



# *LE MANS registry: 12 years of Left Main Stenting*

**Pawel E. Buszman,**  
MD, PhD, FESC, FACC

ICCU and 3rd Dept. Of Cardiology, Upper-Silesian Heart Center  
Ist and IInd Department Of American Heart of Poland

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Pawel Buszman, MD, PhD

FESC, FACC, FSCAI

Upper Silesian Heart Center, Silesian Medical University, Katowice, Poland

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## Presenter Disclosure Information

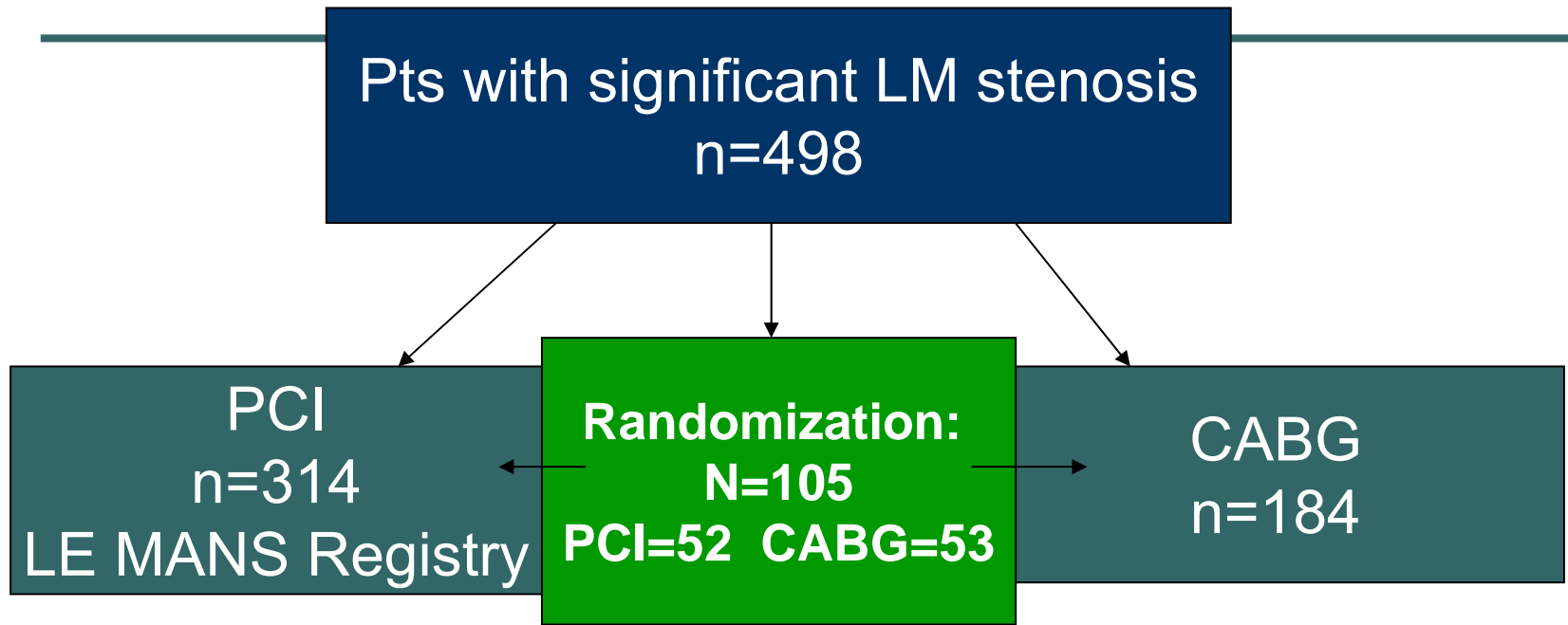
- Chairman of the Executive Board and co-owner, American Heart of Poland Inc.
- Share holder of NAFIS Inc, Intercard Inc.
- Chairman of Scientific Committee and Advisory Board, Balton Ltd

## Left Main Stenting Study-LE MANS

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- Concept and protocol of the study designed in 1997
- Unique description of the technique of the left main stenting in the protocol
- Grant from Ministry of Science and Informatics (Poland)

# LE MANS Study



*P. Buszman et al. JACC, 2008.*

*A Grant from Polish Ministry of Science and Informatics No. 4P05B00819.*

# LE MANS Randomized study

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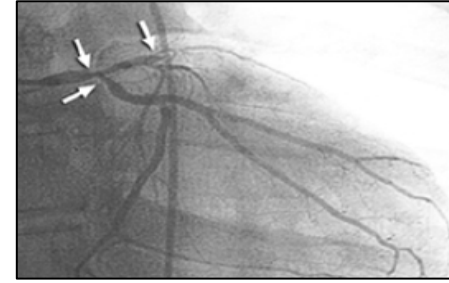
## Acute and Late Outcomes of Unprotected Left Main Stenting in Comparison With Surgical Revascularization

Pawel E. Buszman, MD, FACC,\*†‡ Stefan R. Kiesz, MD, FACC,†‡ Andrzej Bochenek, MD,\*  
Ewa Peszek-Przybyla, MD,§ Iwona Szkrobka, MD,§ Marcin Debinski, MD,§  
Bozena Bialkowska, MD,§ Dariusz Dudek, MD,|| Agata Gruszka, MD,§ Aleksander Zurakowski, MD,§  
Krzysztof Milewski, MD,§ Mirosław Wilczynski, MD,§ Lukasz Rzeszutko, MD,|| Piotr Buszman,\*  
Jan Szymaszal, PhD,¶ Jack L. Martin, MD, FACC,# Michal Tendera, MD, FACC\*  
*Katowice, Ustron, and Krakow, Poland; San Antonio, Texas; and Philadelphia, Pennsylvania*

<b>Objectives</b>	The purpose of this study was to compare the early and late results of percutaneous and surgical revascularization of left main coronary artery stenosis.
<b>Background</b>	Unprotected left main coronary artery (ULMCA) stenting is being investigated as an alternative to bypass surgery.
<b>Methods</b>	We randomly assigned 105 patients with ULMCA stenosis to percutaneous coronary intervention (PCI; 52 patients) or coronary artery bypass grafting (CABG; 53 patients). The primary end point was the change in left ventricular ejection fraction (LVEF) 12 months after the intervention. Secondary end points included 30-day major adverse events (MAE), major adverse cardiac and cerebrovascular events (MACCE), length of hospitalization, target vessel failure (TVF), angina severity and exercise tolerance after 1 year, and total and MACCE-free survival.
<b>Results</b>	A significant increase in LVEF at the 12-month follow-up was noted only in the PCI group ( $3.3 \pm 6.7\%$ after PCI vs. $0.5 \pm 0.8\%$ after CABG; $p = 0.047$ ). Patients performed equally well on stress tests, and angina status improved similarly in the 2 groups. PCI was associated with a lower 30-day risk of MAE ( $p < 0.006$ ) and MACCE ( $p = 0.03$ ) and shorter hospitalizations ( $p = 0.0007$ ). Total and MACCE-free 1-year survival was comparable. Left main TVF was similar in the 2 groups. During the $28.0 \pm 9.9$ -month follow-up, there were 3 deaths in the PCI group and 7 deaths in the CABG group ( $p = 0.08$ ).
<b>Conclusions</b>	Patients with ULMCA disease treated with PCI had favorable early outcomes in comparison with the CABG group. At 1 year, LVEF had improved significantly only in the PCI group. After more than 2 years, MACCE-free survival was similar in both groups with a trend toward improved survival after PCI. (Study of Unprotected Left Main Stenting Versus Bypass Surgery [LE MANS study]; NCT00375063). (J Am Coll Cardiol 2008;51:538–45) © 2008 by the American College of Cardiology Foundation

## Aim

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- Early and Late Outcomes after UPLMCA stenting
- To determine independent risk factors influencing early/late survival and Major Acute Cardiac and Cerebral Events (MACCE)
- To compare Bare Metal Stents (BMS) vs Drug Eluting Stents (DES) late outcome

## Methods

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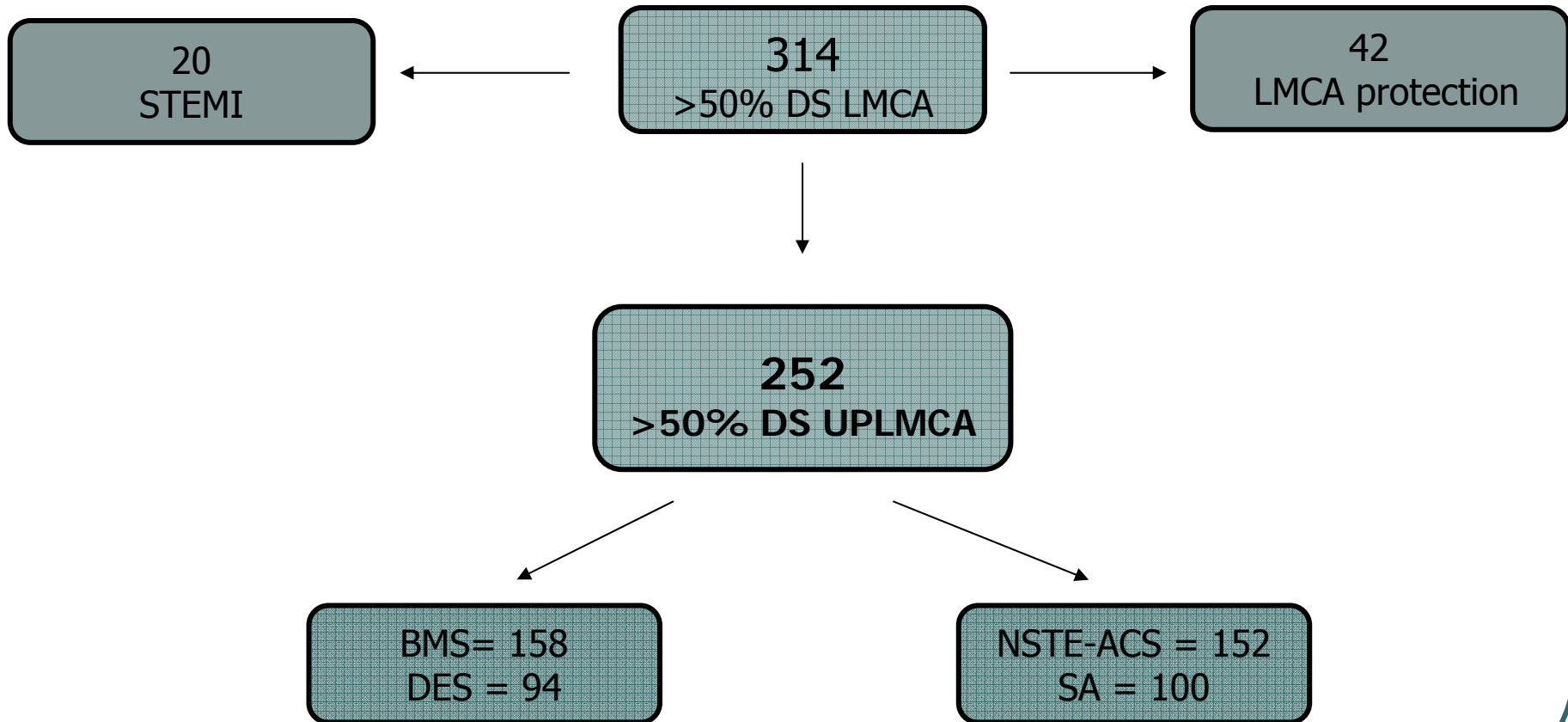
- A Prospective, Multicenter Registry of patients with significant UPLMCA stenosis (>50%DS)
- Enrollment period:  
January 1997 – March 2008
- Centers participating in the study:  
Upper Silesian Heart Center  
1st and 2nd Department of American Heart Of  
Poland (Ustroń, Dąbrowa)

## Inclusion/Exclusion criteria

Inclusion	Exclusion
Significant LMCA stenosis >50%DS	LMCA protection – a patent graft to LAD and/or CX
Unprotected LMCA	ST Elevation Myocardial Infarction (STEMI)
	Total Occlusion (100% DS) of LMCA



# Study population



Enrollment period : may 1997 – march 2008

# Demographics

LEMANS PCI n=252	
Sex (M)	173 (68,6%)
Age	68,5±12
DM	61 (24,21%)
HA	193 (76,59%)
Hch	145 (57,54%)
Tobacco	105 (41,7%)
LVEF	48,6 %± 7
Euroscore	6 ± 2,8
dystal LM	149 (59%)
NSTE-ACS	152 (60,3%)

## Interventional treatment protocol

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- Direct LM stenting preferred, unless critical stenosis or calcifications
- Kissing postdilatation for distal LM stenting
- Provisional stenting of a side branch
- Stent selection
  - BMS in first period 1997-2002
  - DES for LM diameter  $\leq 3.8\text{mm}$ , BMS for LM  $> 3.8\text{mm}$
- A routine control coronary angiography 6-12 months after procedure
- IVUS pre and post procedure recommended, but left to operator preference

## Procedural Data

LEMANS PCI n=252	
DES:	94 (37%)
-PES	60 (63,8%)
-SES	34 (36,2%)
BMS	158 (63%)
Direct stenting	204 (81%)
Stent Length	15,9 ±5,7
Stent Diameter	3,7 ± 0,7
No. of diseased vessels	2,1 ± 0,9
Complete revascularization	196 (78%)
Distal LM involvement:	149 (59%)
-POBA side branch	76 (51%),
-T-Stenting	30 (20,1%)
-Culotte technique	43 (28,9%)
Kissing postdilatation	149 (59%)

## Endpoints and Statistics

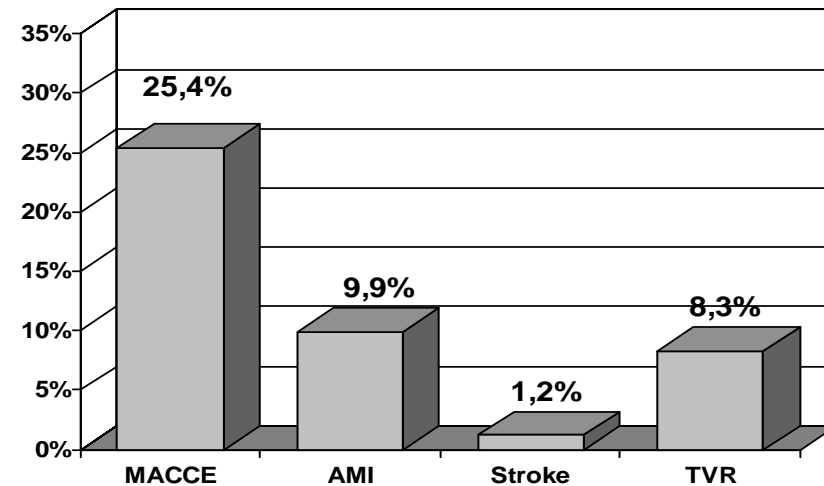
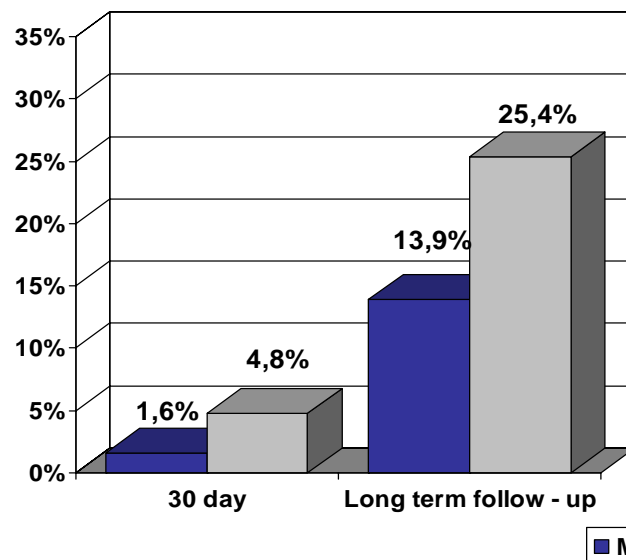
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- Mortality and MACCE in early- (30 days) mid- (12 months) and long-term (av.4 years, longest 12 year ) follow – up in the whole study group and in DES vs. BMS subgroups
- Survival in the whole study group and BMS vs. DES subgroups according to Kaplan-Meier Analysis and F-Cox test for curve comparison.
- Uni and Multivariate analysis of single risk factors influencing early/late survival.
- A propensity score analysis was performed to adjust for differences in demographical and procedural data in groups receiving DES and BMS.

# Results

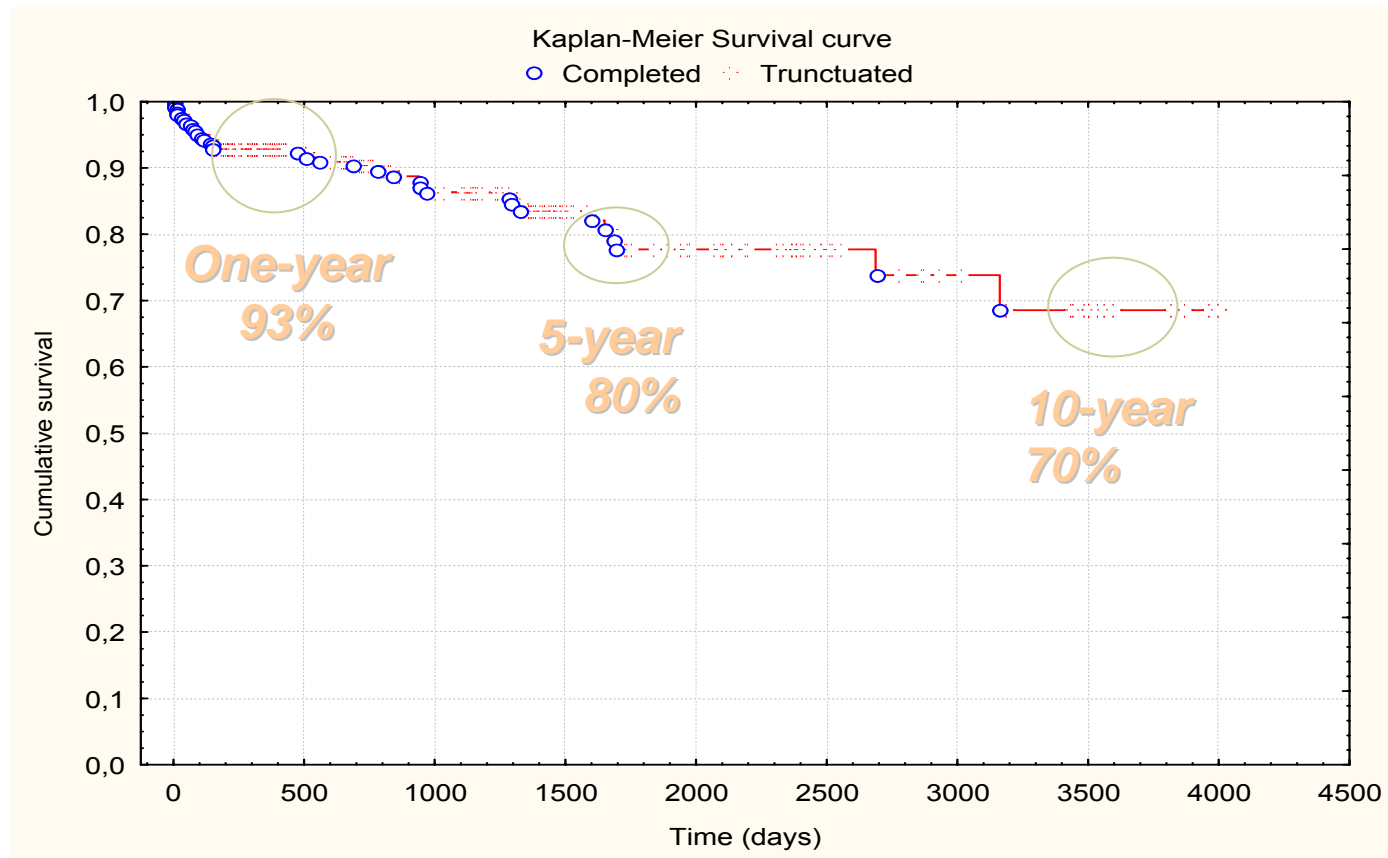
## Mortality/MACCE in early/long term follow - up

## MACCE in long – term follow up

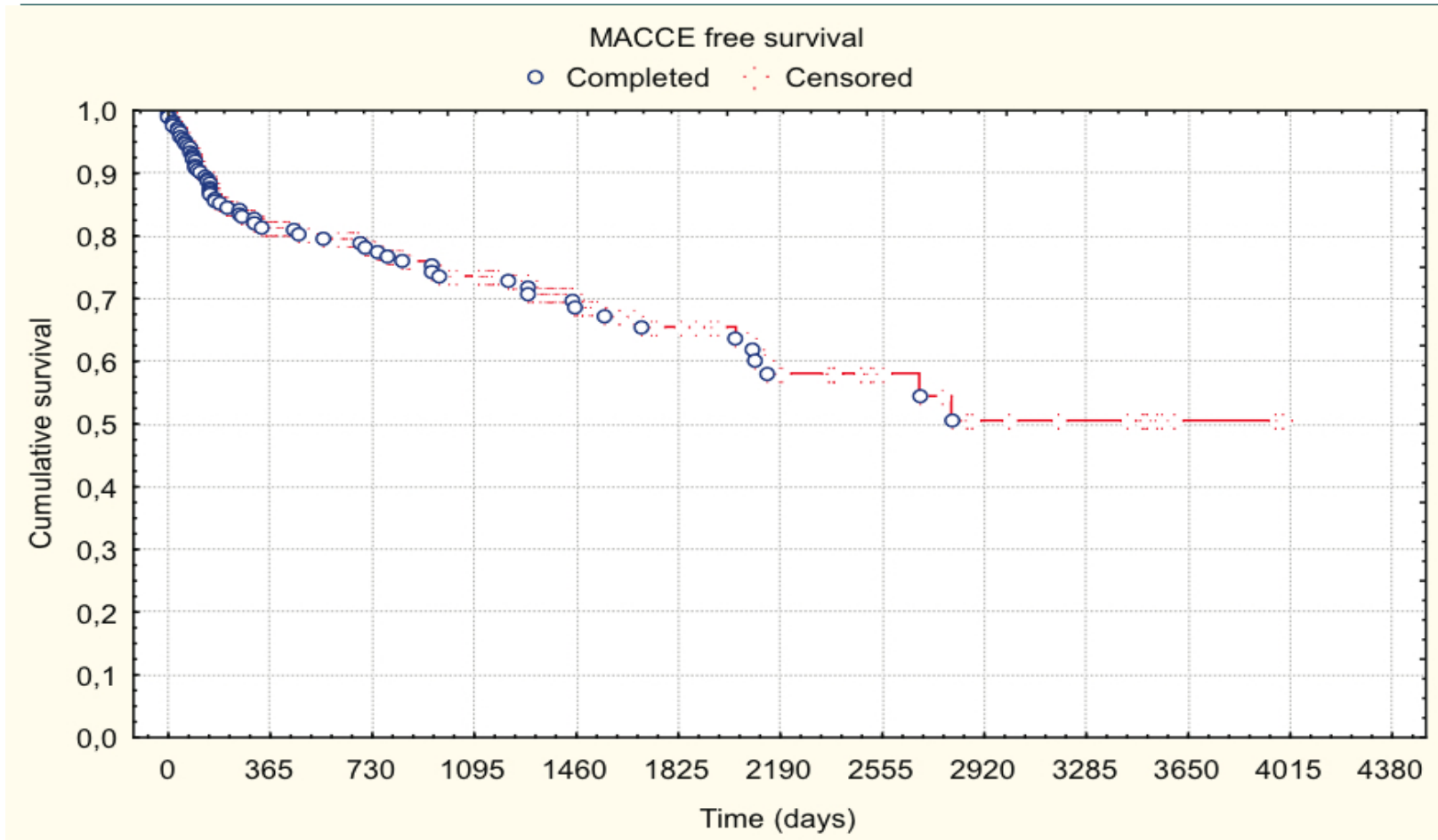


- **Long term follow-up: 12 months-12 years (mean 4 years)**
- 12,2% cases of angiographically confirmed restenosis
- One case of definite and one of probable incidence late in-stent thrombosis

# Results: Survival Curve



# Results: MACCE free Survival Curve



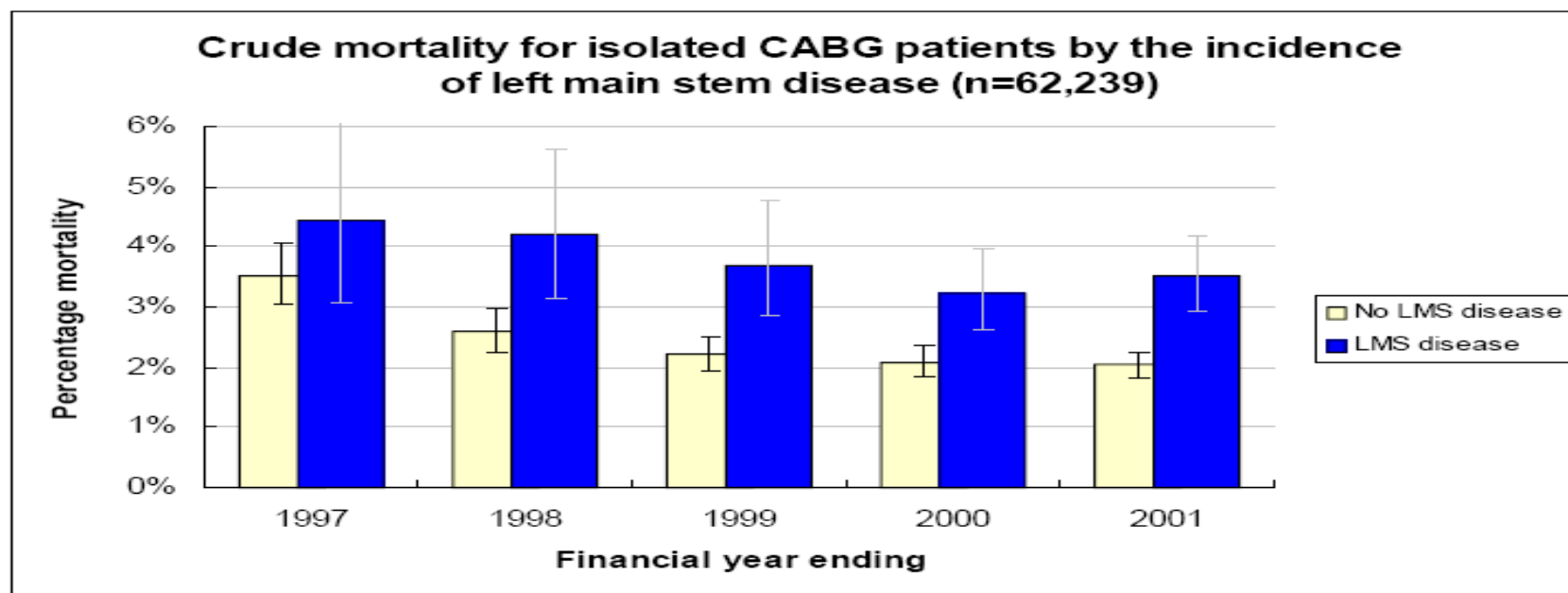


# Early mortality based on The British Registry



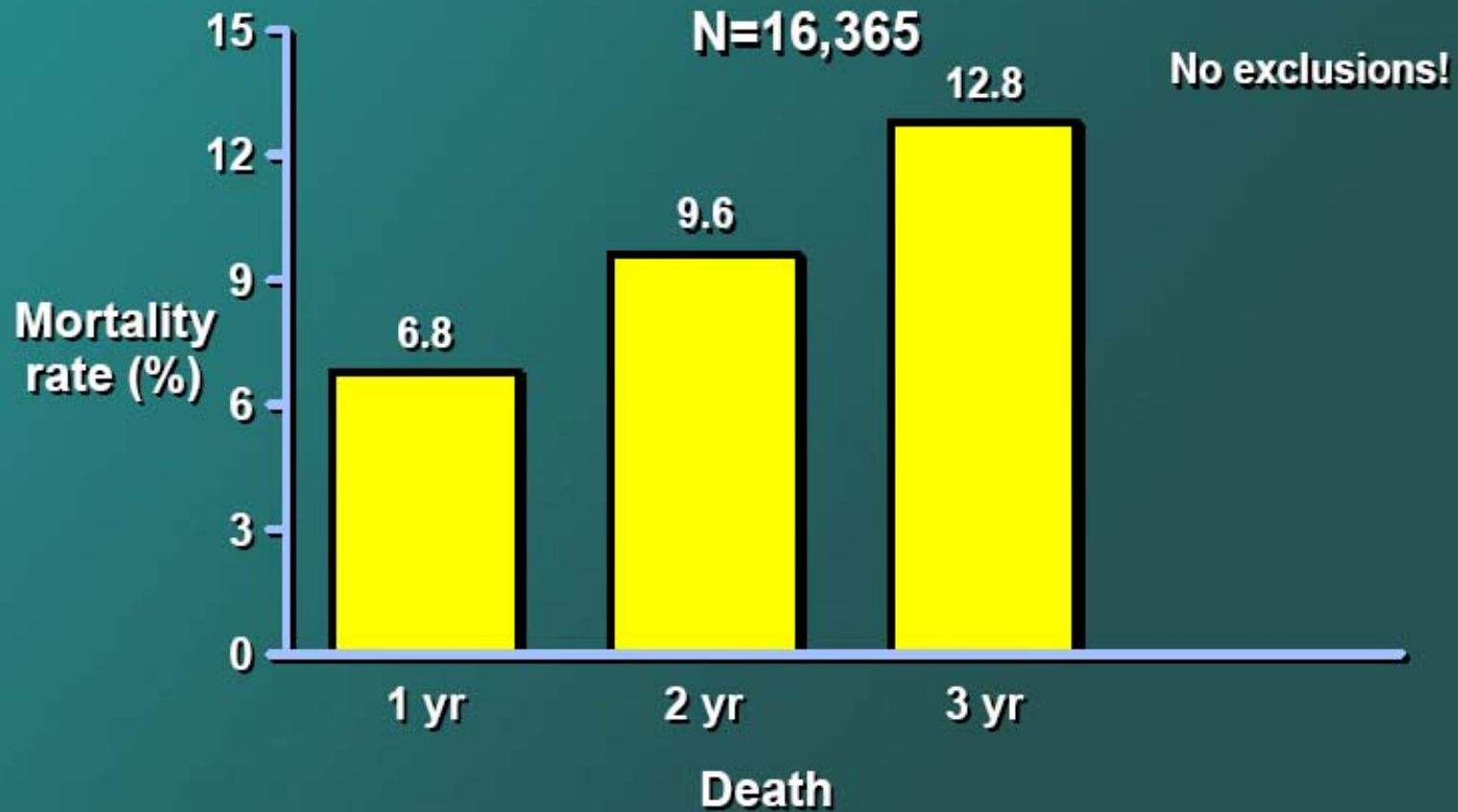
National Adult Cardiac Surgical Database Report 2000 - 2001

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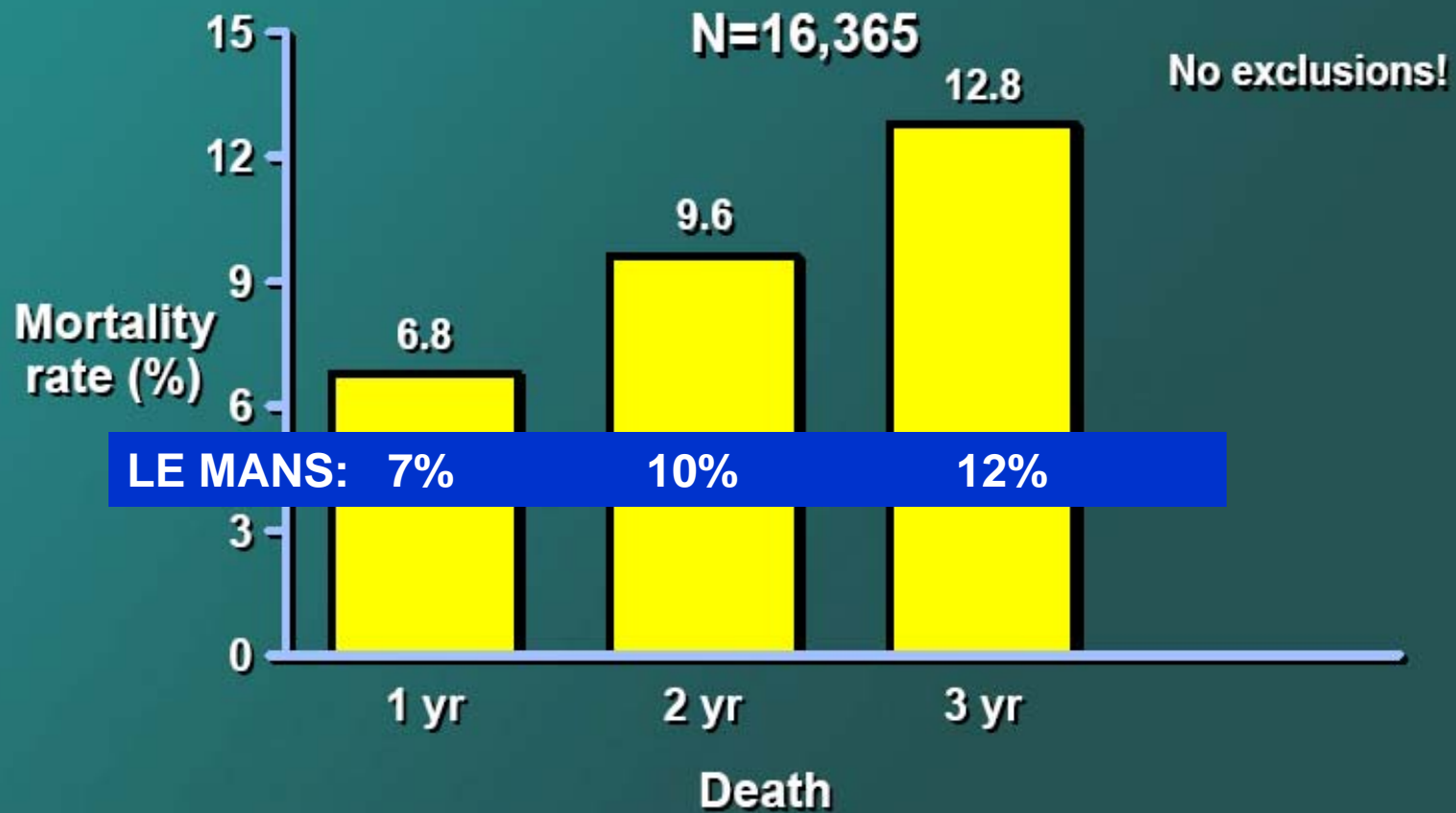
# NYS Database

## CABG for Left Main Disease 1997-2000



Ed Hannon, David Faxon: Personal communication

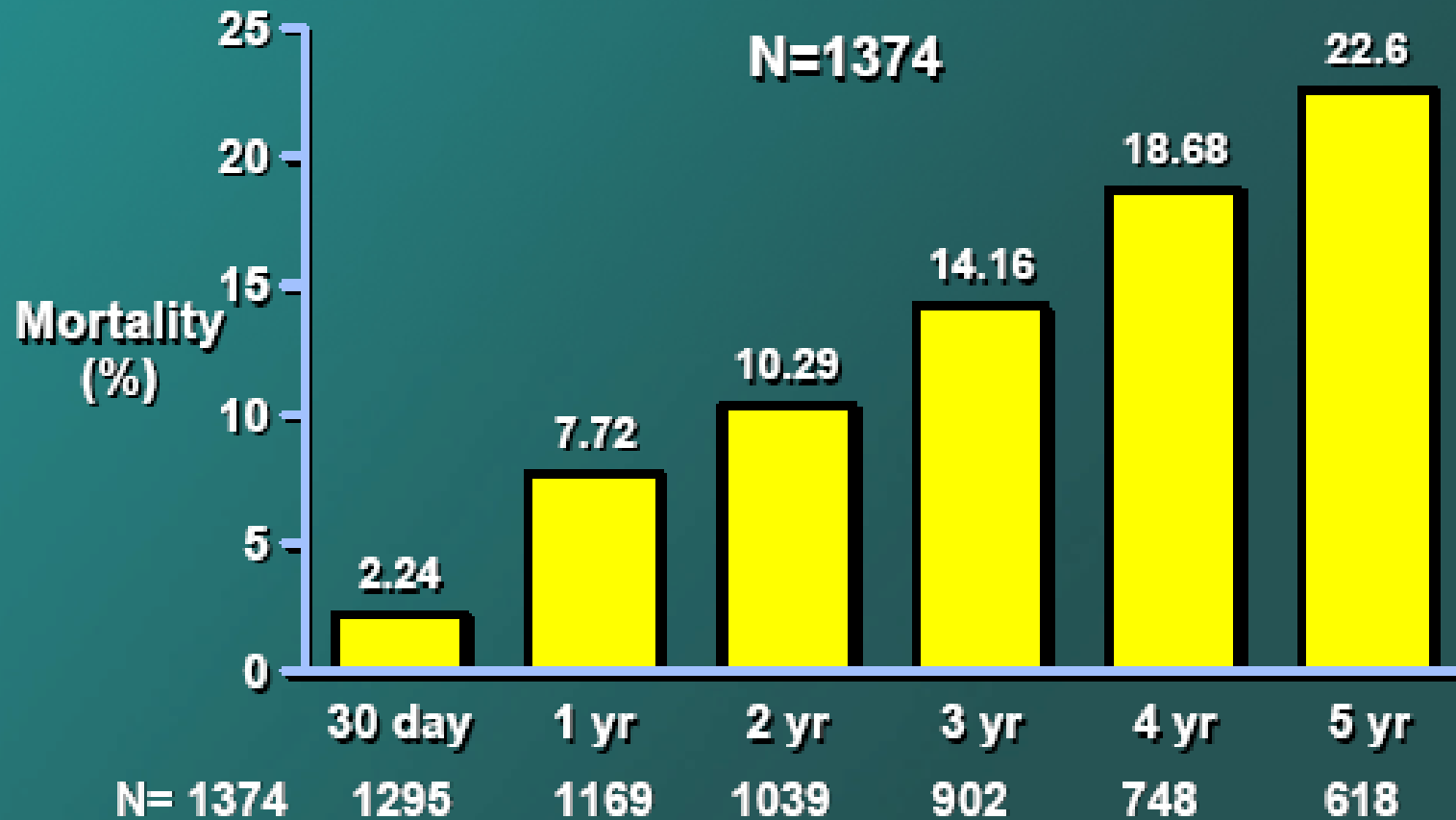
# NYS Database CABG for Left Main Disease 1997-2000



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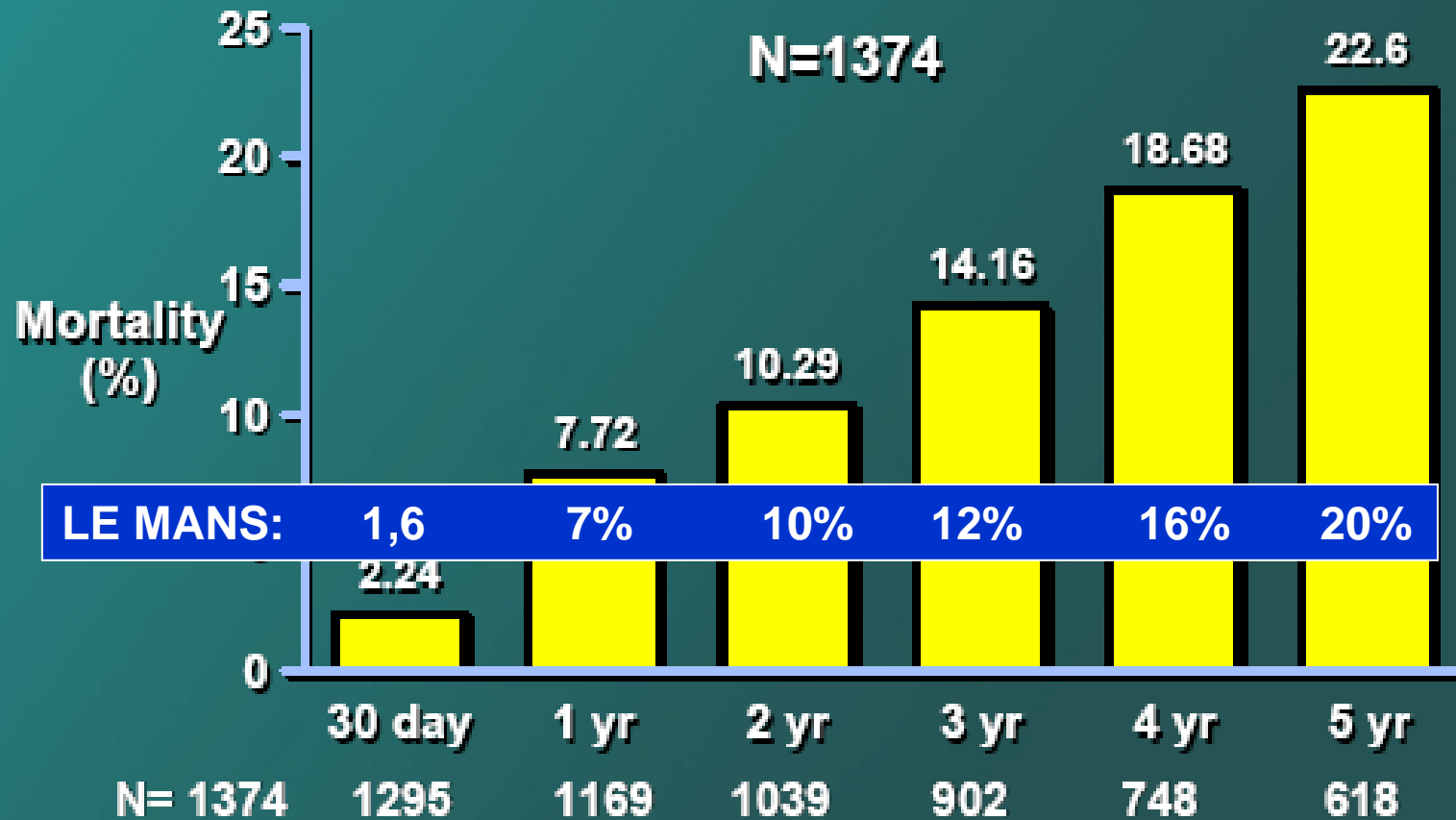
# Duke Database

## CABG for Left Main Disease



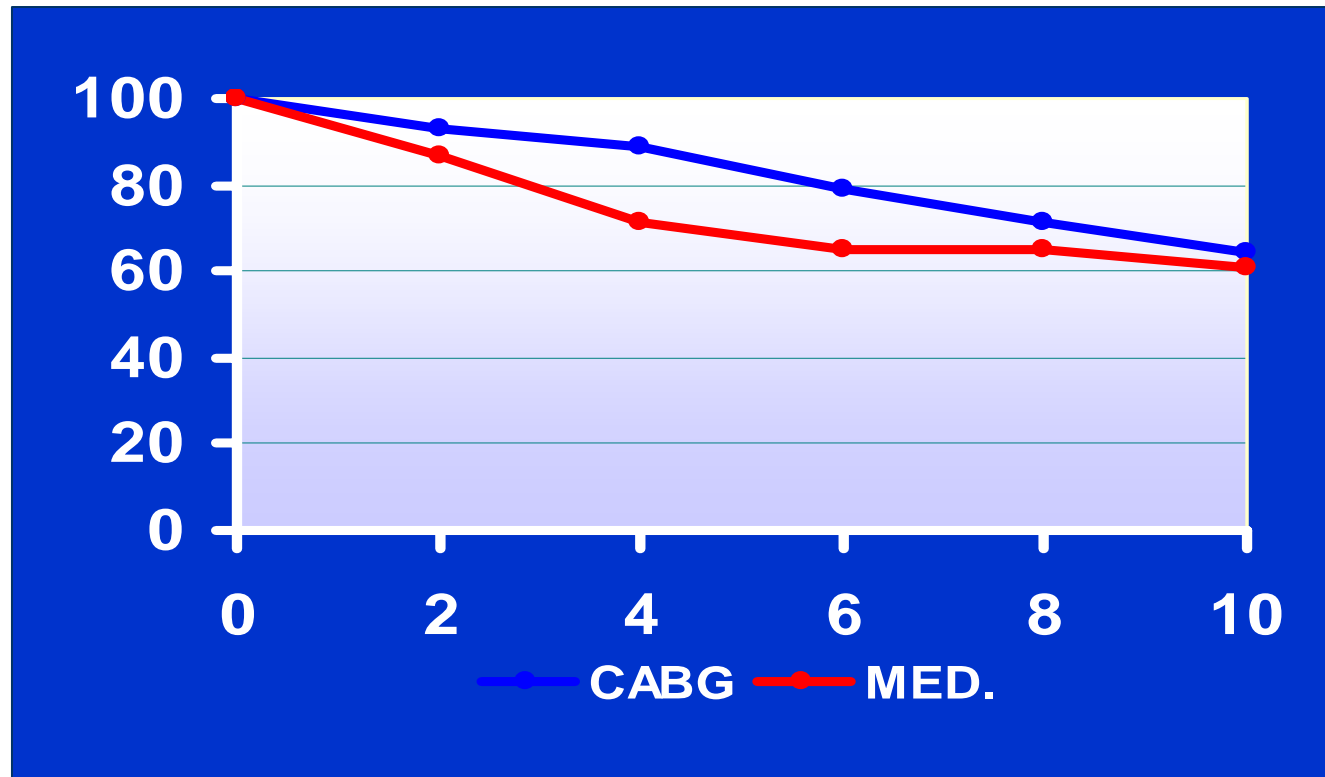
# Duke Database

## CABG for Left Main Disease

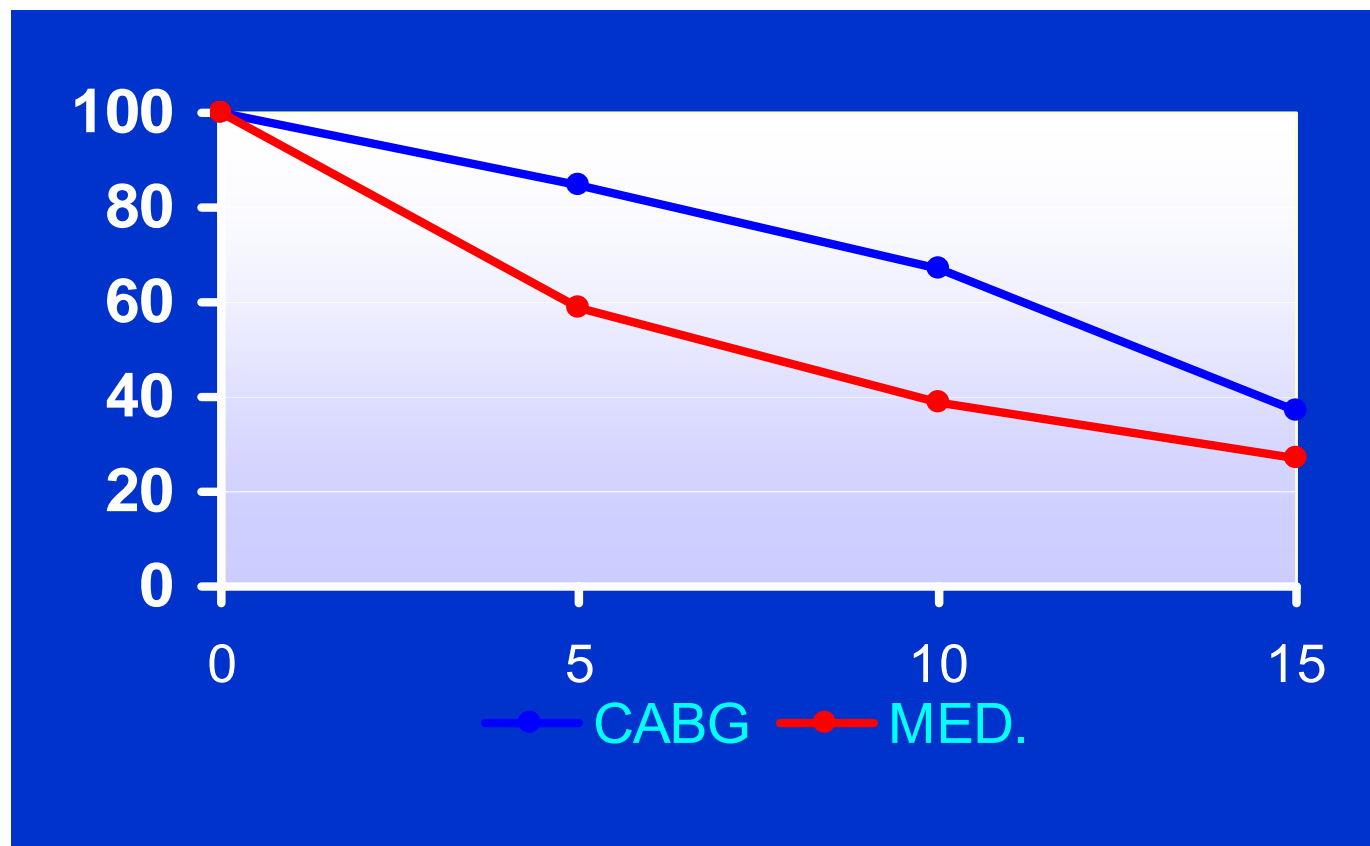


# LMCA disease treatment Rx vs CABG: ECSS study

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# LMCA disease treatment Rx vs CABG : CASS study

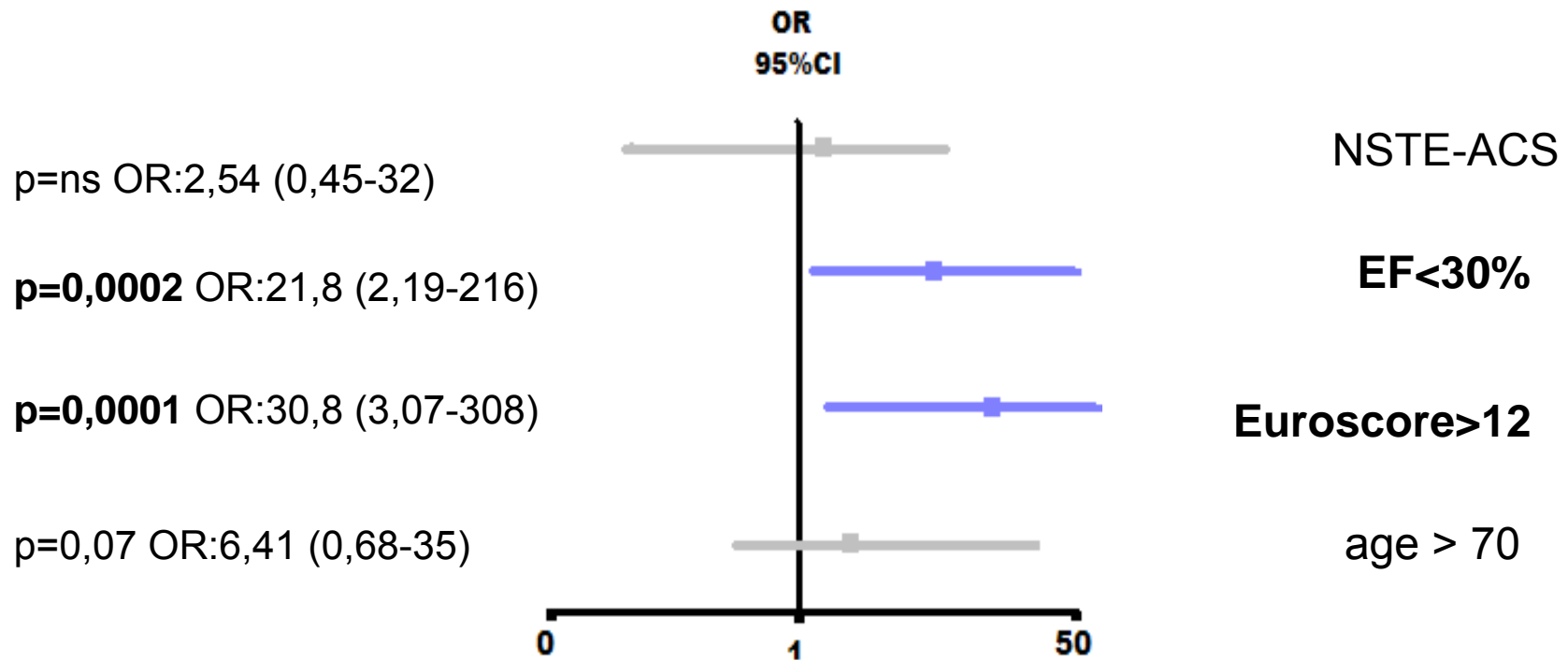


# Univariate analysis

	Early survival		p	Late survival		p
	yes	no		yes	no	
age>60	98,1%	1,9%	p=,62879	83,0%	17,0%	0,04
age>70	96,5%	3,5%	p=0,07			
sex M	98,8%	1,2%	p=,40529	98,8%	1,2%	0,41
DM	96,6%	3,4%	p=,21228	96,7%	3,3%	0,2
HA	99,0%	1,0%	p=,20270	99,0%	1,0%	0,2
Hch	99,3%	0,7%	p=,17668	99,3%	0,7%	0,18
NSTE-ACS	97,4%	2,6%	p=,10789	97,4%	2,6%	0,1
EF<30%	90,9%	9,1%	p= ,0002			
EF<50%	97,0%	3,0%	p=,05767	97,0%	3,0%	0,05
ES<9	98,4%	1,6%	p=,98122	78,3%	21,7%	0,04
ES>11	89,3%	10,7%	p= ,0000			
Lmdyst	98,7%	1,3%	p=,85769	85,0%	15,0%	0,8
stent<3,8mm	100,0%	0,0%	p=,12598	91,0%	9,0%	0,08
kissing	98,7%	1,3%	p=,94918	88,2%	11,8%	0,7
DES	97,9%	2,1%	p=,61043	90,4%	9,6%	0,1

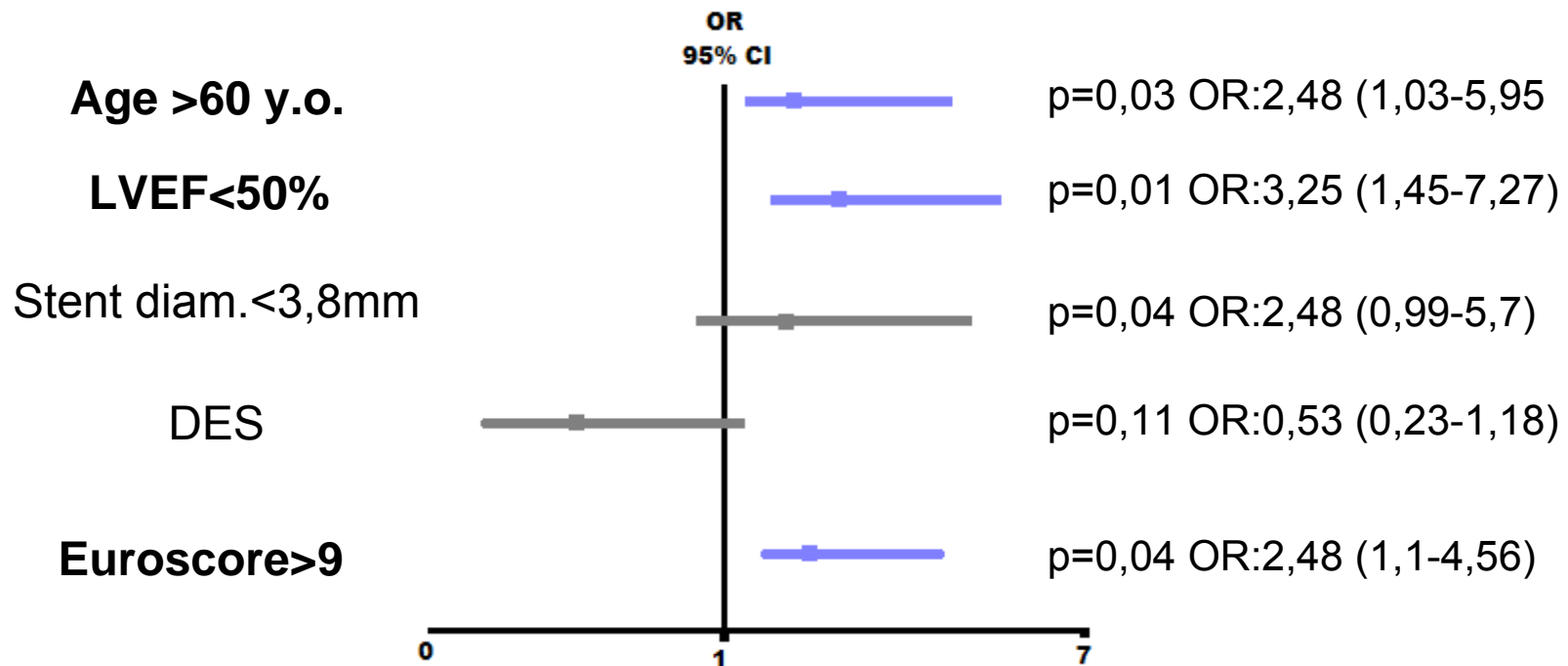


## Results: uni and multivariate analysis with Odds Ratio for 30-day follow-up



**Multivariate discriminant analysis showed that Euroscore > 12 was the independent risk factor influencing early survival**

## Results: uni and multivariate analysis with Odds Ratio for long term follow-up



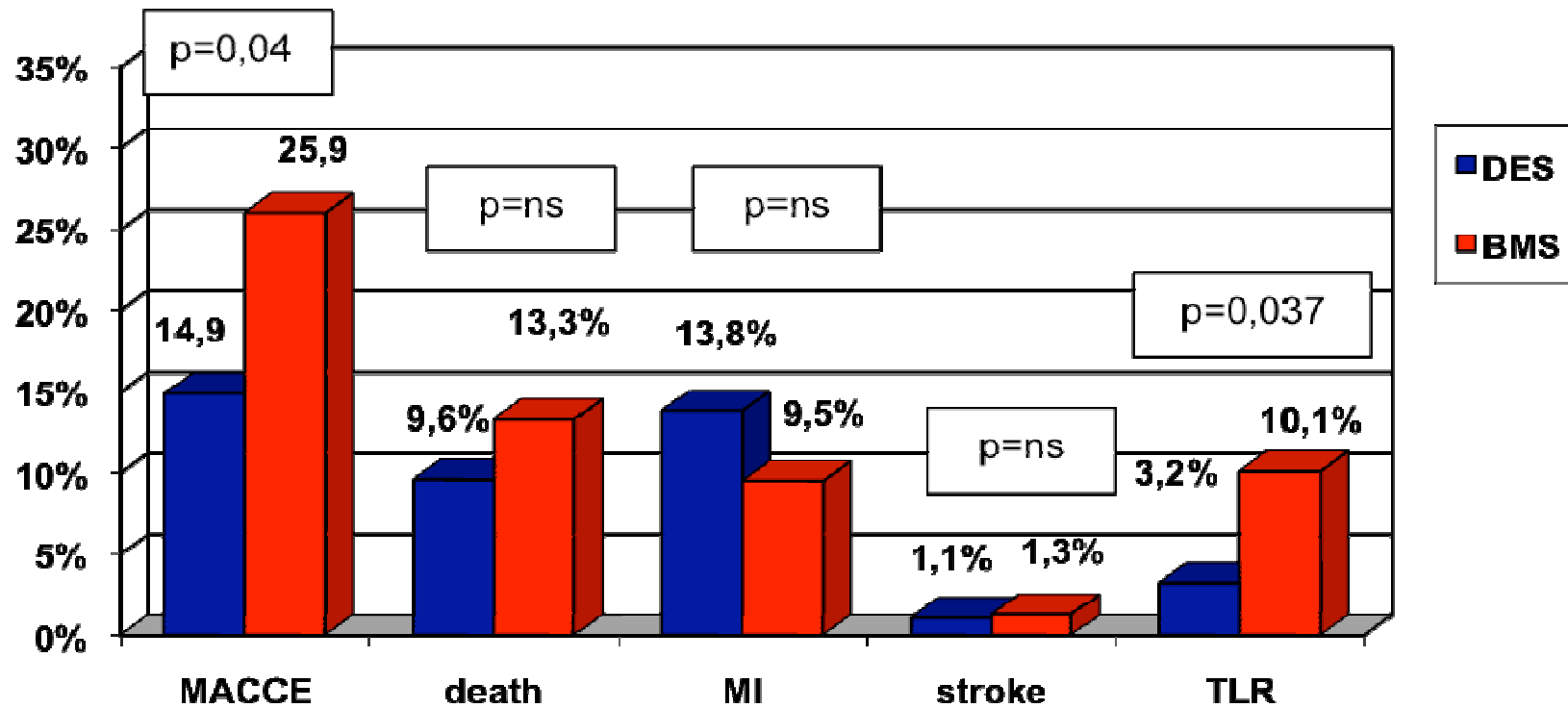
The Cox multivariate analysis for independent risk factors showed that:  
-EF<50% decreased late survival rate,  
-DES implantation decreased and stent diameter <3,8mm increased the risk of MACCE.

## Long term follow – up: DES vs BMS demographics

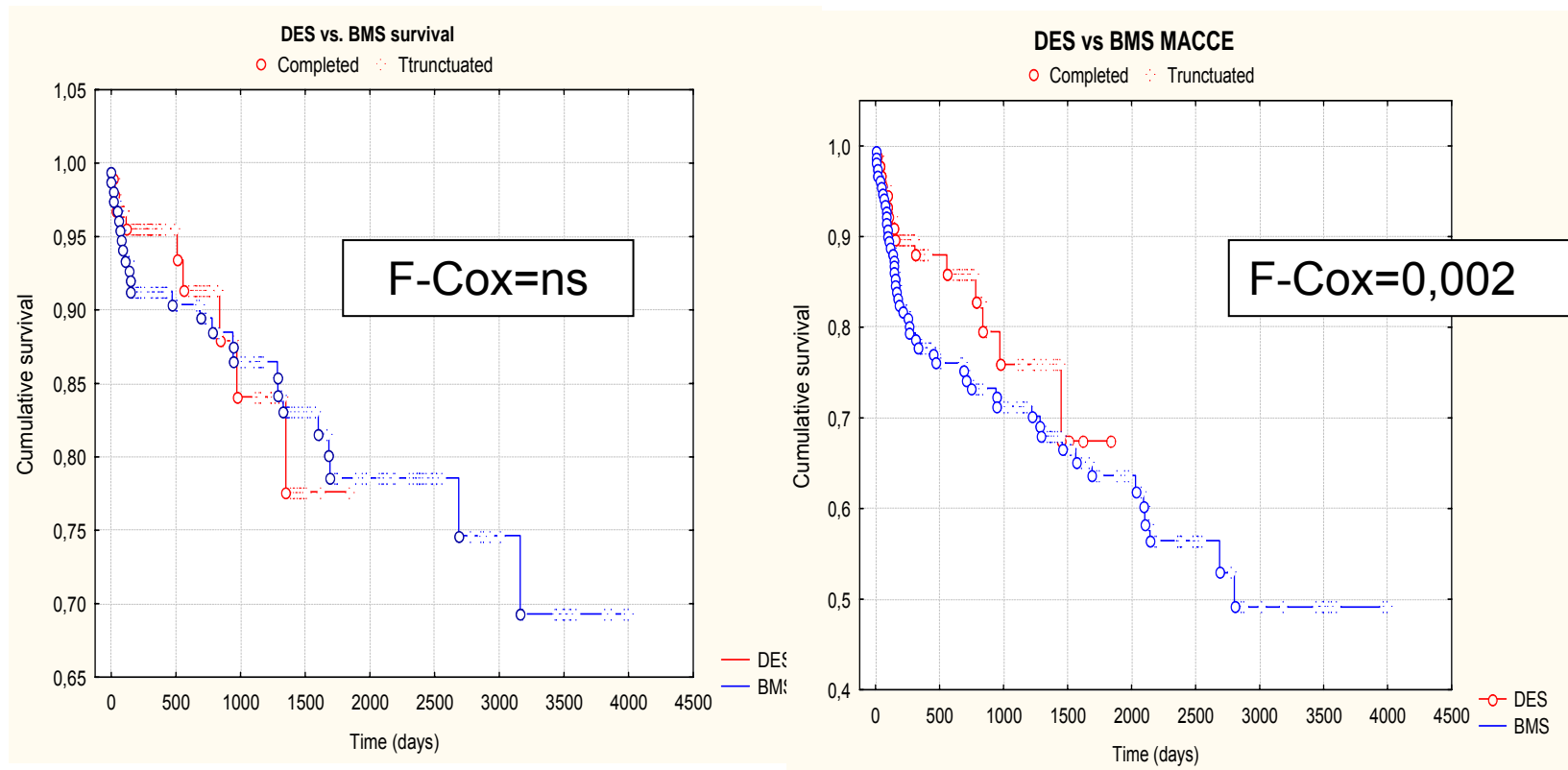
	DES n=94	BMS n=158	p
Sex (M)	59 (61,4%)	114 (72,6%)	0,09
Age	62,03 ± 10,3	64,9 ± 10,7	<b>0,03</b>
DM	29 (30,5%)	32 (20,9%)	<b>0,05</b>
HA	74 (77,9%)	119 (75,8%)	ns
Hch	56 (58,9%)	89 (56,7%)	ns
Tobacco	40 (42%)	65 (41,4%)	ns
EuroScore	6,82 ± 3,8	5,52 ± 3,8	<b>0,009</b>
NSTE-ACS	65 (69,1%)	86 (54,4%)	<b>0,04</b>
LVEF	49,2% ± 12,9%	48,27 ± 13,3	ns
Lm dyst	68 (72,3%)	81 (51,6%)	<b>0,004</b>
No.of dis. vessels	2,1 ± 0,84	2,02 ± 0,8	ns
Stent diameter	3,36 ± 0,44	3,92 ± 0,8	ns

# Long term follow - up: DES vs BMS

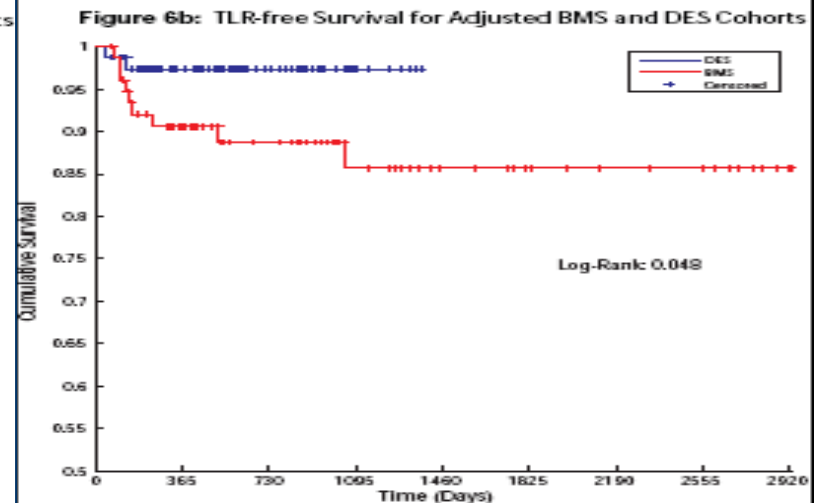
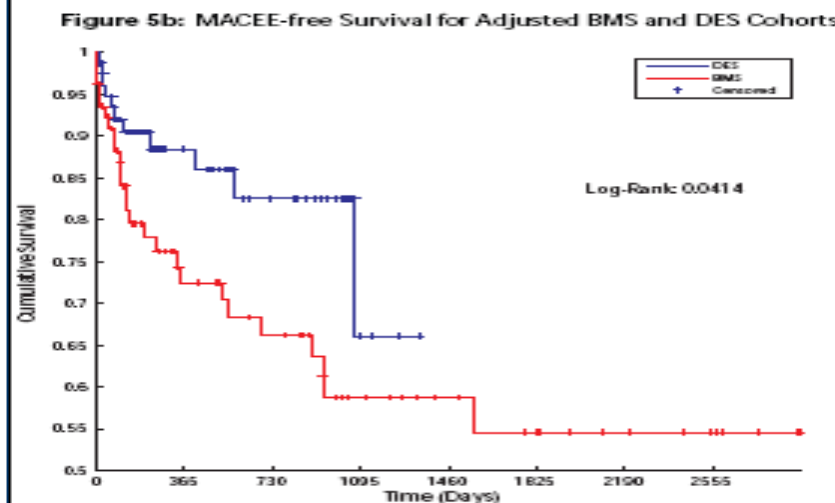
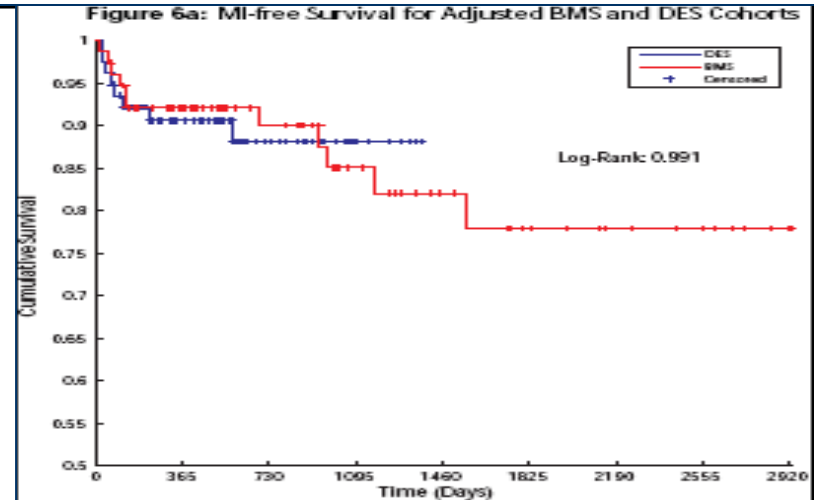
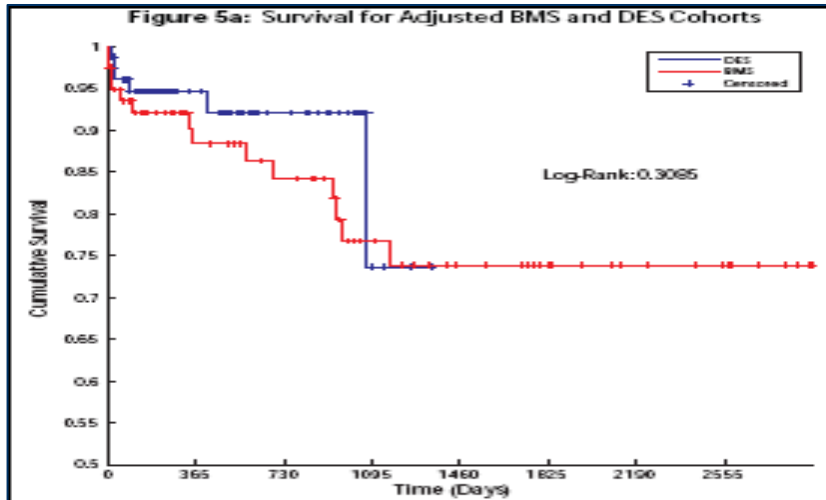
## Mortality and MACCE



# Survival and MACCE free curves (non-adjusted): DES vs BMS



# Survival and MACCE free curves (adjusted): DES vs BMS



# Distal LM subgroup

Figure 7a: Survival Curve for Patient Cohorts with Distal LM and Proximal and Medial LM Involvement

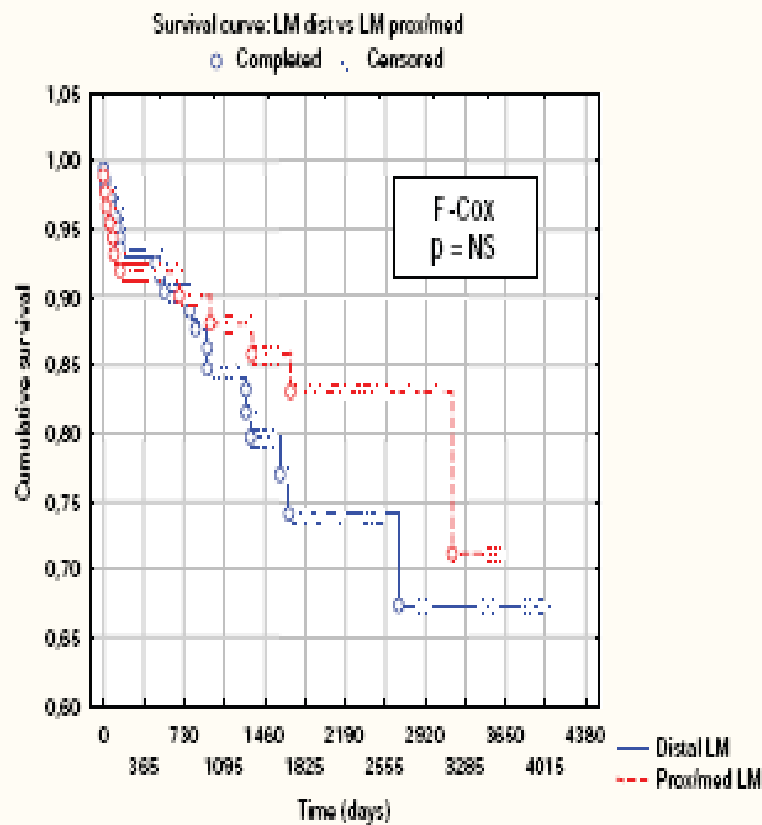
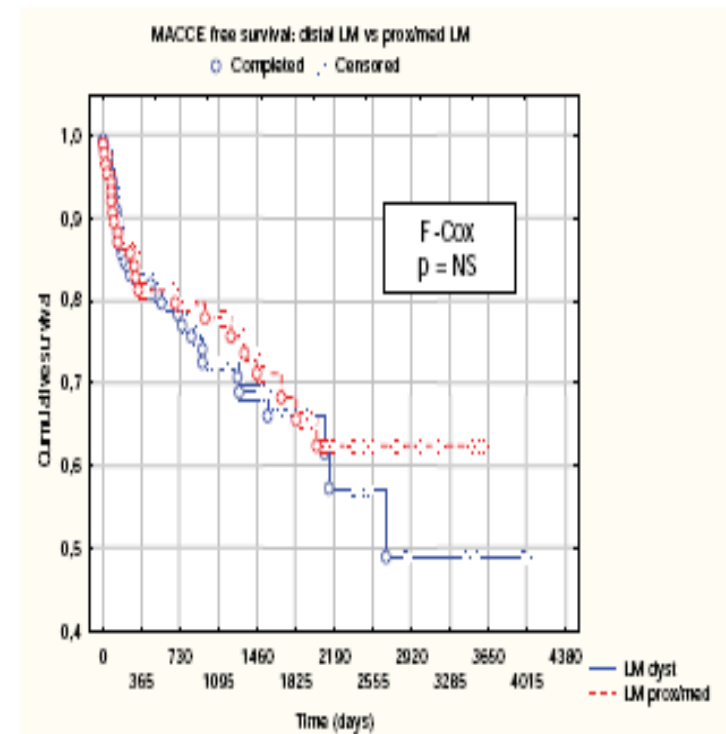
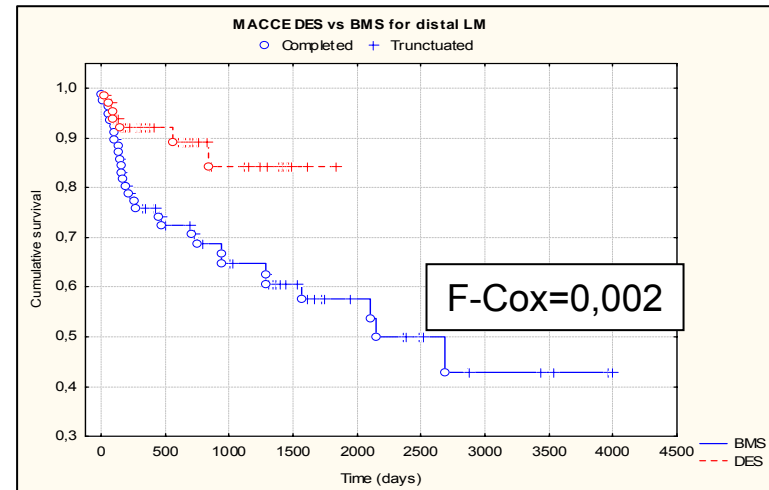
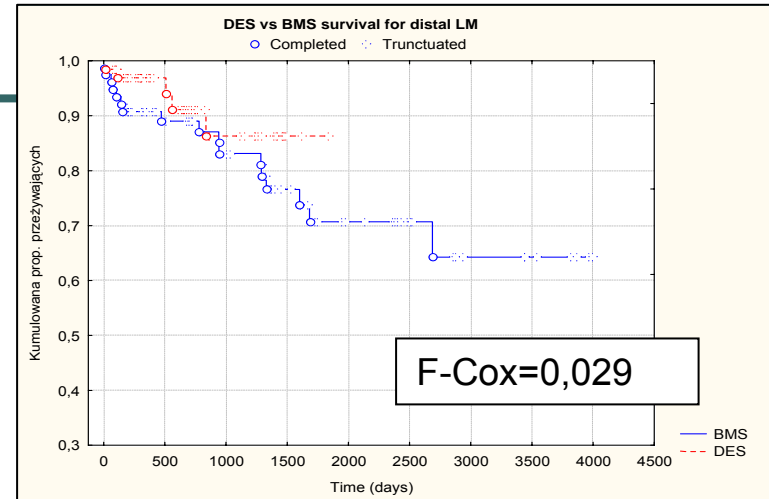
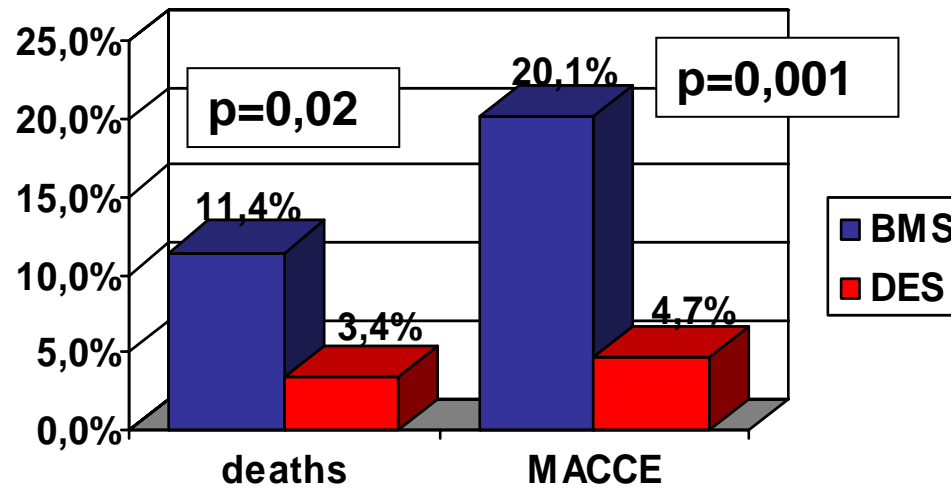


Figure 7b: MACCE-free Survival Curve for Patient Cohorts with Distal LM and Proximal and Medial LM Involvement



# BMS vs DES for distal LM

Stent in distal LM  
BMS vs DES  
n=149





# Conclusions

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1. **Stenting of UPLMCA is feasible and is associated with good short- and long-term outcomes as long as 12 years.**
2. **The use of DES decreased MACCE risk for the whole population, as well as lowered death and MACCE rate for distal LM stenosis.**
3. **EF < 30% and EuroScore > 12 were the risk factors influencing early survival.**
4. **The Cox multivariate analysis for independent risk factors showed that EF < 50% decreased survival rate, while DES implantation decreased and stent diameter < 3,8mm increased the risk of MACCE.**

# Prometheus' Fire

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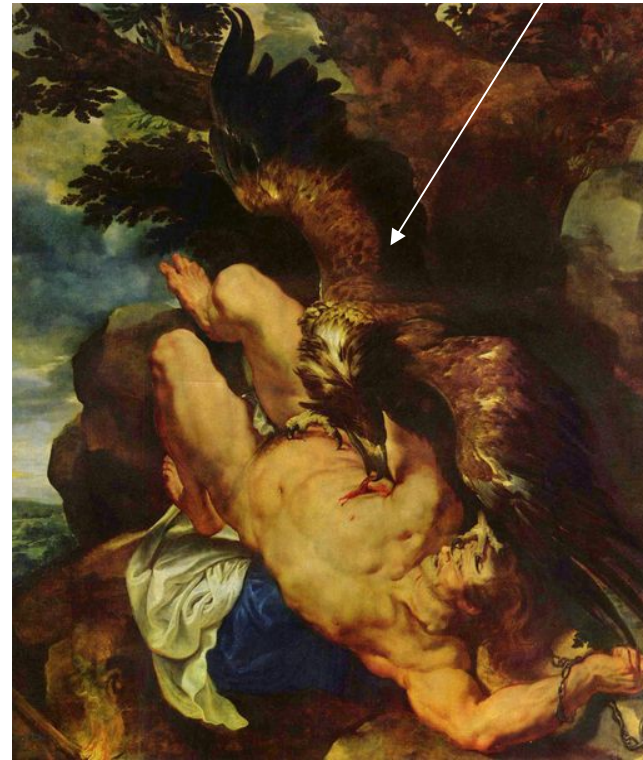
**Heinrich Friedrich Fuger  
„Prometheus bringing the fire”**

# Potential risk

CT surgeon



**Dick van Baburen:  
Vulcan chaining Prometheus**



**Peter Paul Rubens:  
Ethon biting Prometheus' liver**

# Pandora's Box

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- Is the procedure for all Patients with LM disease?
- Can every interventionalist do ULMS?
- What is a learning curve?



A Hope at the bottom  
of the box:  
The late results of Syntax  
Study!



## *LE MANS registry: 12 years of Left Main Stenting*

Pawel E Buszman, Piotr P Buszman, Blazej Trela, Magdalena Konkolewska, Marek Krol, Marek Kondys, Aleksander Zurakowski, Iwona Szkrobka, Michal Tendera, Stefan R Kiesz

ICCU and 3rd Dept. Of Cardiology, Upper-Silesian Heart Center  
Ist and IInd Department Of American Heart of Poland



## Introduction

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- **Unprotected Left Main Coronary Artery Stenosis (UPLMCA) is associated with high mortality risk (CASS, ECSG studies)**
- **Current ESC/AHA/ACC guidelines in this cases strongly recommend surgical revascularization (CABG) - class IA**
- **PCI of UPLMCA is becoming a very popular method of revascularization due to progress in stent technology and stent implantation technique.**
- **Stent implantation for UPLMCA is associated with low periprocedural risk, however there is limited data on long –term survival, especially with the use of drug eluting stents (DES)**

*Varnauskas E, for the European Coronary Surgery Study Group.. N Engl J Med  
Caracciolo EA,. Long-term CASS experience. Circulation.  
ESC PCI Guidelines. EHJ 2005*

# BMS vs DES: LM ref. diameter <3,8mm

## BMS vs DES <3,8mm

