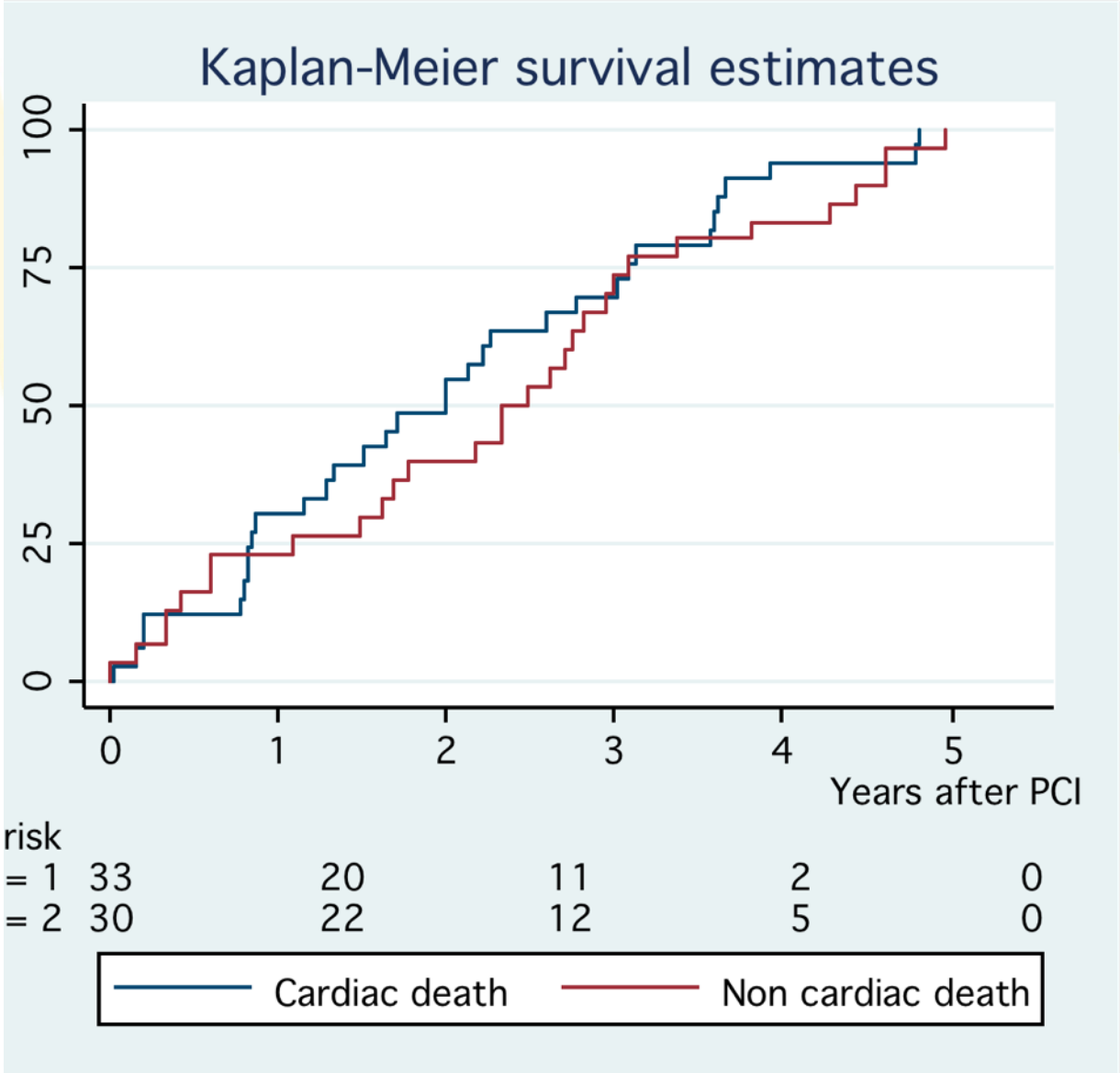
T shape angulation, use of two stents, stent type and finally lesions complexity in patients with multivessel disease, may play an important role in the outcome.

EBC

French Left Main Taxus Pilot Study

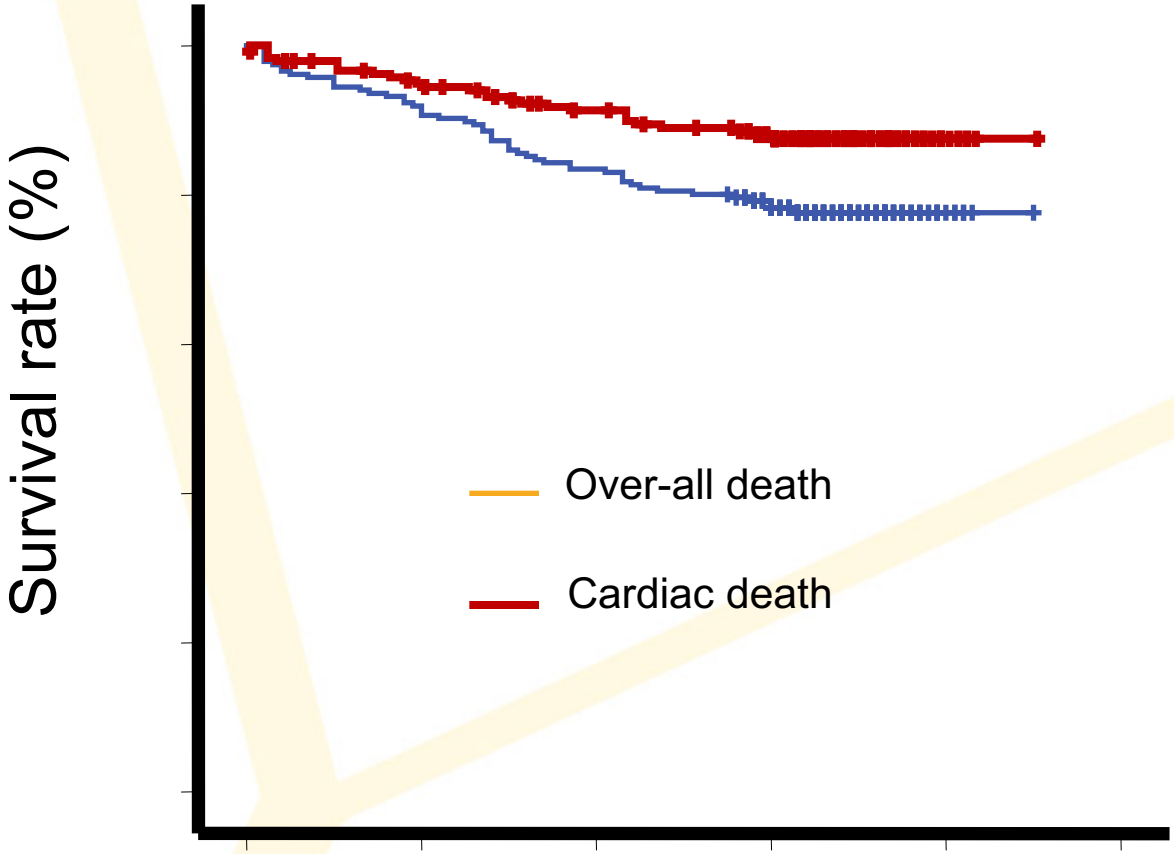


French Left Main Taxus Pilot Study



French Left Main Taxus Pilot Study

Cumulative incidence of mortality by the Kaplan-Meier method



French Left Main Taxus Pilot Study

Predictors of any ST (All Pts, n= 291)

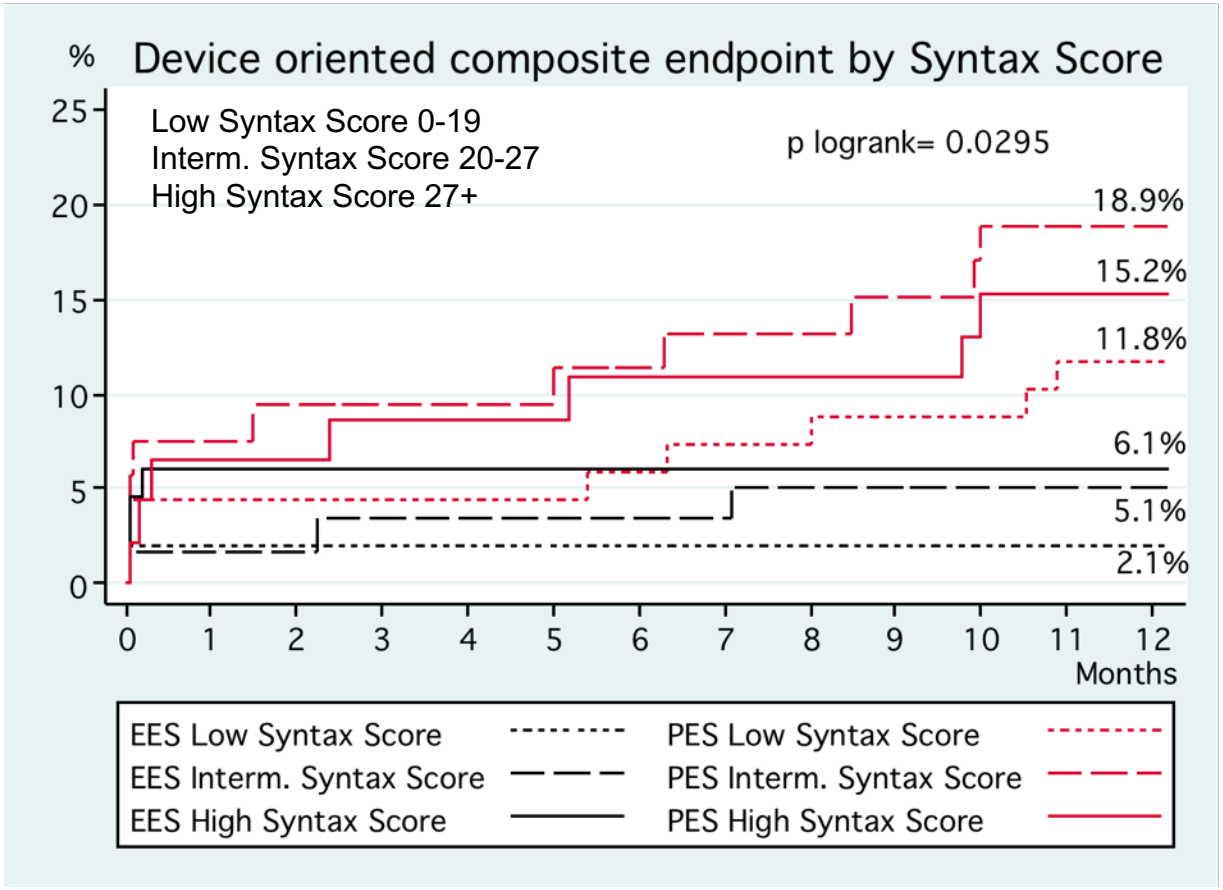
	Univariable		Multivariable	
	HR 95% CI	*P*	HR 95% CI	*P*
Creatinine clearance	0.979 (0.959-0.999)	0.041		
SB MLD, mm	0.049 (0.005-0.428)	0.006		
SB diameter stenosis, %	1.064 (1.019-1.110)	0.004		

French Left Main Taxus Pilot Study

Predictors of any ST (Pts with bifurcation, n= 228)

	Univariable		Multivariable	
	HR 95% CI	*P*	HR 95% CI	*P*
Additive EuroSCORE	1.153 (0.987-1.347)	0.07		
SB MLD, mm	0.049 (0.005-0.432)	0.007		
SB diam. stenosis, %	1.064 (1.019-1.10)	0.005		
SB stenting	9.556 (1.175-77.67)	0.035	9.273 (1.140-75.37)	0.037

DEVICE-ORIENTED COMPOSITE: Cardiac Death + MI + TLR



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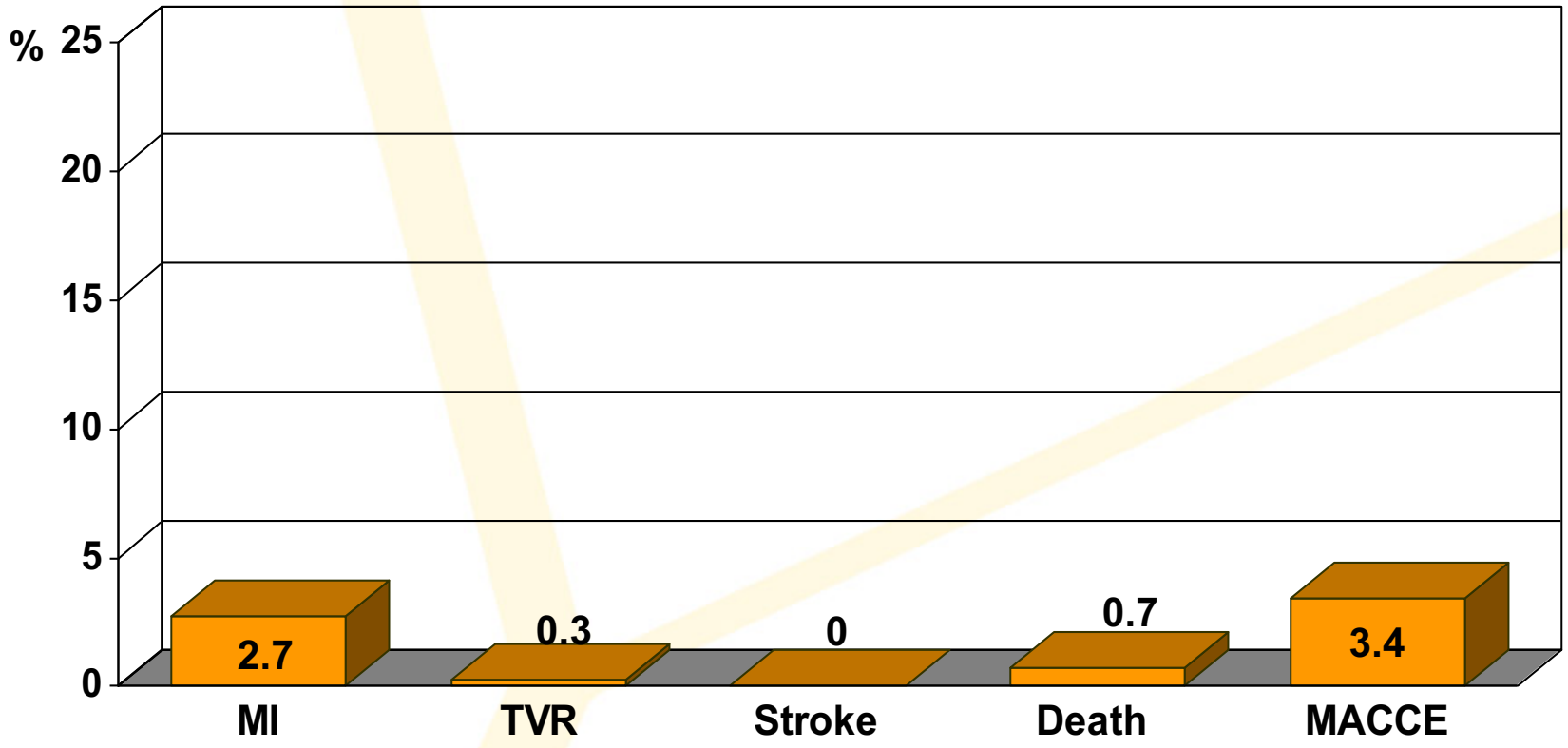
French Left Main Taxus Pilot Study

In-hospital Outcome

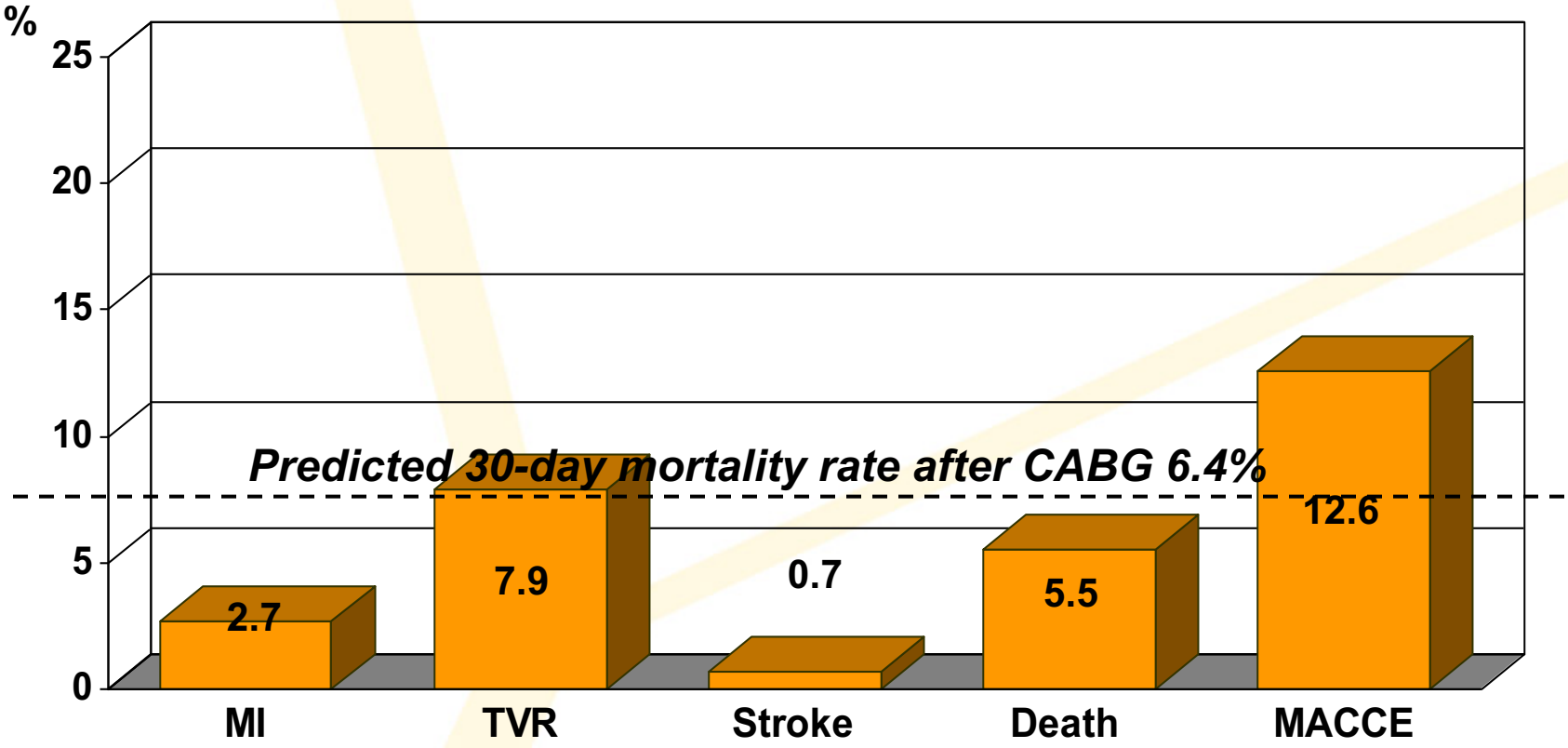
n=291/291 (Follow-up completed 100%)



French Left Main Taxus Pilot Study

12 months F-Up (13.3±2.1 months)

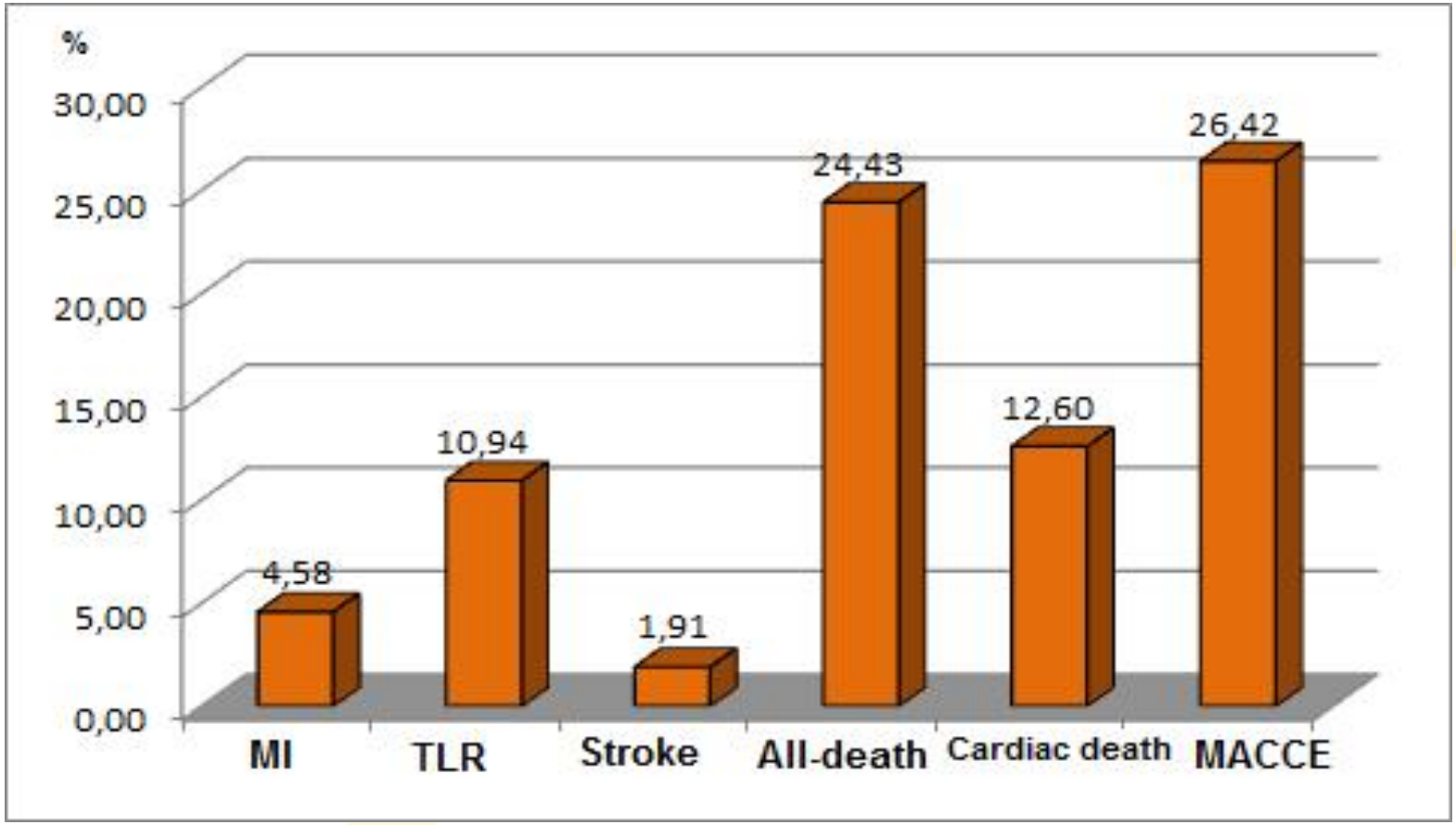
n=286/291 (Follow-up 98%)



French Left Main Taxus Pilot Study

5years F-Up

n=262/291 (Follow-up 91%)



EBC

Unprotected Left Main Stenting in the Real World

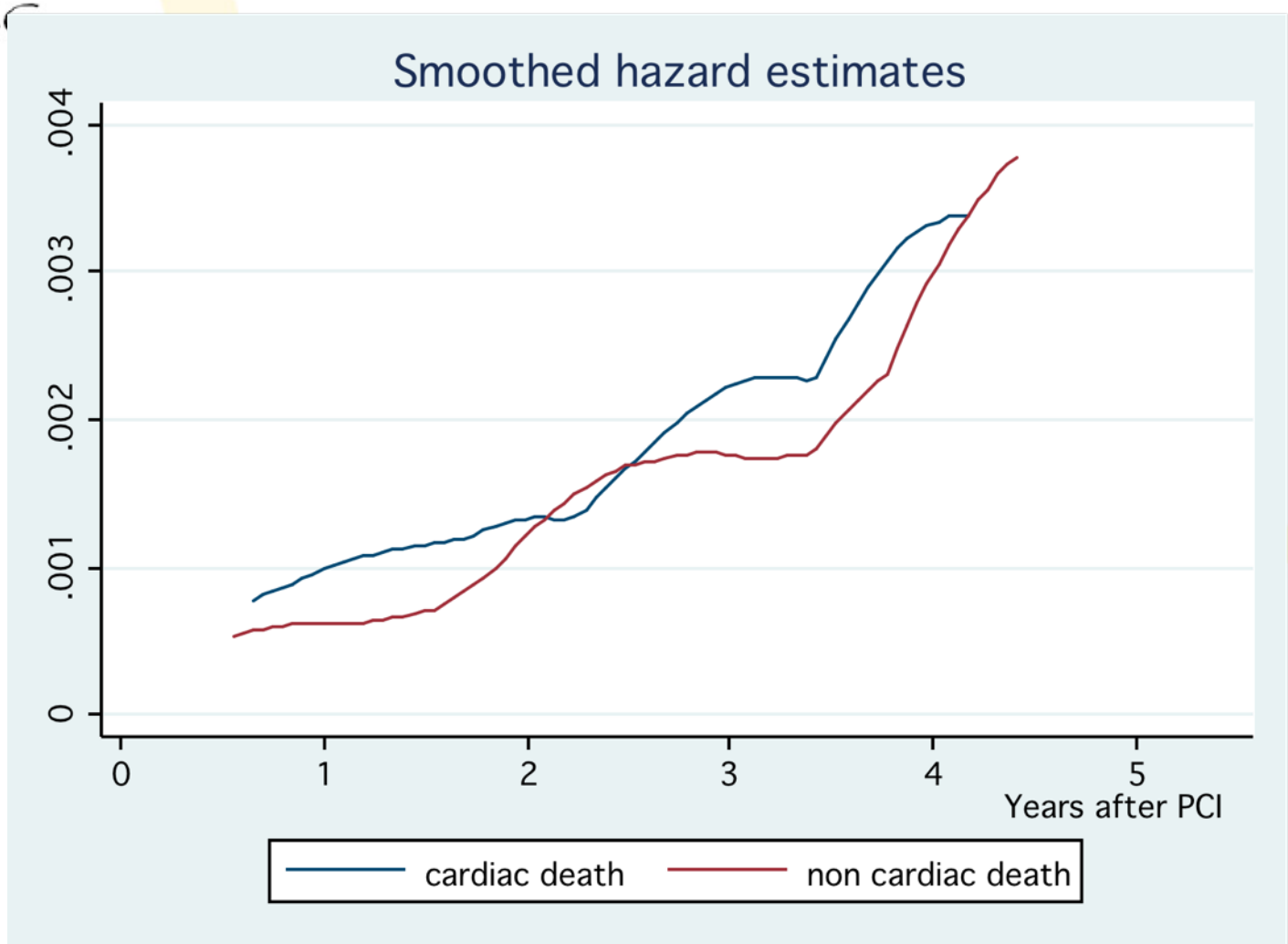
Two-Year Outcomes of the French Left Main Taxus Registry

Beatriz Vaquerizo, MD; Thierry Lefèvre, MD; Olivier Darremont, MD; Marc Silvestri, MD; Yves Louvard, MD; Jean Louis Leymarie, MD; Philippe Garot, MD; Helen Routledge, MD; Federico de Marco, MD; Thierry Unterseeh, MD; Marcel Zwahlen, PhD; Marie-Claude Morice, MD

Background—Cardiac surgery is the reference treatment for patients with left main (LM) disease, although percutaneous coronary intervention with drug-eluting stents is emerging as a possible alternative. The objective of this registry was to evaluate the 2-year outcome of elective percutaneous coronary intervention for unprotected LM disease with paclitaxel-eluting stents.

Methods and Results—A total of 291 patients were prospectively included from 4 centers. Acute myocardial infarction and cardiogenic shock were the only exclusion criteria. Patients were 69±11 years old, 29% were diabetic, and 25% had 3-vessel disease. For distal LM lesions (78%), the provisional side-branch T-stenting approach was used in 92% of cases and final kissing balloon inflation in 97%. Angiographic success was obtained in 99.7% of cases. At 2-year follow-up, the total cardiac death rate was 5.4% (1 EuroSCORE point was associated with a 15% [95% confidence interval 2.9% to 28.2%, P=0.013] higher risk of cardiac death), target-lesion revascularization was 8.7%, and incidence of Q-wave or non–Q-wave myocardial infarction was 0.9% and 3.1%, respectively. The combined end point occurred in 15.8% of cases and stroke in 0.7%. The incidence of definite and probable LM stent thrombosis was 0.7%, whereas the incidence of any stent thrombosis was 3.8%, with a higher risk in patients with side-branch stenting in the presence of LM bifurcation lesions (hazard ratio 9.6, 95% confidence interval 1.2 to 77.7, P=0.035).

Conclusions—Unprotected LM stenting with paclitaxel-eluting stents, with a strategy of provisional side-branch T-stenting for distal lesions, provides excellent acute angiographic results and good mid-term clinical outcomes, with a 15.8% rate of major adverse cardiac events at 2-year follow-up. (***Circulation*. 2009;119:2349-2356.**)


Smoothed hazard estimates
0
.001
.002
.003
.004
0
1
2
3
4
5
Years after PCI
cardiac death
non cardiac death

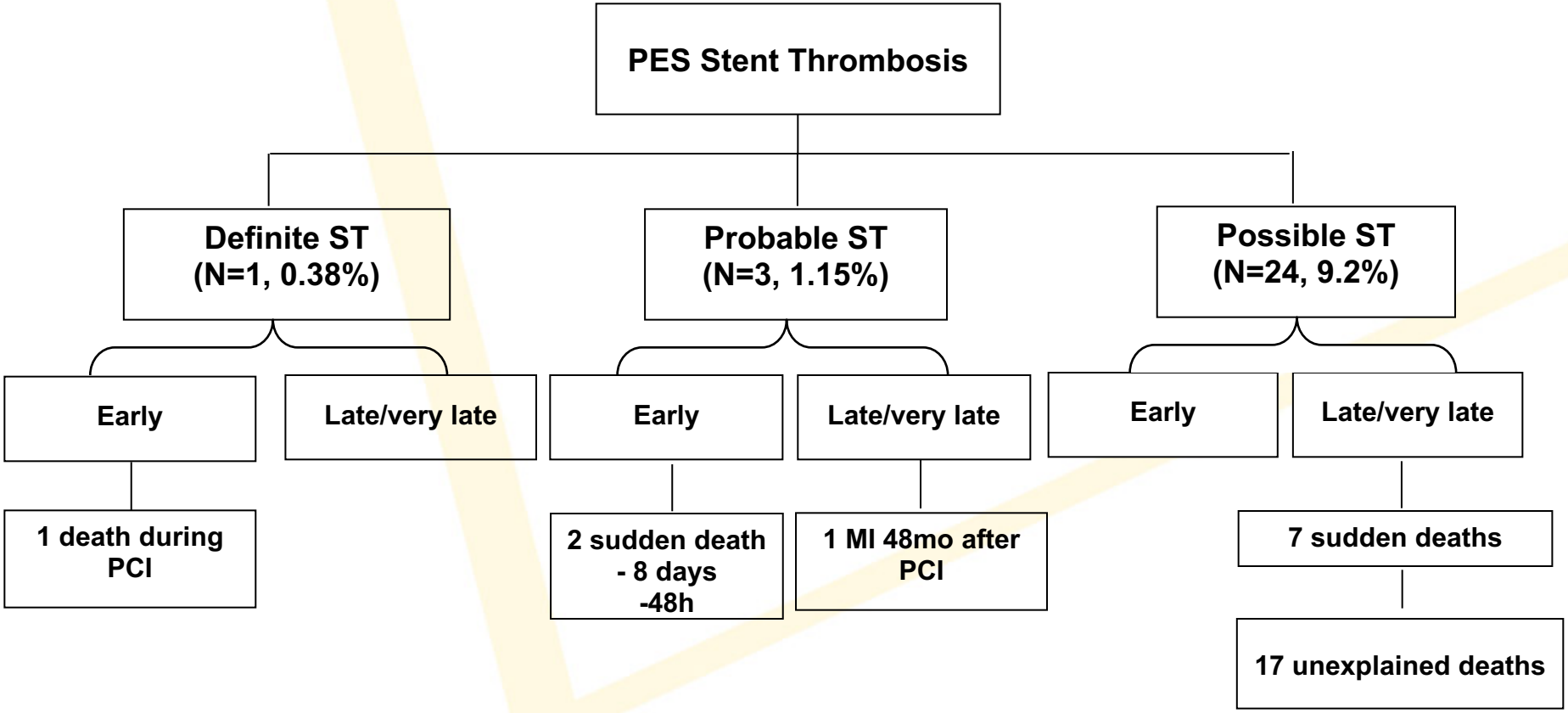
French Left Main Taxus Pilot Study

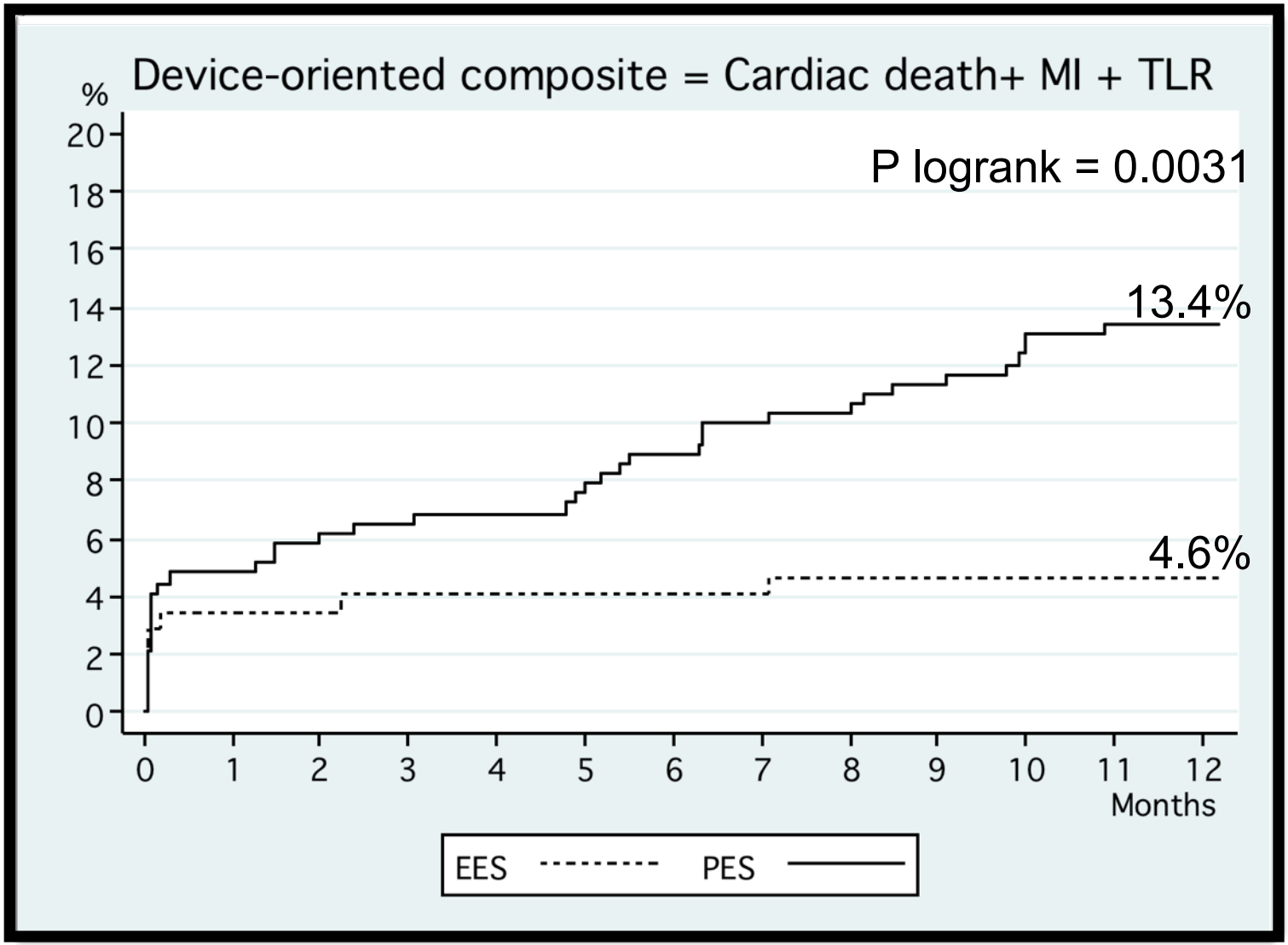
Predictors of device oriented MACE (Cardiac death, TLR and MI) (all Pts, n= 291)

Variables	Univariate p value	Multivariate p value	Odds ratio	95%CI
Age	0.024			
Euroscore	0.059			
Hypertension	0.003			
Diabetes	0.022			
Creatinine clearance	0.004			
LVEF	0.004			
2 stents	0.011			
Troponin	**0.025**	**0.019**	**1.301**	**1.044 – 1.623**

Including Troponin

French Left Main Taxus Pilot Study




Device-oriented composite = Cardiac death+ MI + TLR
%
20
18
16
14
12
10
8
6
4
2
0
P logrank = 0.0031
13.4%
4.6%
0
1
2
3
4
5
6
7
8
9
10
11
12
Months
EES
PES

French Left Main Taxus Pilot Study