Percutaneous treatment of unprotected left main coronary stenoses with paclitaxel-eluting stents.

3-year clinical follow-up of a French prospective multicenter study : Friend Registry

Didier Carrié
On behalf of the Friend study group

CHU Toulouse Rangueil
France

EBC Budapest 10-23-2010

Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

FRIEND TRIAL

French multicenter study assessing angioplasty with Taxus drug eluting stent in unprotected left main coronary artery associated to other coronary lesions or not

Initiative of the Interventional Cardiology French Group

23 centers with recognized experience of ULMCA stenting

Unrestricted Grant from Boston Scientific

Provisional T-stenting, final Kissing balloon

Clinical follow-up at 1, 18 and 36 months

Angiographic follow-up at 9 months (primary endpoint)

Clinact (monitoring, statistical analysis)

e-CRF : Kika Médical

Angiographic analysis : Dr Glatt, Corisis, France

Ethical and Adverse events Committees

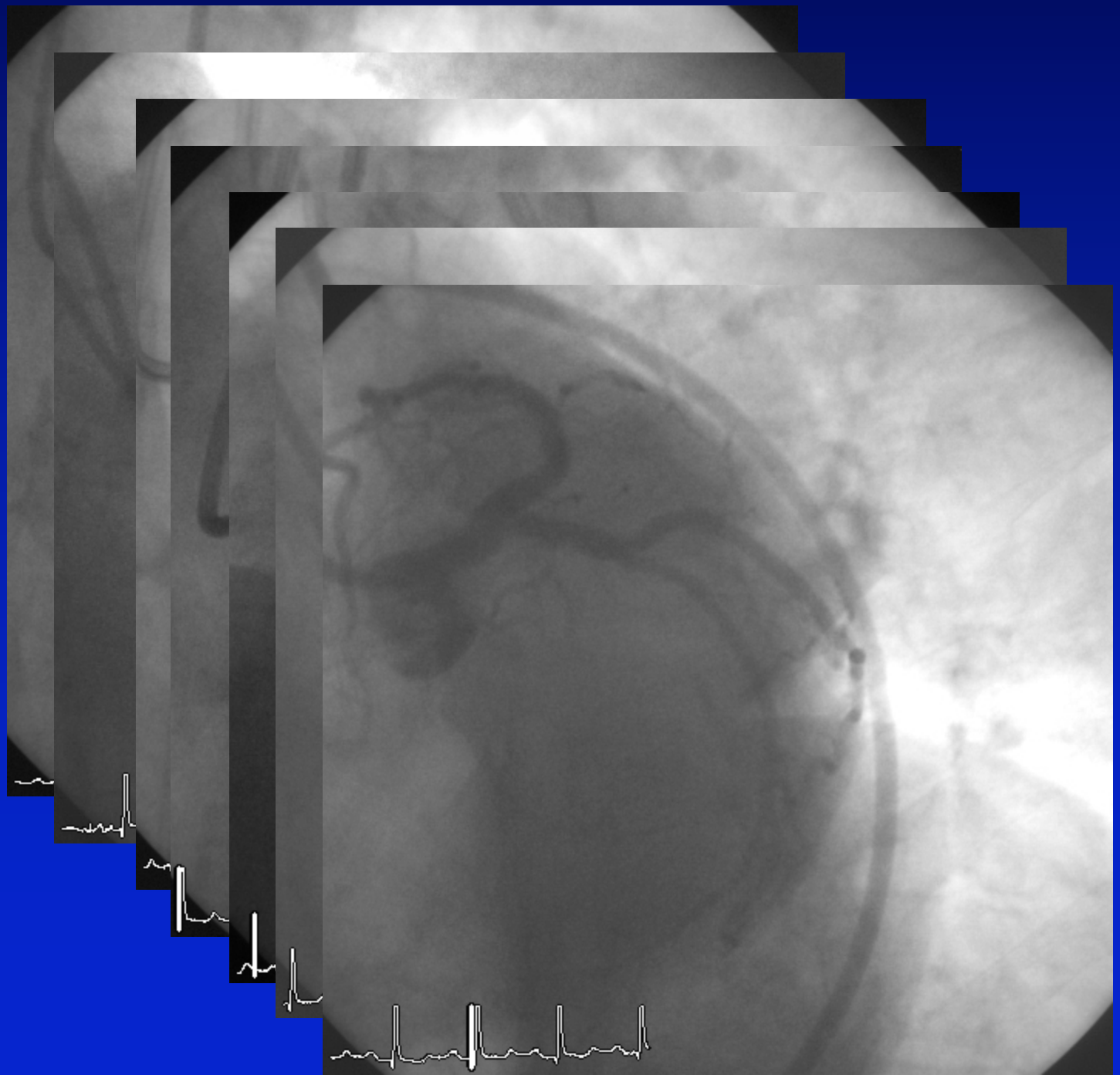
Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

Sample Size Calculation

Primary endpoint : 9-month LM angiographic in-stent restenosis

Bare stent angiographic restenosis rate	:	30 %
PES angiographic restenosis rate:	:	15 %
Power	:	90 %
α Risk	:	5 %
Sample size	:	131 patients
Lost to follow-up rate	:	10 %
Number of patients to be included	:	150 patients



Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

Main Inclusion Criteria

- ✓ Combined Antiplatelet therapy ≥ 12 h before PCI
- ✓ Signed informed consent
- ✓ Age ≥ 18 yrs
- ✓ Documented myocardial ischemia
- ✓ Unprotected LM coronary disease > 50%
- ✓ Unprotected LM amenable to coronary stenting

Main Exclusion Criteria

- ✓ LM Restenosis
- ✓ Contra-indication to Clopidogrel, Ticlopidin or Aspirin
- ✓ History of allergy to iodine
- ✓ < 48 h acute coronary syndrome
- ✓ Renal insufficiency (creatinemia ≥ 180 µmol/l)
- ✓ life expectancy < 3 years
- ✓ Participation in other clinical trial

Main Clinical Characteristics

Patients (n)	152
Age (yrs)	68.3
Male (%)	83
Risk factors (%)	
Diabetes	5
Hypertension	63
Hypercholesterolemia	68
Previous smoker	38
Current smoker	18
Family history	23

December 2005 – July 2006

Main Clinical Characteristics

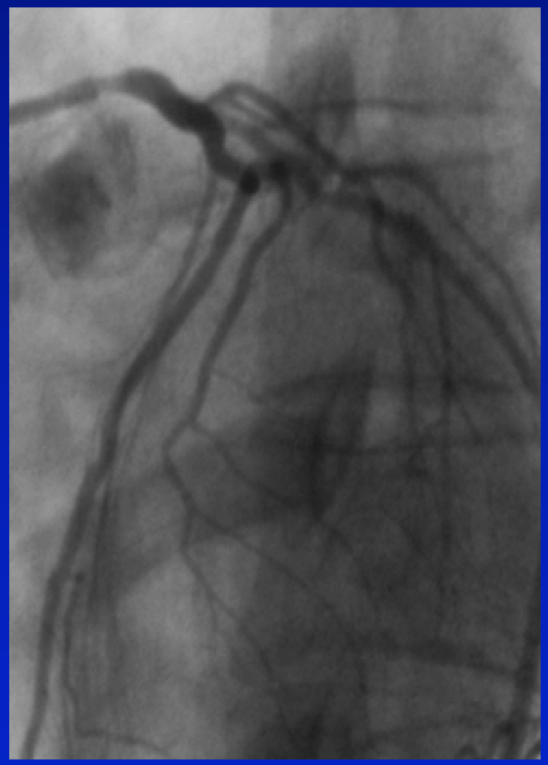
Previous PCI (%)	30
Previous CABG (%)	0
Unstable angina (%)	32
AMI > 48 h (%)	15
Cardiac failure (%)	5
CRP (mg/l)	7.5 ± 11.4
Creatinin (mg/l)	10.6 ± 2.8
Three-vessel disease	46
EF (%)	59 ± 10
Euroscore	4.2 ± 2.8

Predicted in-hosp. mortality 4.1%

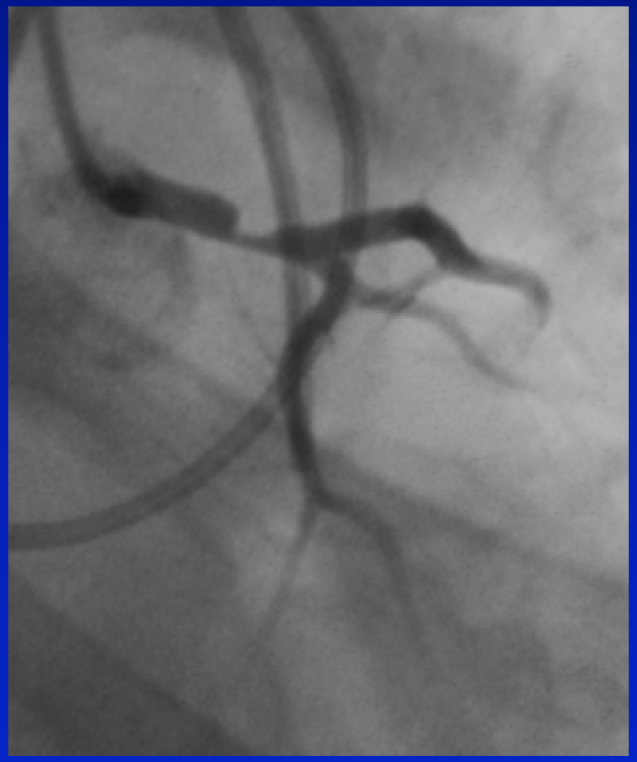
Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

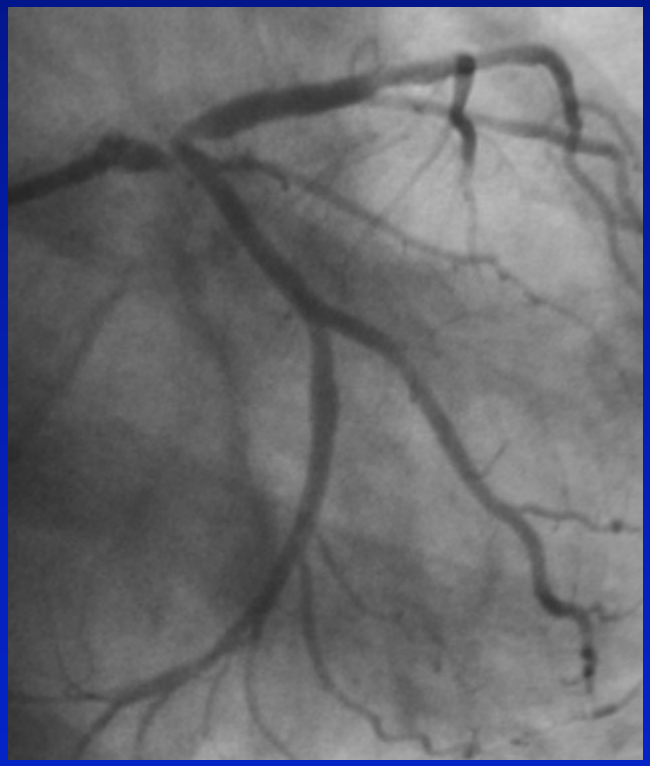
Localization of the LM Lesion



Ostial-proximal 20 %



Mid-segment 11 %



Distal 69 %

Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

Distal Left Main in 69% of cases

Systematic T stenting (%)	2
Simultaneous kissing stent (%)	1
Provisional SB T-stenting (%)	97
Main stent LM – LAD (%)	83
Side branch stented in bifurcation (%)	**26**
Side branch stent diameter (mm)	3.28 ± 0.43
Final Kissing balloon (%)	89
Angiographic success rate (%)	**98**

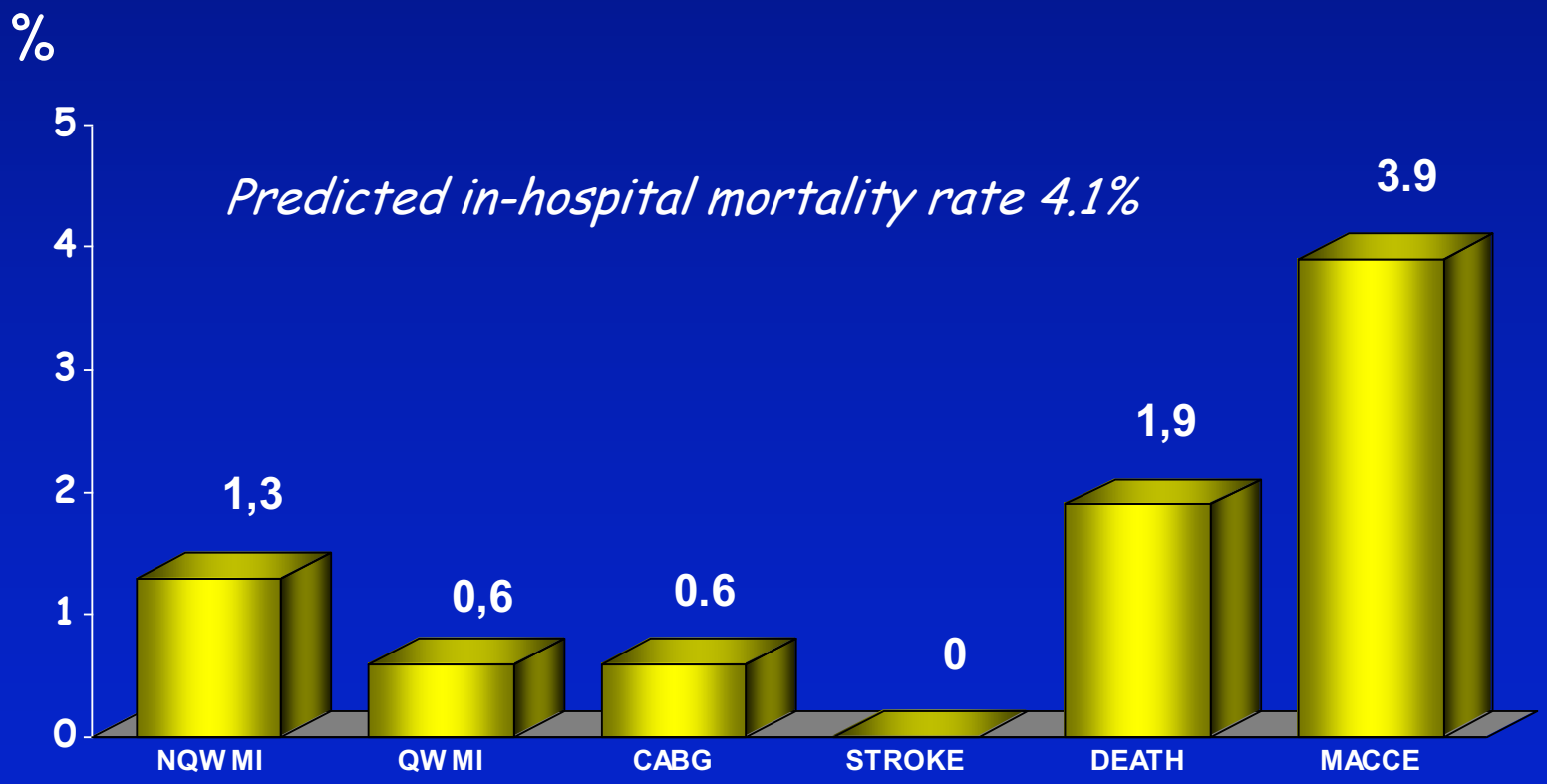
QCA Analysis Post Procedure

Left main reference (mm)	4.26±0.61
Theoretical LM reference (mm) *	4.41±0.62
Acute gain LM (mm)	1.91±0.79
% stenosis LM (%)	16±12
Acute gain LAD (mm)	1.40+0.78
% stenosis LAD (%)	14±11
Acute gain LCx (mm)	0.49±0.79
% stenosis LCx (%)	29±19

* Murray Law

FRIEND TRIAL

IN-HOSPITAL OUTCOME (n = 152)

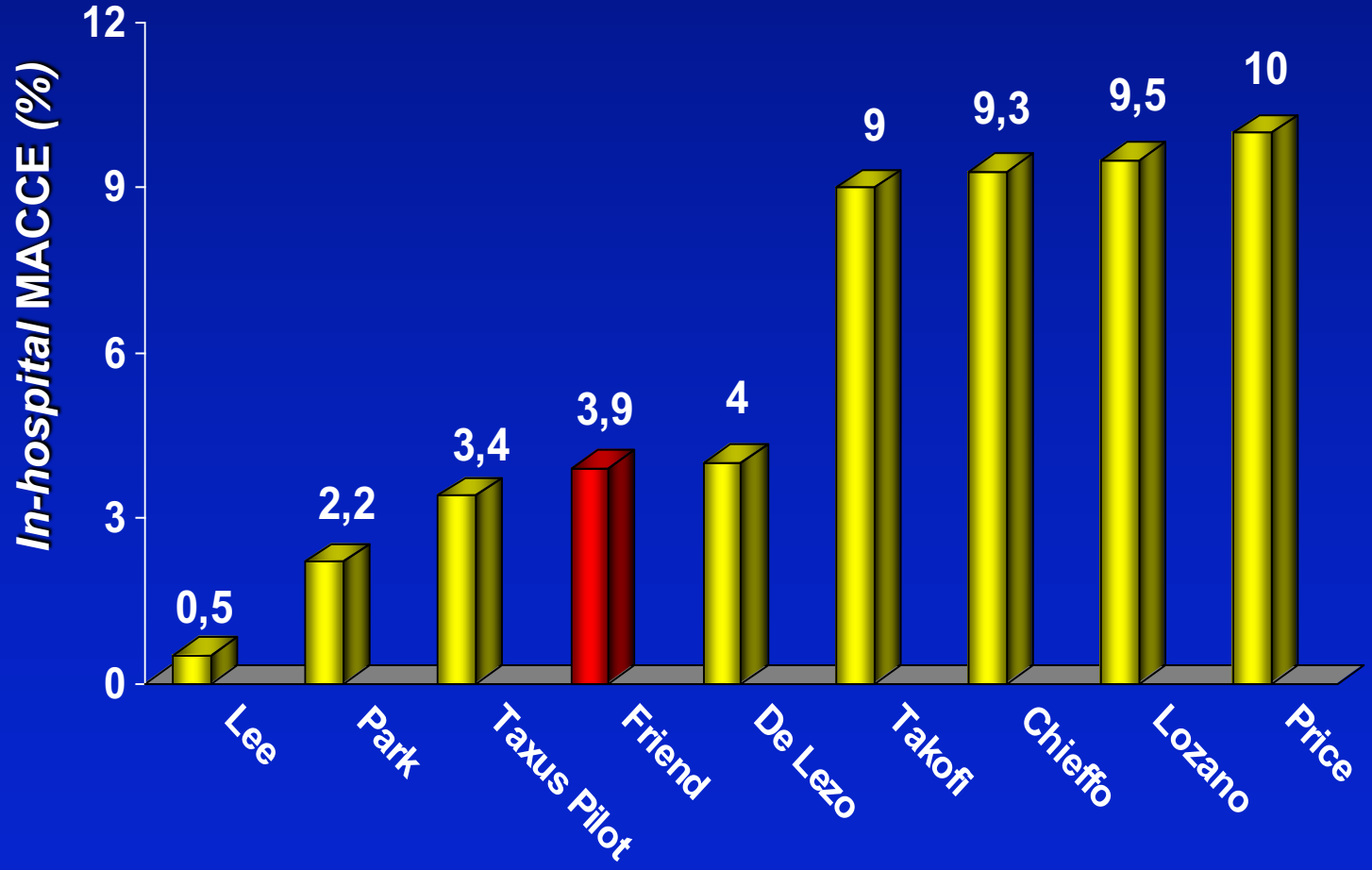


* Stent thrombosis (D2, D3, D5) 3 pts

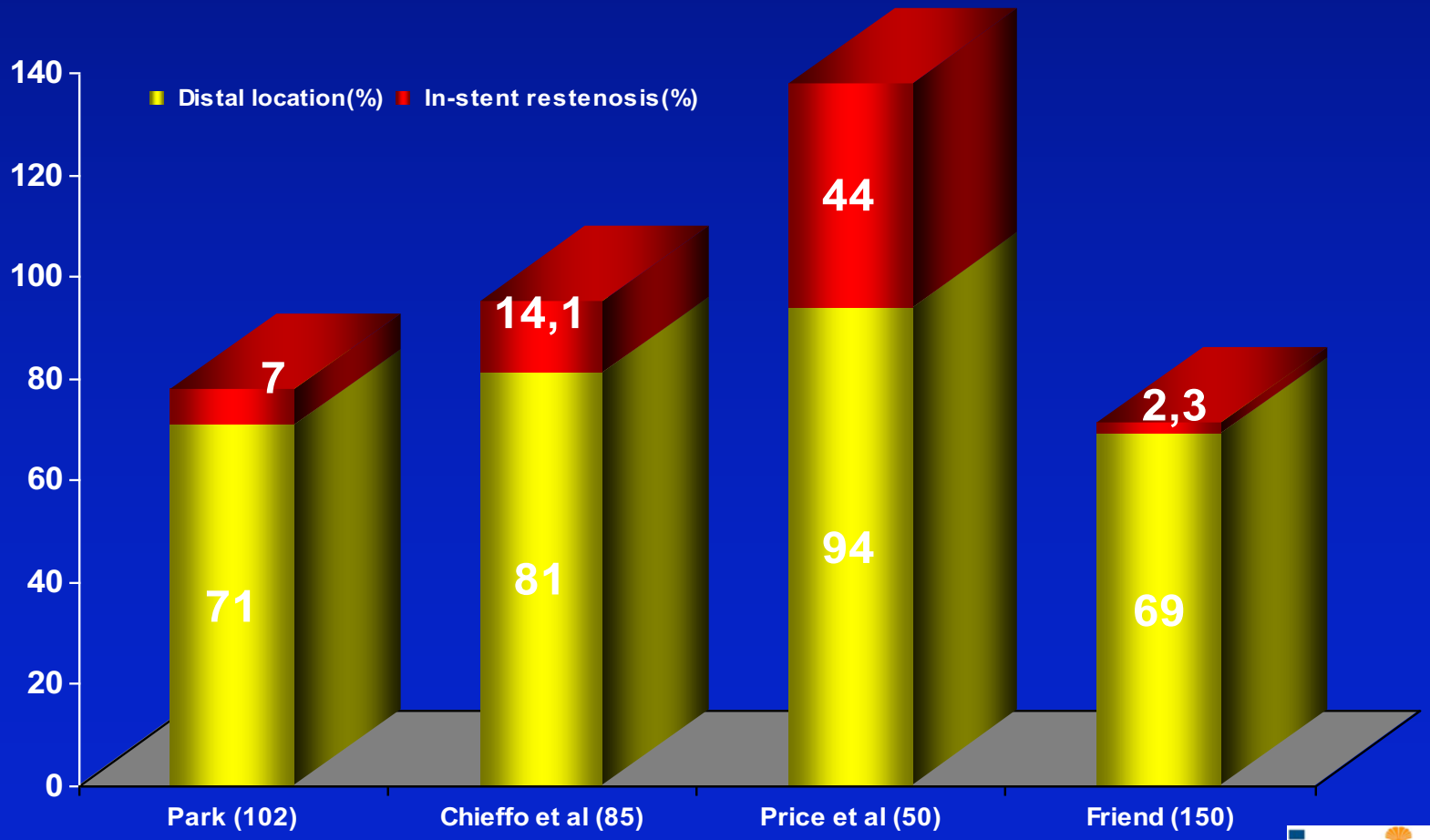
Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

In-Hospital Outcome



FRIEND TRIAL
9 months F-Up (281 ± 30 days)
Angiographic control

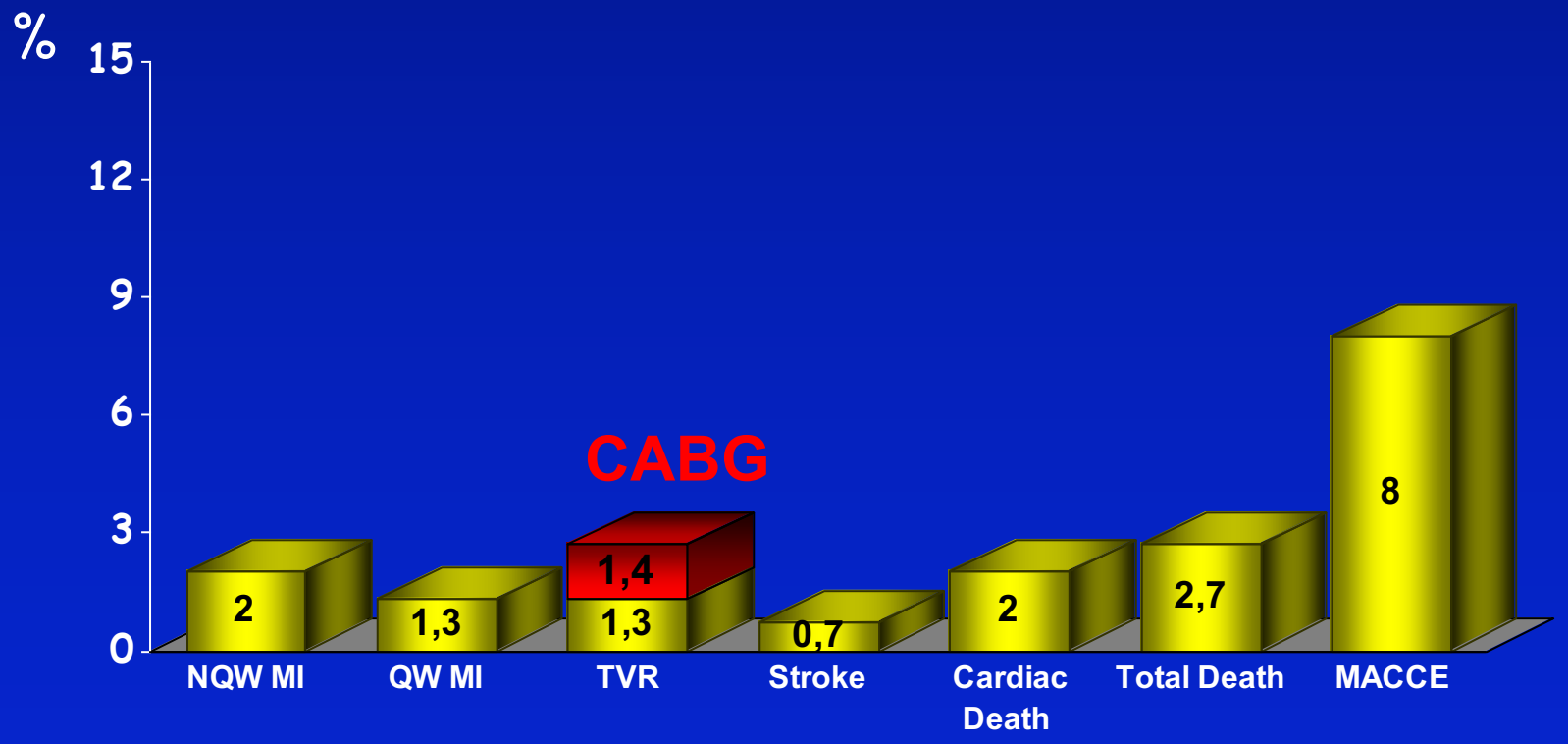


Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

FRIEND TRIAL

12 months F-Up (381 ± 30 days)



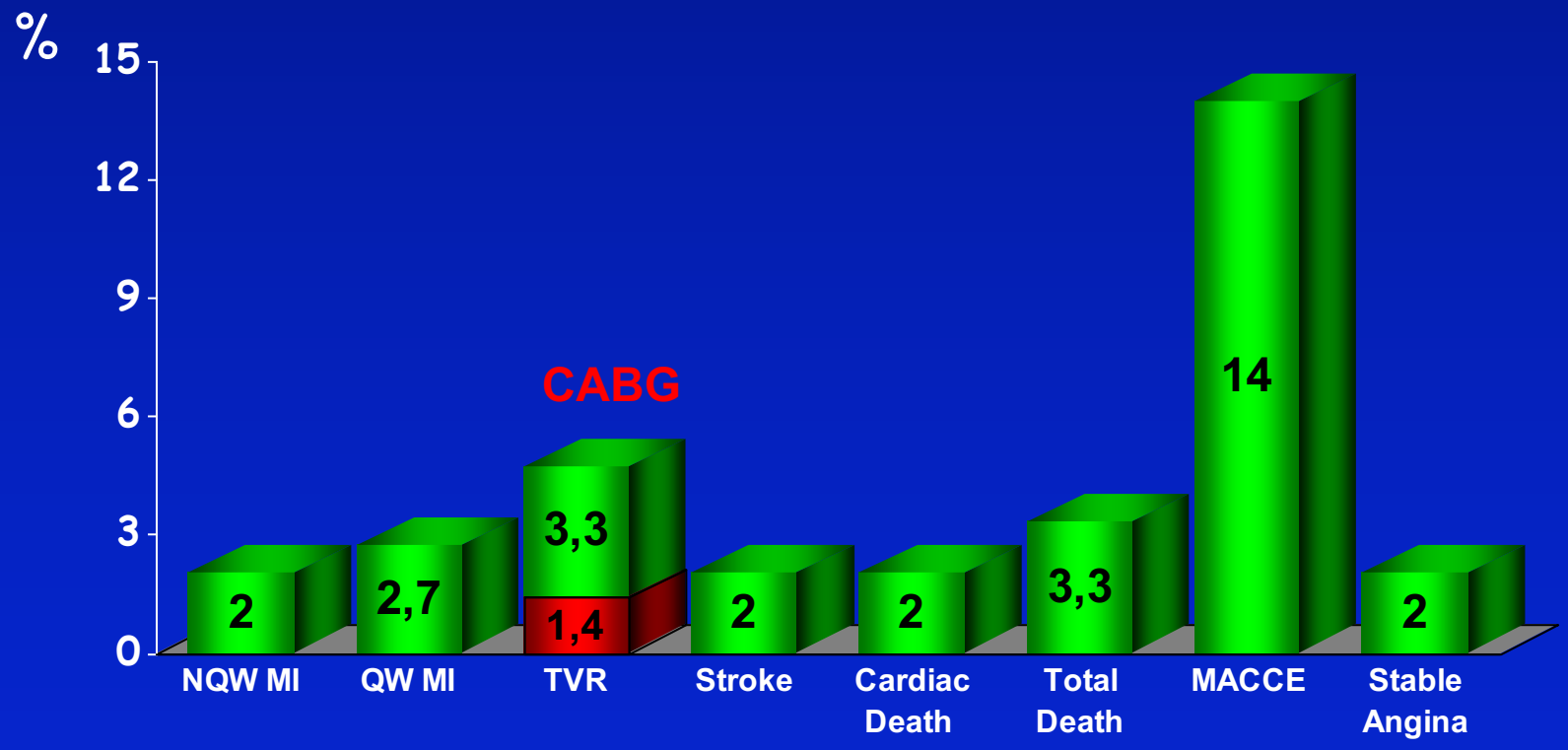
Carrié et al EuroIntervention January 2009

Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

FRIEND TRIAL

18 months F-Up (381 ± 30 days)

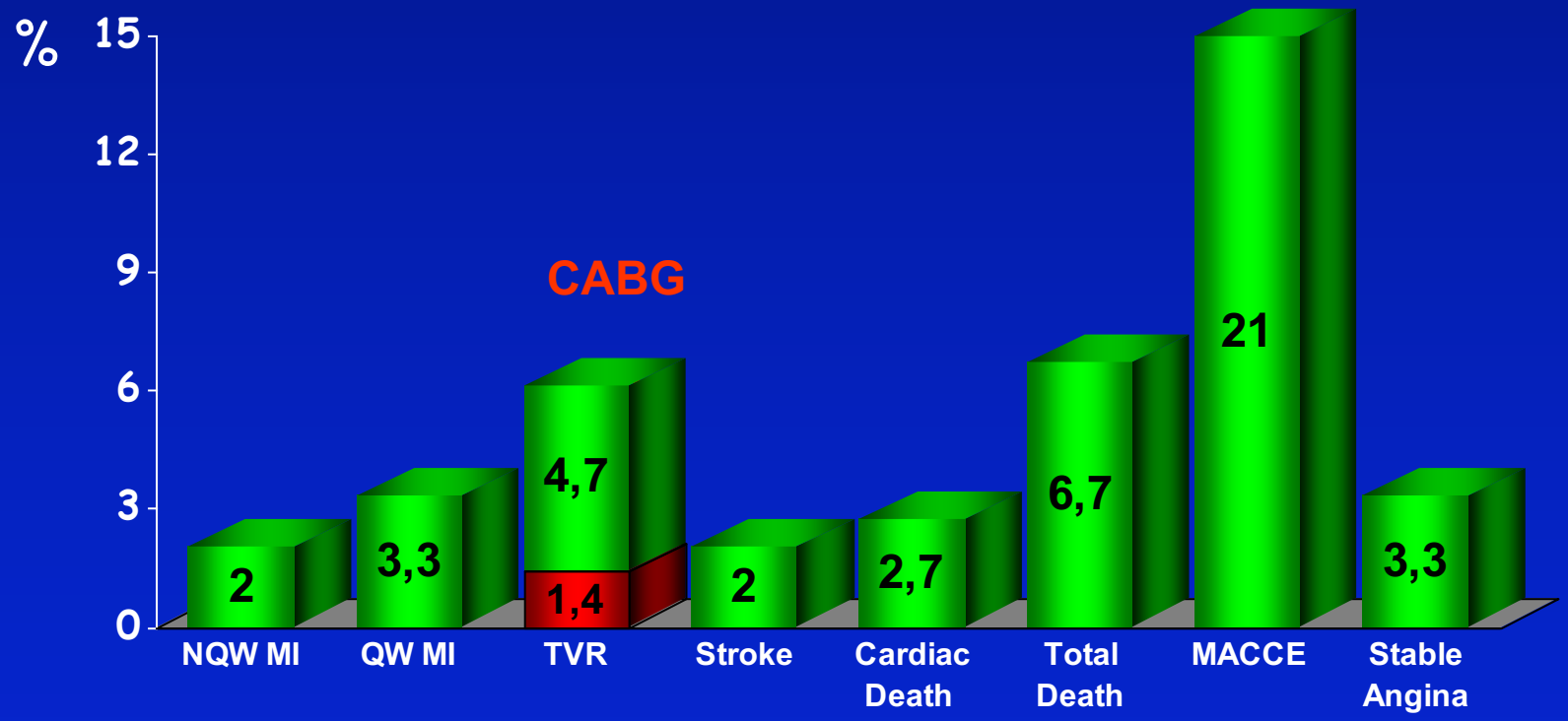


Hôpitaux de Toulouse

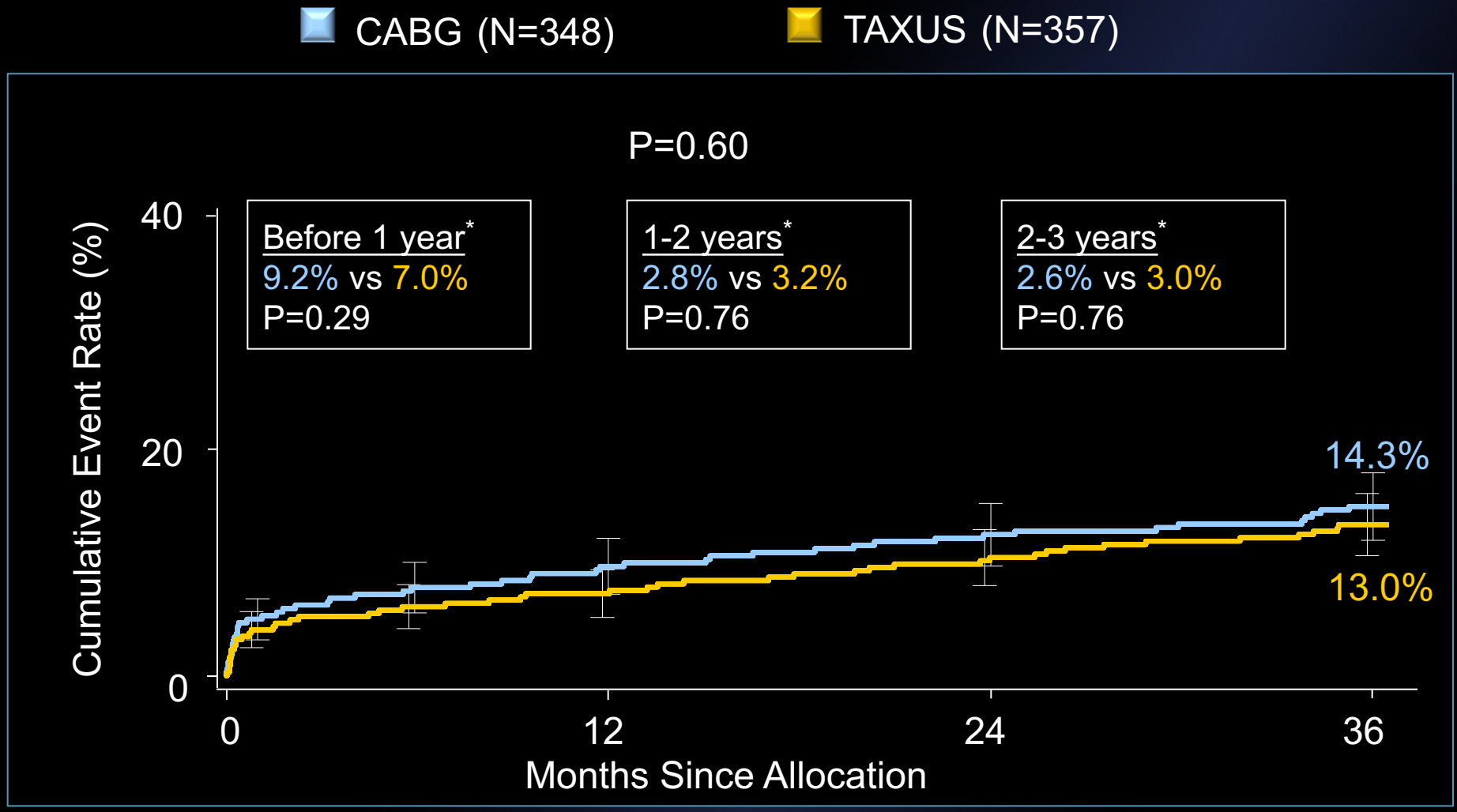
Pôle Cardiovasculaire et Métabolique

FRIEND TRIAL

36 months F-Up (381 ± 30 days)



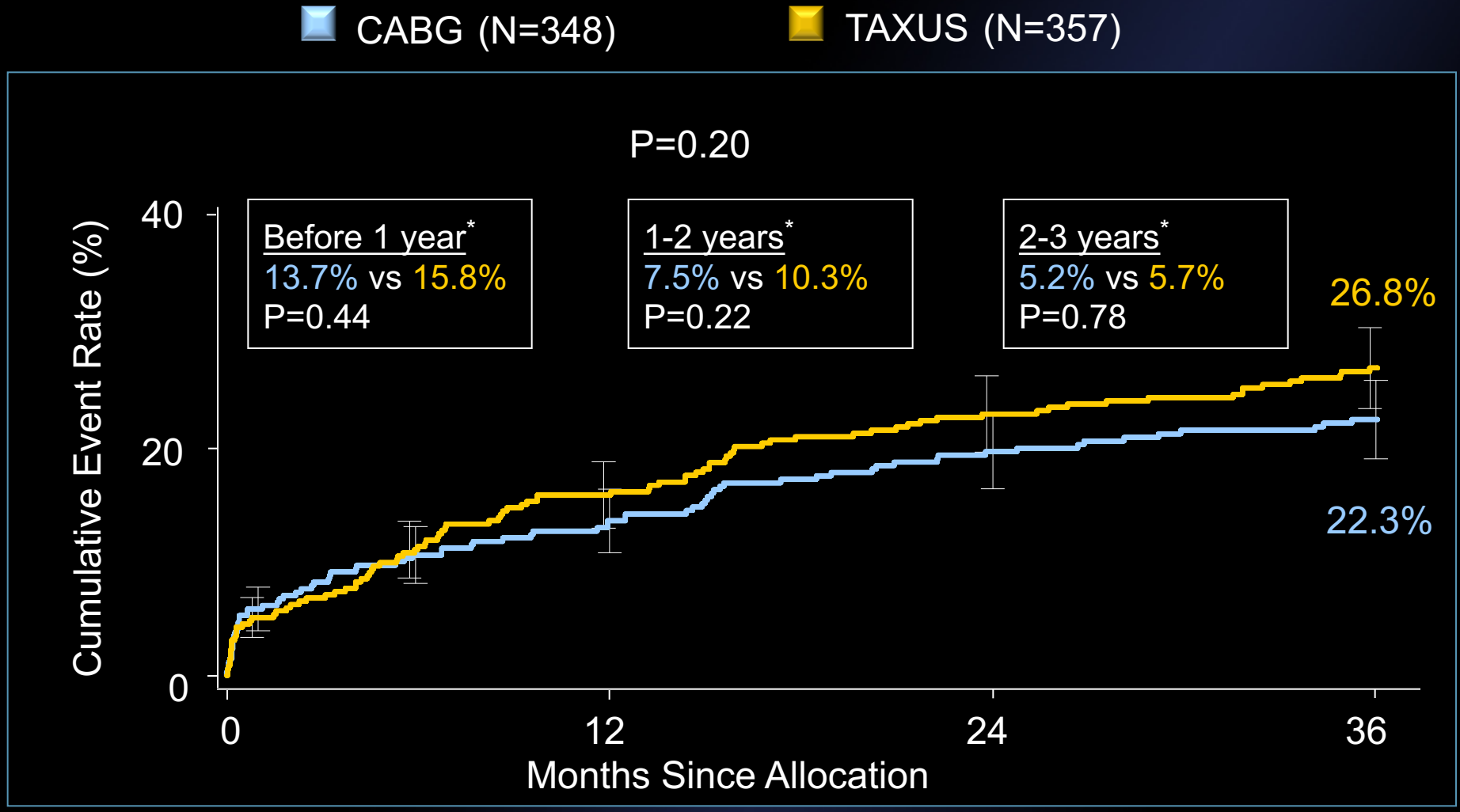
All-Cause Death/CVA/MI to 3 Years
LM Subset



Cumulative KM Event Rate ± 1.5 SE; log-rank P value; *Binary rates

ITT population

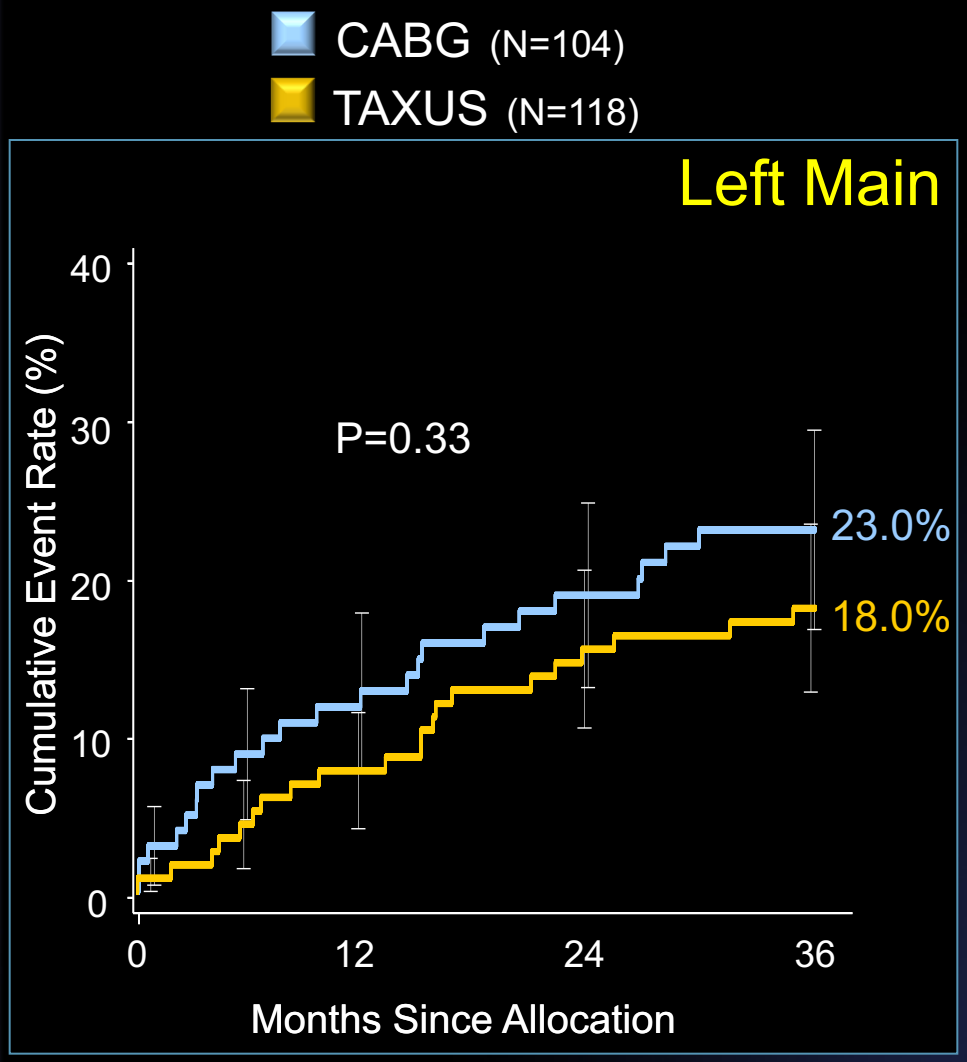
MACCE to 3 Years
LM Subset



Cumulative KM Event Rate ± 1.5 SE; log-rank P value; *Binary rates

ITT population

MACCE to 3 Years by SYNTAX Score Tercile *Low Scores (0–22)*

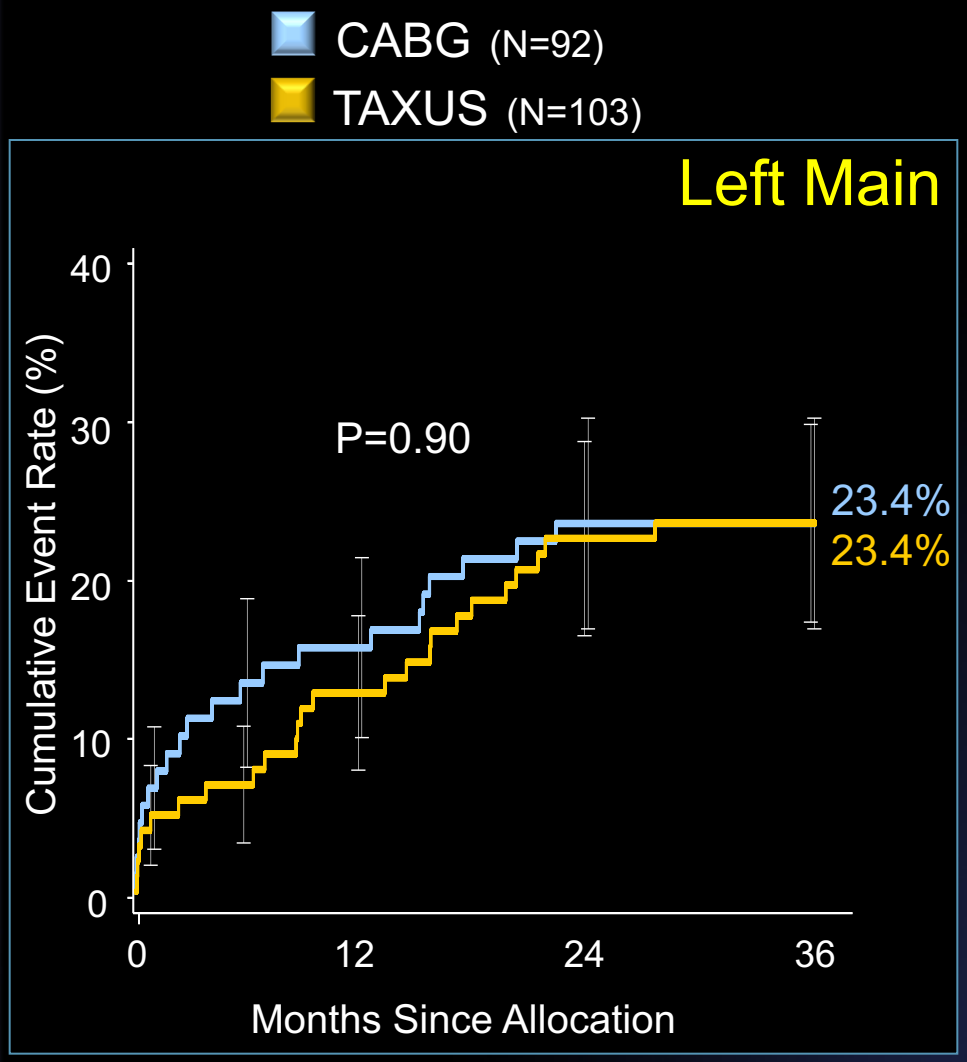


	CABG	PCI	*P* value
Death	6.0%	2.6%	0.21
CVA	4.1%	0.9%	0.12
MI	2.0%	4.3%	0.36
Death, CVA or MI	11.0%	6.9%	0.26
Revasc.	13.4%	15.4%	0.69

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Site-reported Data; ITT population

MACCE to 3 Years by SYNTAX Score Tercile *Intermediate Scores (23–32)*

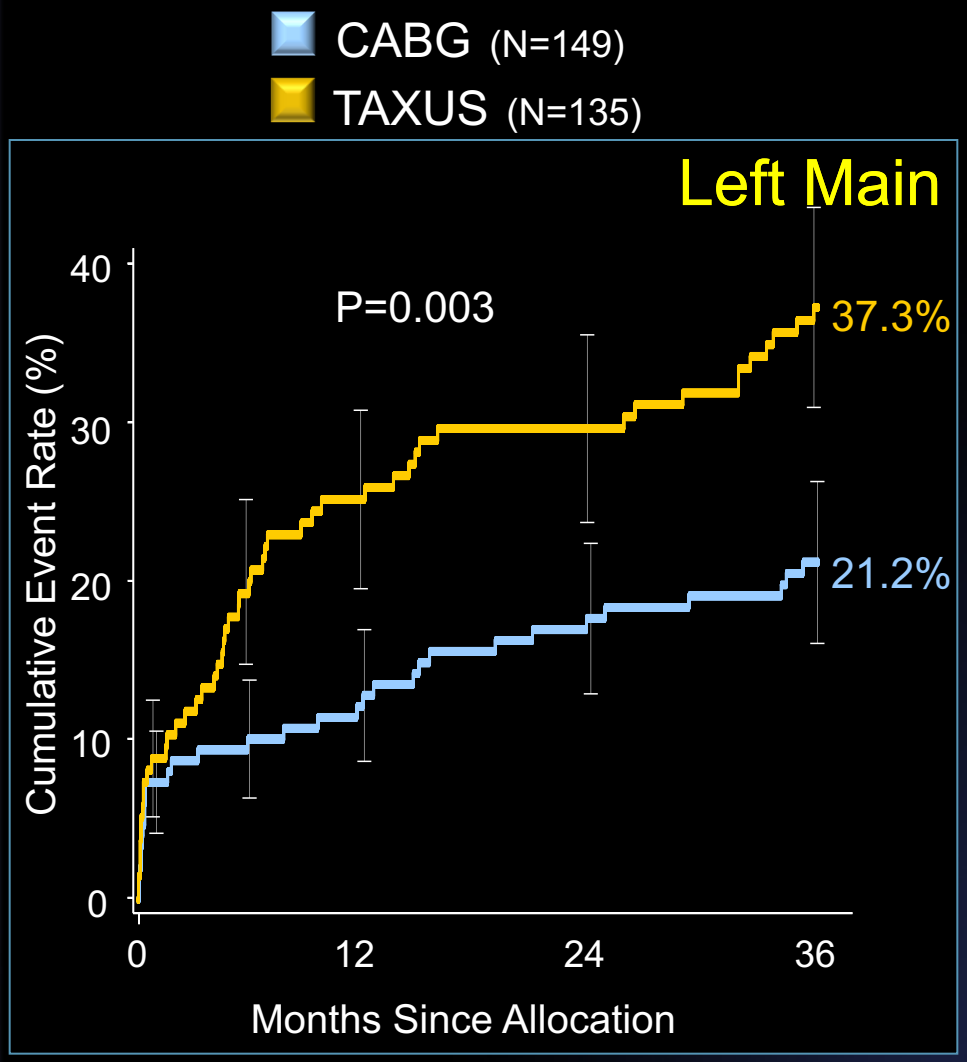


	CABG	PCI	*P* value
Death	12.4%	4.9%	0.06
CVA	2.3%	1.0%	0.46
MI	3.3%	5.0%	0.63
Death, CVA or MI	15.6%	10.8%	0.29
Revasc.	14.0%	15.9%	0.75

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Site-reported Data; ITT population

MACCE to 3 Years by SYNTAX Score Tercile *Left Main SYNTAX Score ≥33*



	CABG	PCI	*P* value
Death	7.6%	13.4%	0.10
CVA	4.9%	1.6%	0.13
MI	6.1%	10.9%	0.18
Death, CVA or MI	15.7%	20.1%	0.34
Revasc.	9.2%	27.7%	<0.001

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Site-reported Data; ITT population

CONCLUSION

The **FRIEND Trial** is a large prospective multicenter study on ULM stenting with a single drug-eluting stent and a predefined homogeneous technique in elective patients with a 9-month angiographic follow-up

Single digit of TVR (6,1%), death (6.7%), cardiac death (2.7%) and MACCE (21%) at 36-month FU

ULM stent thrombosis with a provisional T stenting approach is a relatively rare event, with a rate of 1.9% at 36-month-FU

Good long-term efficacy and safety of PCI outcomes in **very selected** patients