

Long-Term Outcomes of Left Main French Taxus Registry

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Disclosure Statement of Financial Interest

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<u>Affiliation/Financial Relationship</u>	<u>Company</u>
Minor Fees	Abbott, Boston, Cordis, Edwards

French Left Main Taxus Pilot Study

Design of the Study

- ✓ May 2003-June 2005
- ✓ Feasibility and Safety Study
- ✓ Taxus express stent
- ✓ 4 French centers
- ✓ Consecutive patients with de novo lesions
- ✓ Informed consent

French Left Main Taxus Pilot Study

Design of the Study (cont')

- ✓ Standardized approach for bifurcation lesions:
Provisional side branch T stenting
- ✓ Plavix 75 mg or 150 mg ($> 80\text{Kg}$) ≥ 6 months
- ✓ Aspirin 75 mg indefinitely
- ✓ Angiographic F-up recommended at 6 months
- ✓ Clinical F-up up to 3 years

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Design of the Study

- ✓ Independant statistical analysis:
M. Zwahlen, (Institute of Social and Preventive
Medicine, University Bern, Switzerland).

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Design of the Study (cont')

Inclusion criteria

- ✓ All consecutive patients with significant ULM disease and ischemia treatable by PCI

Exclusion criteria

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

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Main Clinical Characteristics

Patients (n)	291
Age (years)	68.8±11.4
Male gender (%)	76.5
Risk factors (%)	
Diabetes	28.9
Hypertension	65.5
Hypercholesterolemia	63.2
Smoker	43.1
Family history	19.2
Renal failure *	27.6

* Creatinine clearance < 90ml/min/1.73m²

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Main Clinical Characteristics (cont')

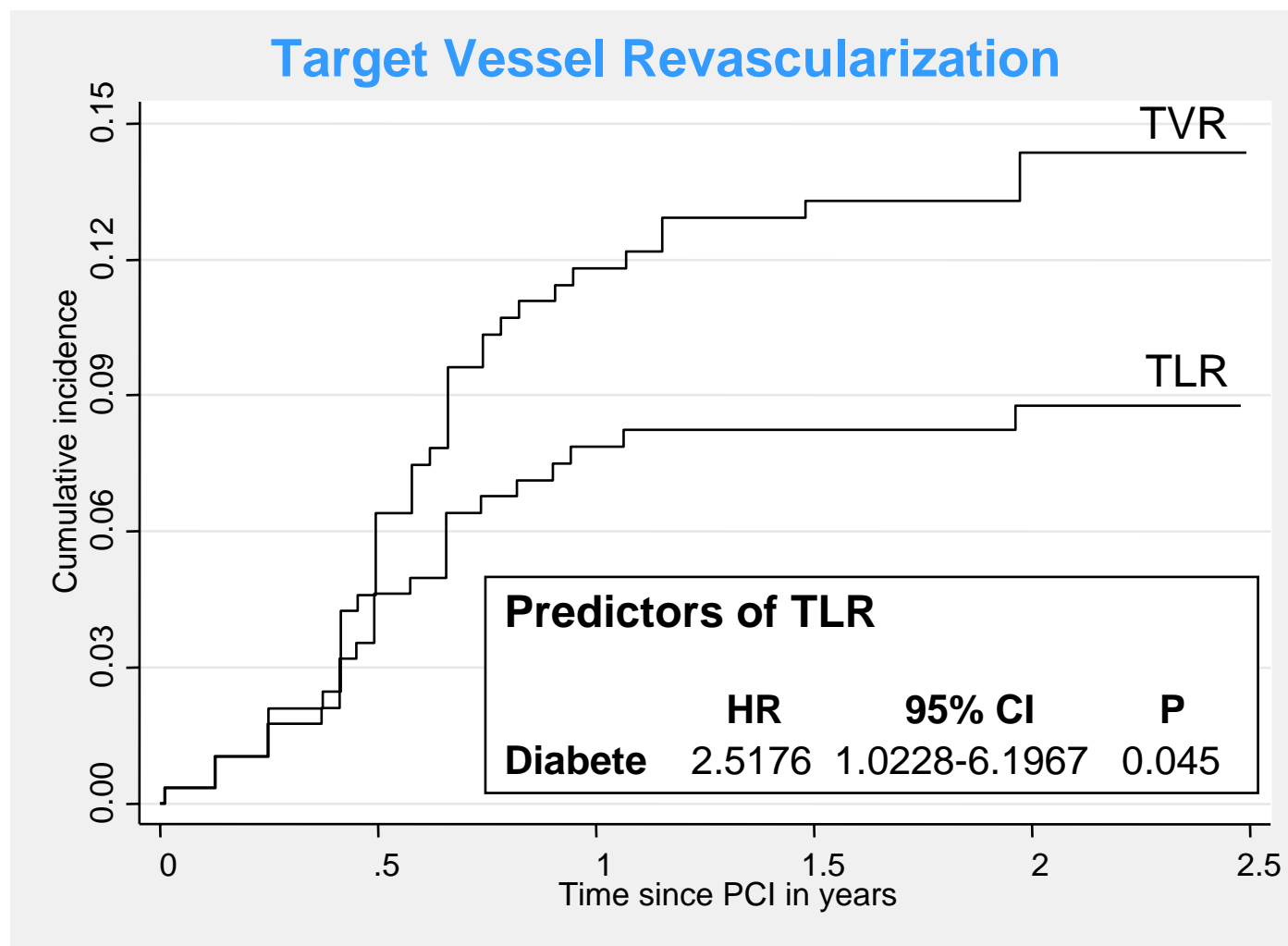
Previous MI (%)	11.3
Previous PCI (%)	20.1
Previous CABG (%)	1.0
Unstable angina (%)	35.4
Recent MI (%)	6.5
3 vessel disease (%)	30.9
EF (%)	60 \pm 13
Additive Euroscore	4.8 \pm 3.4
Logistic Euroscore (%)	6.4\pm10.5

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Main Procedural Data

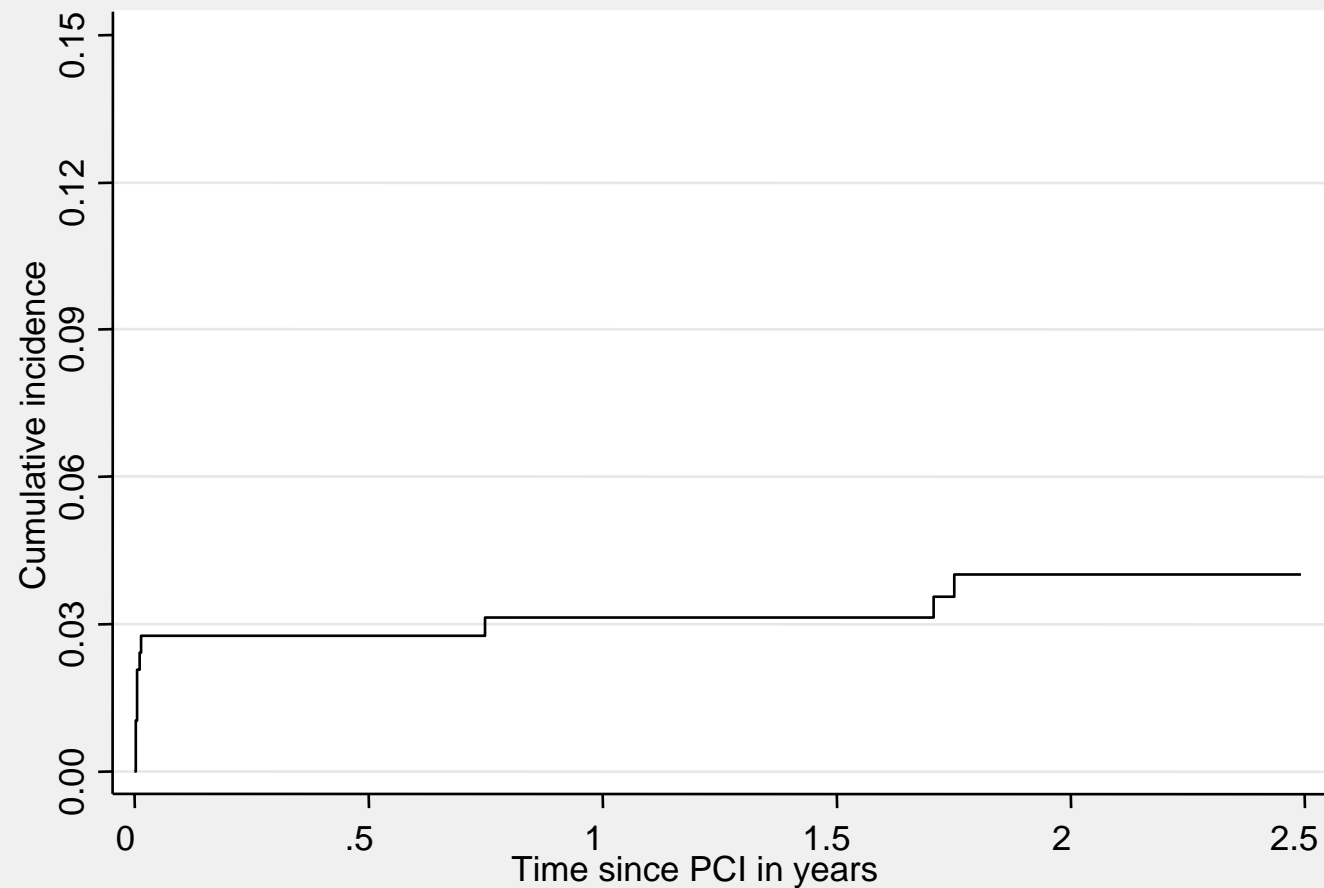
Gp2b3a inhibitors (%)	4.2
IABP (%)	4.5
Left main reference (mm)	3.66±0.50
Other treated vessel (%)	78.4
Total stent length (mm)	53±23
LM angiographic success (%)	99.6
Distal LM (%)	78.4
T shape bifurcation (%)	38.0
Side branch stented (%)	42.5
Final Kissing balloon (%)	97.4

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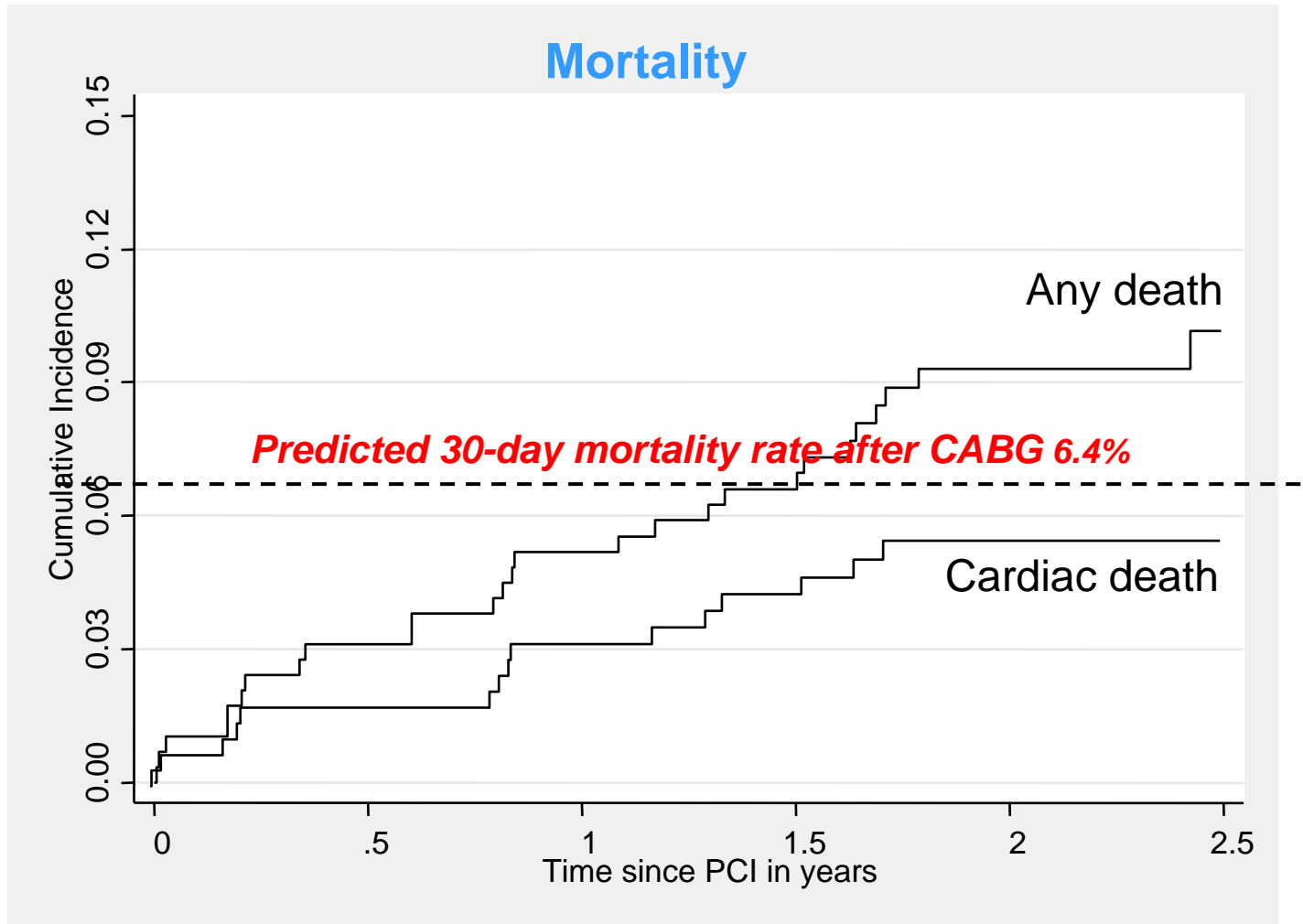


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Myocardial Infarction



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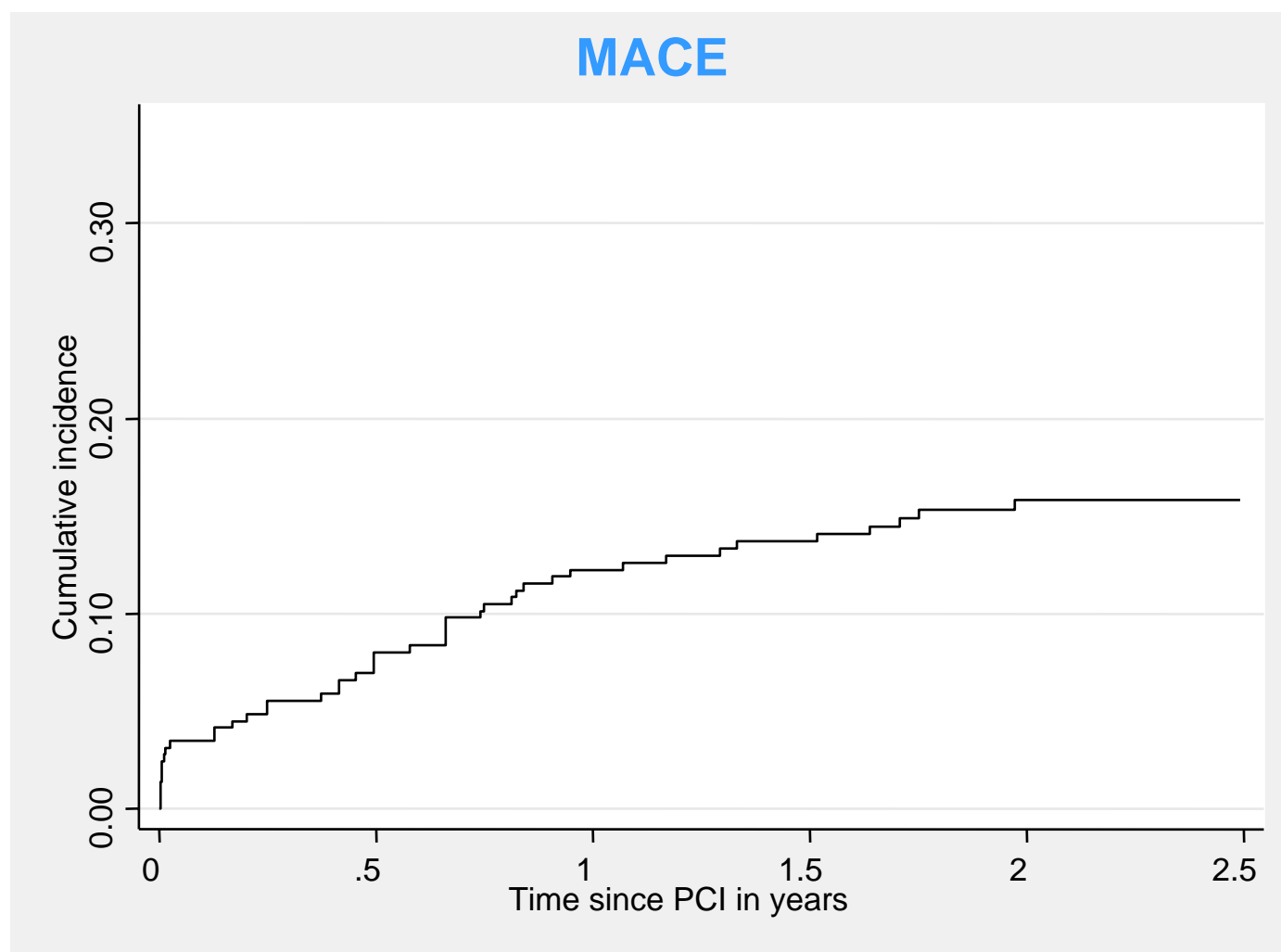


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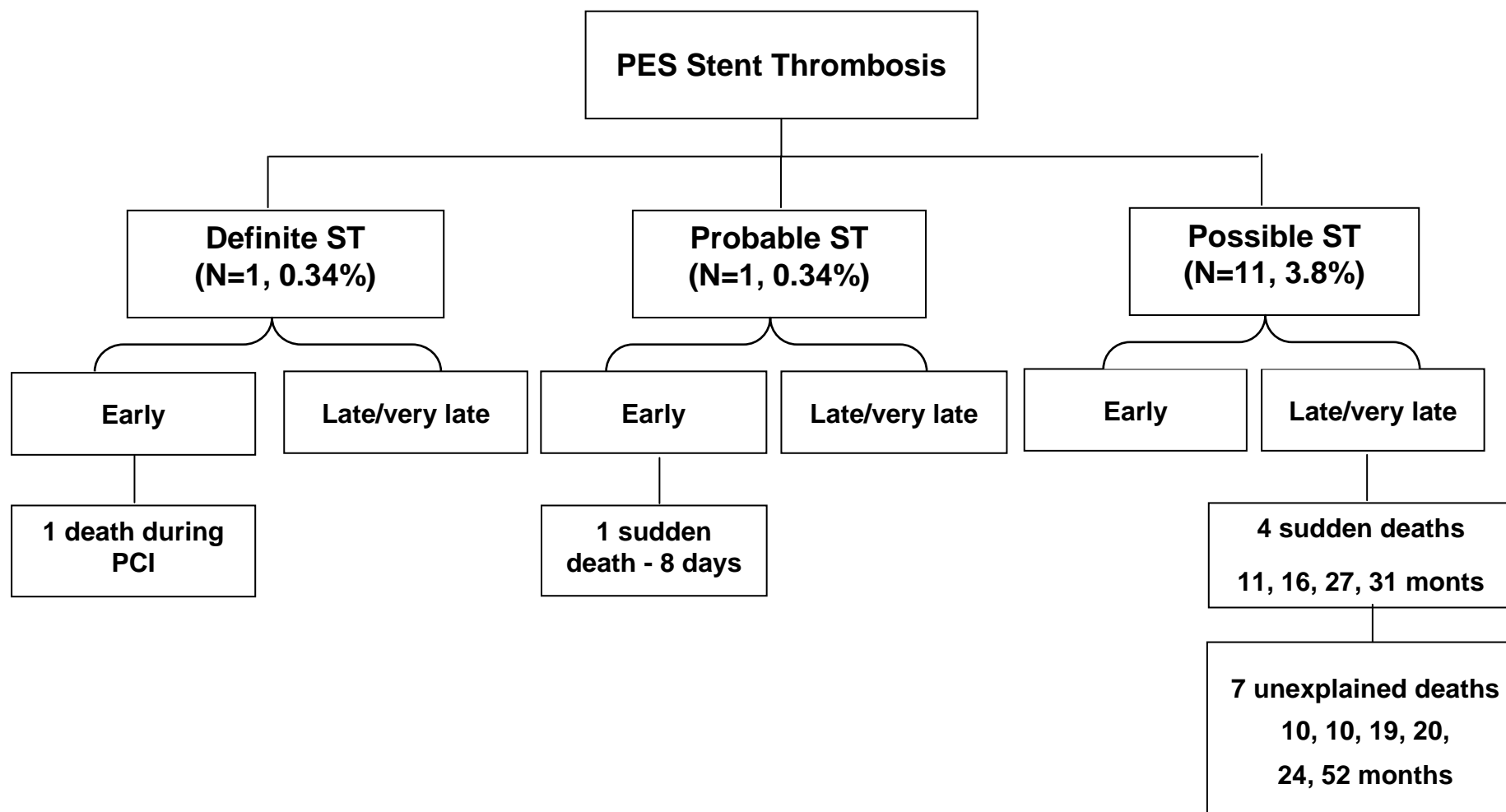
Predictors of cardiac death (Pts with bifurcation, n= 228)

	Univariate		Multivariate	
	HR 95%IC	<i>P</i>	HR 95%IC	<i>P</i>
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		

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

	Univariable		Multivariable	
	HR 95% CI	<i>P</i>	HR 95% CI	<i>P</i>
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

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Conclusion

Left main PCI using the TAXUS Express 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.

French Left Main Taxus Pilot Study

Conclusion

- ✓ The only independent predictor of cardiac death at follow-up is Euroscore.
- ✓ The only predictor of stent thrombosis is side branch stenting in patients with distal left main lesions.

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 Untersee, 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.)

Key Words: angioplasty ■ stents ■ restenosis ■ drug-eluting stents ■ coronary artery disease