DELFT Registries

and SYNTAX trial updates

Meliga E, Garcia-Garcia HM, Valgimigli M, Chieffo A, Biondi-Zoccai G, Maree AO, Cook S, Reardon L, De Servi S, Palacios IF, Windecker S, Colombo A, van Domburg R, Sheiban I, Serruys PW.

Symposium arena

16:18-16:30, April 23

Professor Serruys declares no conflict of interest

The DELFT registry

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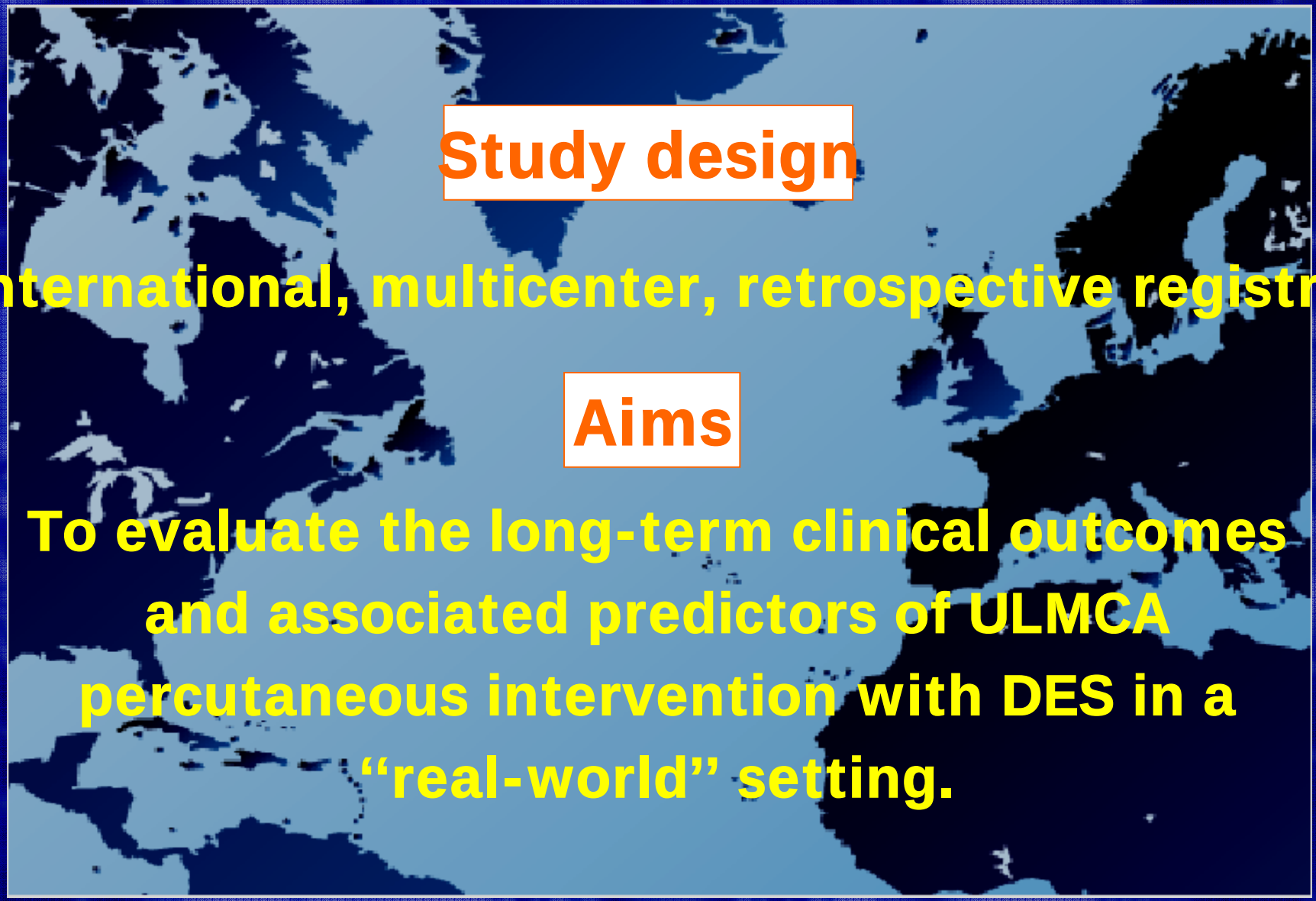
The DELFT registry



Study design

International, multicenter, retrospective registry.

Aims

To evaluate the long-term clinical outcomes and associated predictors of ULMCA percutaneous intervention with DES in a "real-world" setting.

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The DELFT registry

Study population

April 2002 → April 2004

358
consecutive patients with
de novo ULMCA disease

↓

SES or PES

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The DELFT registry

Procedures and medications

All patients were prescribed lifelong aspirin (75-100 mg/day) and prolonged (at least 6m) DAT of aspirin + clopidogrel or aspirin + ticlopidine was recommended.

Repeated revascularization was only performed if there was either symptom recurrence or inducible ischemia related to the ULMCA disease.

Definitions

Events were adjudicated according to the ARC definitions and were hierarchically reported

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The DELFT registry

Data collection and follow-up

All data relating to hospital admissions, procedures and in-hospital outcomes were collected in each centre using the hospital recording network.

Information regarding clinical status was collected by:

- clinical visits
- telephone interviews
- referring physician
- hospital electronic database
- Municipal Civil Registries.

At 3 years the clinical follow-up was **100%.**

This protocol was approved by the hospital ethics committees and is in accordance with the Declaration of Helsinki. Written informed consent was obtained from every patient.

Baseline clinical characteristics - 1

Age (yrs)	66.1±11.2
Men	73.7%
BMI (kg/m²)	26.7±4.7
Arterial Hypertension	66.5%
Hypercholesterolemia	64.2%
Current Smoking	33.5%
Diabetics	30.2%
IDDM	16.2%
NIDDM	14%
Family history of CAD	26%
Previous AMI	45.3%
Previous PCI	30.2%
Previous CABG	24.6%

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Baseline clinical characteristics - 2

Diagnosis at admission		
	Stable Angina	44.1 %
	Unstable Angina	41.9 %
19.6 % Emrgt PCI	AMI	8.4 %
	AMI + shock	2.8 %
	Silent Ischemia	2.8 %
LVEF		48.6 ± 12.8 %
EuroScore		6.4 ± 4.1
	>6	20.1 %
	>9	31.0 %
	Elective	5.7 ± 3.8
	Emergent	9.9 ± 3.5

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Procedural and angiographic characteristics - 1

Emergent PCI	19.6%
UA with Hemodynamic Instability	41.4%
AMI	44.3%
Cardiogenic Shock	14.3%
Lesion Location	
Ostium/shaft	26.3%
Distal	73.7%
DES	
Cypher	54.5%
Taxus	45.5%
Approach	
Single stent	56.7%
Multiple stent	43.3%
Stenting Technique	
Provisional	56.7%
V stenting	8.3%
T stenting	3.9%
Crushing	26.5%
Culotte	4.4%
Additional multivessel treatment	50.8%

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Procedural and angiographic characteristics - 2

Stents per patient	1.47 (529/358)
Stent diameter (mm)	3.23 ± 0.31
Stent length (mm)	17.3 ± 6.7
TIMI flow at baseline	
0-1	17%
2	6.7%
3	76.3%
Pre-dilation	47.2%
Thrombectomy	1.4%
Cutting	7.8%
Rotablator	2.2%
Atherectomy	1.4%
Post-dilation	52.5%
Maximal inflation pressure	16.8 ± 2.8
Final Kissing	37.2%
Bigger balloon size (mm)	3.53 ± 0.55
Post procedural RVD (mm)	3.71 ± 0.54
Post procedural MLD (mm)	3.32 ± 0.57

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Follow-up and clinical outcomes - 1

Hierarchical		Elective	Emergent	Overall	p value
		n=(288)	(n=70)	(n=358)	
In-hospital	CD	0.7%	12.8%	3%	<0.001
	(re)MI	6.9%	8.6%	7.2%	0.39
	TLR	0%	1.4%	0.3%	0.19
	TVR	0.7%	1.4%	0.8%	0.48
	MACE	8.3%	22.8%	11.1%	<0.001
30 days	CD	0.7%	14.3%	3.3%	<0.001
	MI	6.9%	8.6%	7.2%	0.39
	TLR	0.3%	1.4%	0.6%	0.35
	TVR	0.7%	1.4%	0.8%	0.48
	MACE	8.3%	24.3%	11.4%	<0.001

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Follow-up and clinical outcomes - 2

Hierarchical		Elective
		n=(288)
6 months	CD	1.7 %
	MI	6.9 %
	TVR	6.2 %
	TLR	2.7 %
	MACE	14.9 %
1 year	CD	3.8 %
	MI	7.3 %
	TVR	11.1 %
	TLR	4.5 %
	MACE	22.2 %
3 years	CD	6.2 %
	MI	8.3 %
	TVR	16 %
	TLR	6.6%
	MACE	30.5 %

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Follow-up and clinical outcomes - 2

Hierarchical		Elective
		n=(288)
6 months	CD	1.7 %
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Follow-up and clinical outcomes - 2

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	MACE	22.2 %
3 years	CD	6.2 %
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	TVR	16 %
	TLR	6.6%
	MACE	30.5 %

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Follow-up and clinical outcomes - 2

Hierarchical		Elective	Emergent	Overall	p value
		n=(288)	(n=70)	(n=358)	
6 months	CD	1.7 %	17.1%	4.7%	<0.001
	MI	6.9 %	8.6%	7.2%	0.39
	TVR	6.2 %	4.3%	5.8%	0.38
	TLR	2.7 %	1.4%	2.5%	0.44
	MACE	14.9 %	30%	17.8%	0.003
1 year	CD	3.8 %	18.6%	6.7%	<0.001
	MI	7.3 %	8.6%	7.5%	0.43
	TVR	11.1 %	5.7%	10%	0.12
	TLR	4.5 %	1.4%	3.9%	0.2
	MACE	22.2 %	32.9%	24.3%	0.046
3 years	CD	6.2 %	21.4%	9.2%	<0.001
	MI	8.3 %	10%	8.6%	0.4
	TVR	16 %	7.1%	14.2%	0.037
	TLR	6.6%	2.8%	5.8%	0.18
	MACE	30.5 %	38.5%	32.1%	0.126

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Stent thrombosis

	Acute (<24h)	Sub-acute (<30 days)	Late (<1 year)	Very-late (>1 year)	Total
Definite ST	1 (0.3)	0 (0)	0 (0)	1 (0.3)	2 (0.6)
Probable ST	1 (0.3)	2 (0.6)	0 (0)	1 (0.3)	4 (1.1)
Possible ST	0 (0)	0 (0)	8 (2.2)	8 (2.2)	16 (4.4)
Total	2 (0.6)	2 (0.6)	8 (2.2)	10 (2.8)	22 (6.1)

Characteristics of patients with Definite ST

Clinical Presentation	Euroscore	Lesion Location	Emcy	Day	No. Stent	DAT	M	CD related to ST
UA	9	ostial	Yes	0	1	Yes	TVR	No
SA	11	distal	No	439	3	No	MI	No

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Multivariable analysis

Variable	Cardiac death	MACE	TVR
Age	HR=1.06 (1.01-1.11) p=0.010	-	-
IDDM	-	HR=2.85 (1.29-6.17) p=0,009	HR=2.92 (1.60-5.30) p<0.001
Shock	HR=11.0 (1.88-63.9) p=0.008	-	-
EuroSCORE	HR=1.15 (1.01-1.31) p=0.046	HR=1.10 (1.02-1.19) p=0.014	-
LVEF (<50%)	-	-	HR=1.03 (1.01-1.05) p=0.050
Multiple stenting	-	-	HR=4.51 (1.07-19.0) p=0.040

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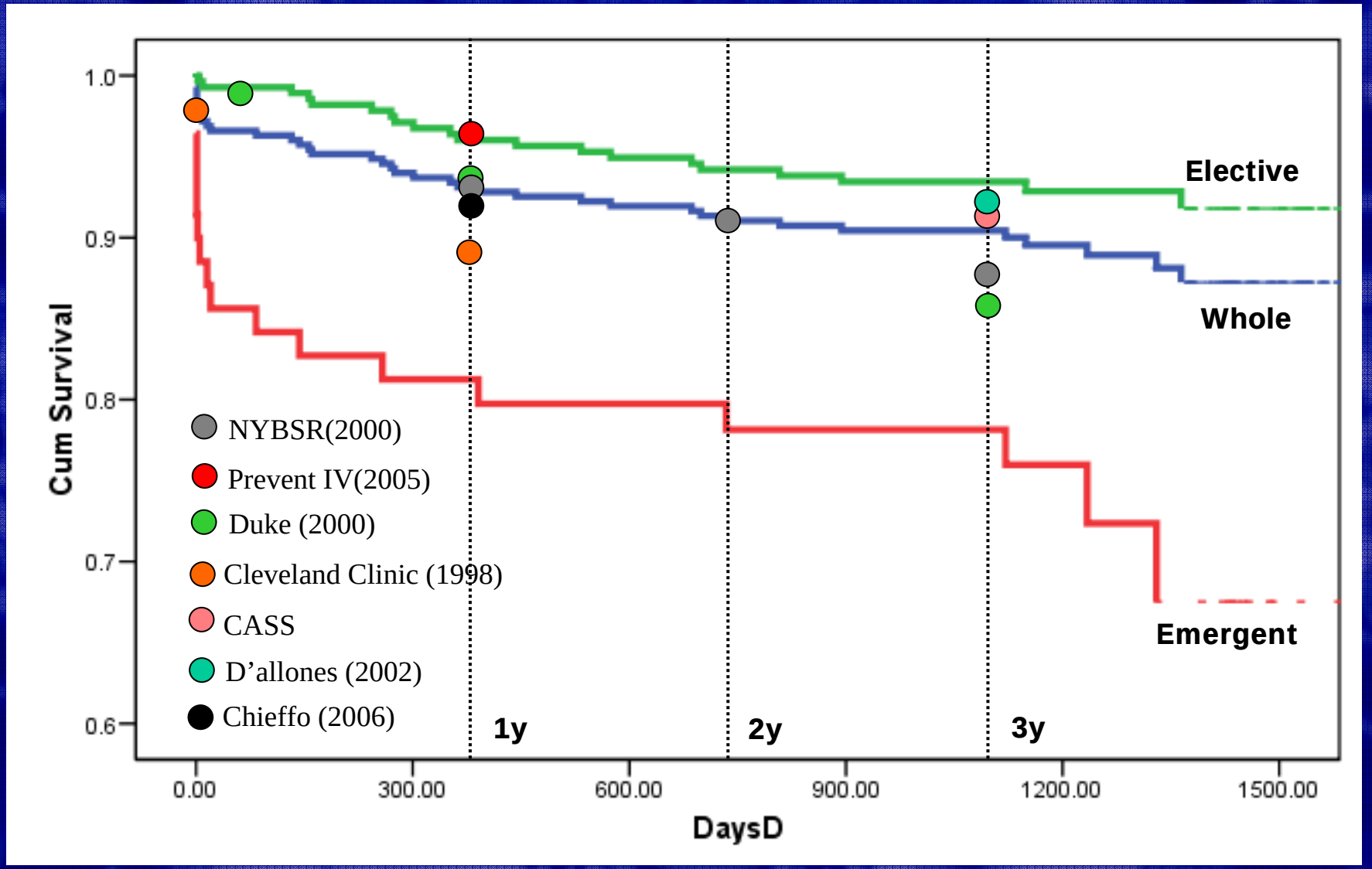
Milk break
Coffee was not yet existing

J.Vermeer
The milkmaid.

PCI vs CABG – Death



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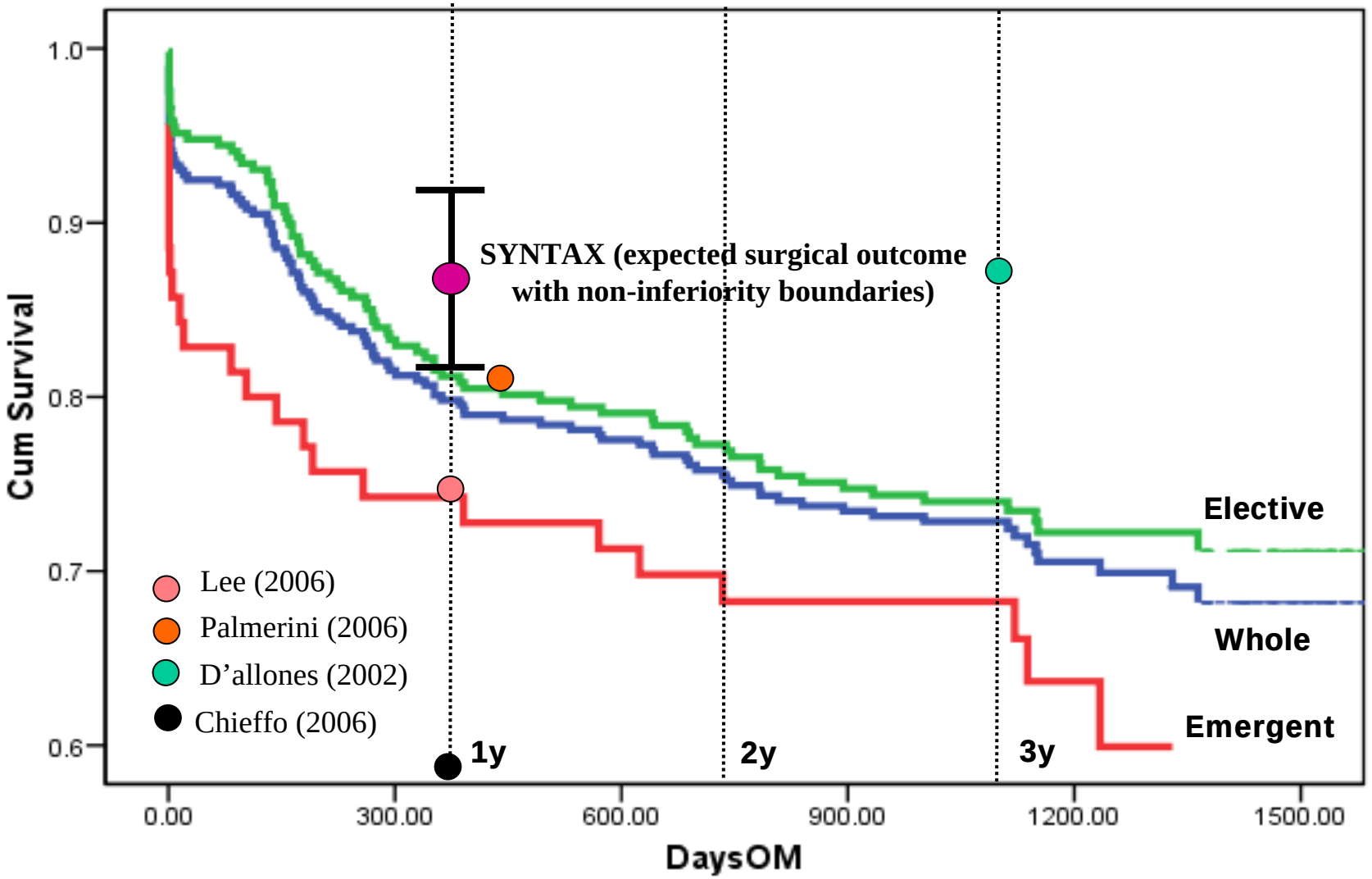
PCI vs CABG – MACE



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Lesion and Patient Complexity
SYNTAX *Randomized vs. Registry Cohorts*

		Randomized N=1800	CABG Registry N=649	PCI Registry N=198
Patient	3 Vessel Disease (%)	60.6%	54.5%	65.2%
	LM (%)	**39.4%**	**45.5%**	**34.8%**
	Diabetics (%)	24.6%	29.4%	35.5%
PCI	Bifurcation (% pts)*	62.7%	n/a	58.6%
	Total Occlusion (% pts)*	27.2%	n/a	39.6%
	Total stent length >100mm (% pts)	34.2%	n/a	11.2%
	Number of stents (per pt)	4.7	n/a	3.1
CABG	Arterial grafts (%)	94.9%	91.5%	n/a
	Complete arterial revascularization (%)	18.6%	12.5%	n/a
	Double IMA grafts (%)	26.9%	16.0%	n/a
	Conduits used to LAD (%)	95.2%	92.5%	n/a

Data is site reported. *Based on baseline SYNTAX score

Conclusions

Mid long-term follow-up of patients with ULMCA disease treated with DES demonstrated a satisfactory rate in both single and composite outcomes.

Elective PCI patients had an excellent event-free survival over the all 3-year period.

PCIs in emergent patients, though hampered by an early lower event-free survival, had also a favorable long-term clinical success rate.

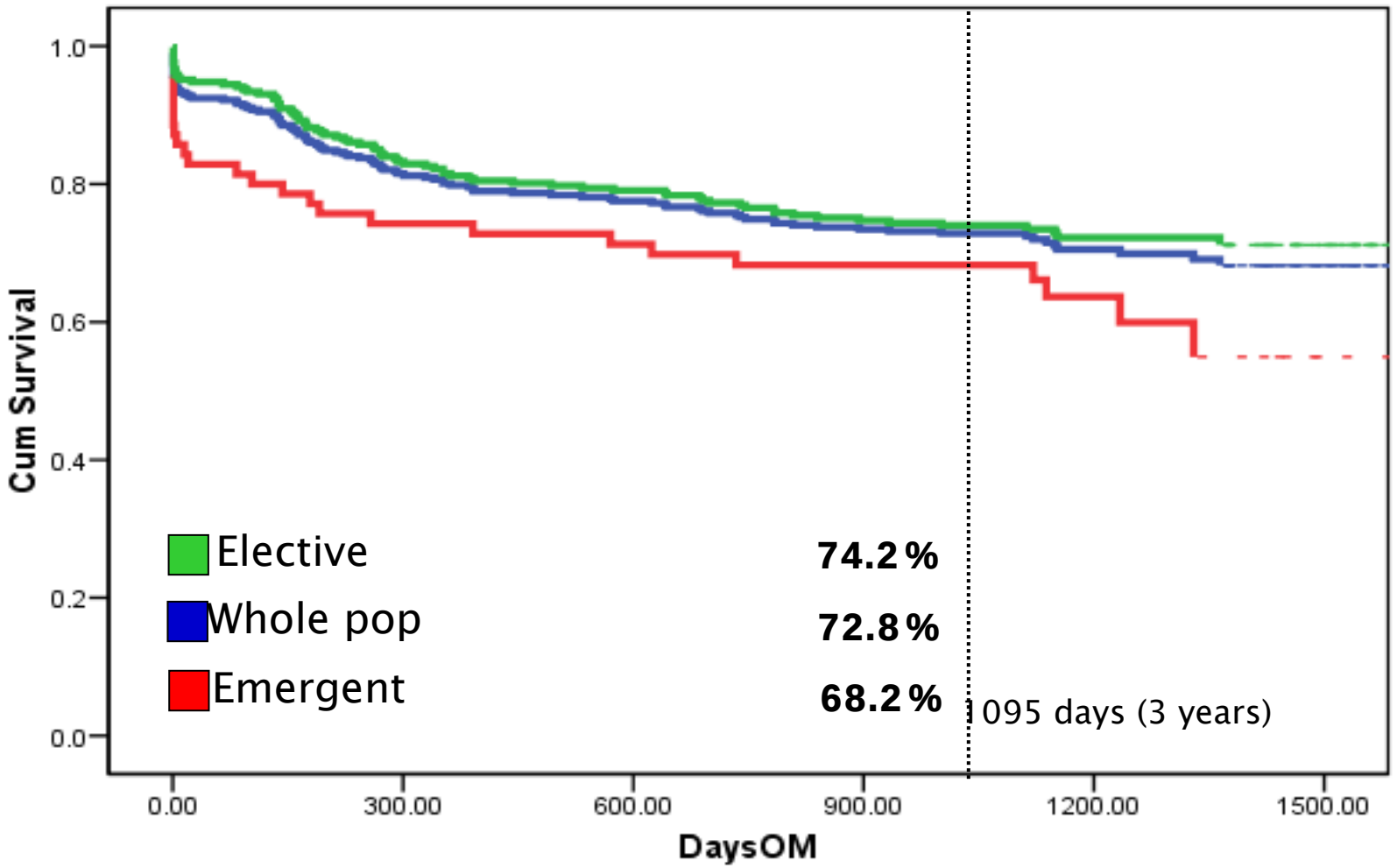
In terms of safety, definite ST rate was lower than in other high-risk lesion subsets.

J. Vermeer, View of Delft.

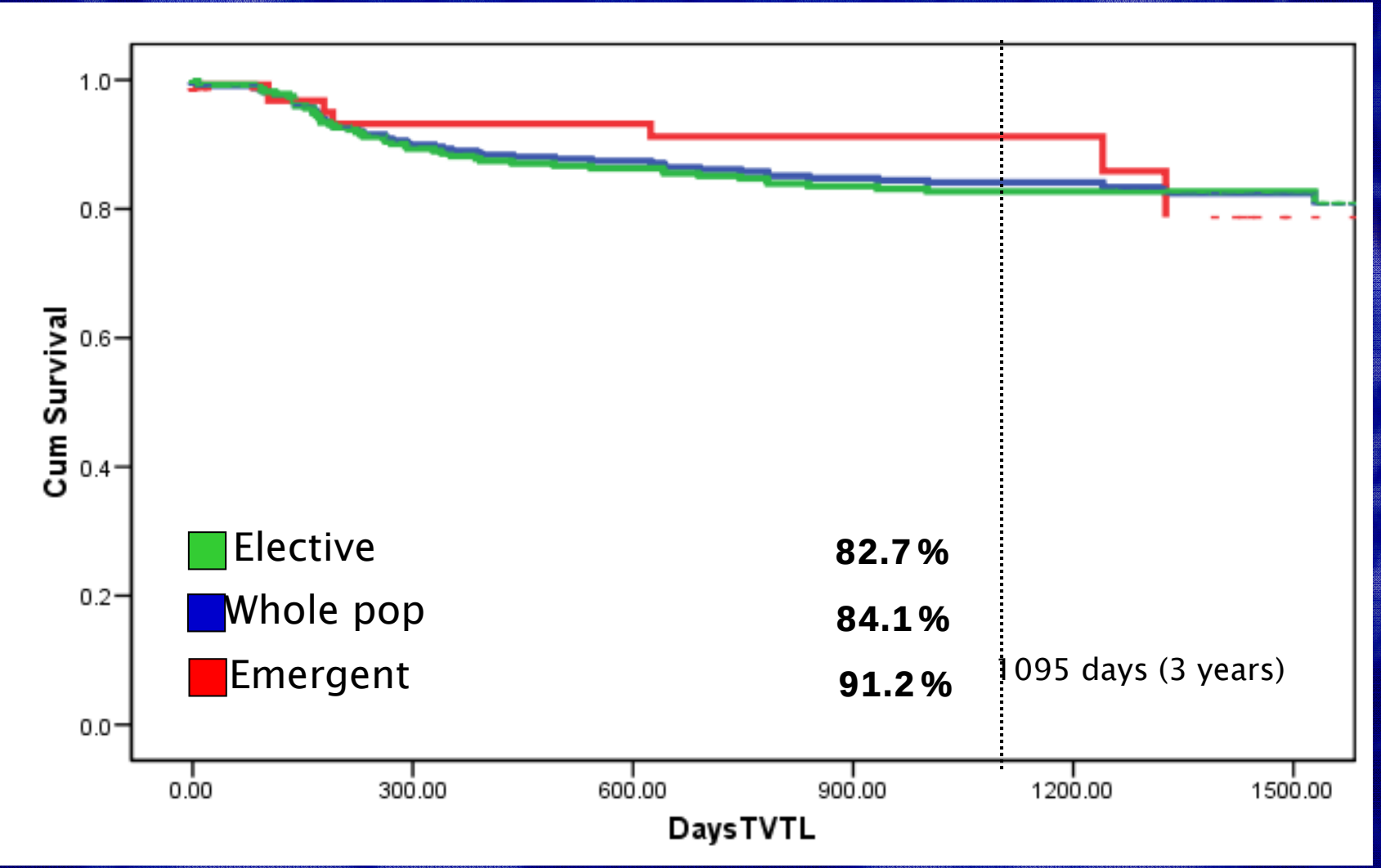
Demographic and angiographic variables relevant for the decision between CABG or PCI in MVD:

Insights from the SYNTAXstudy

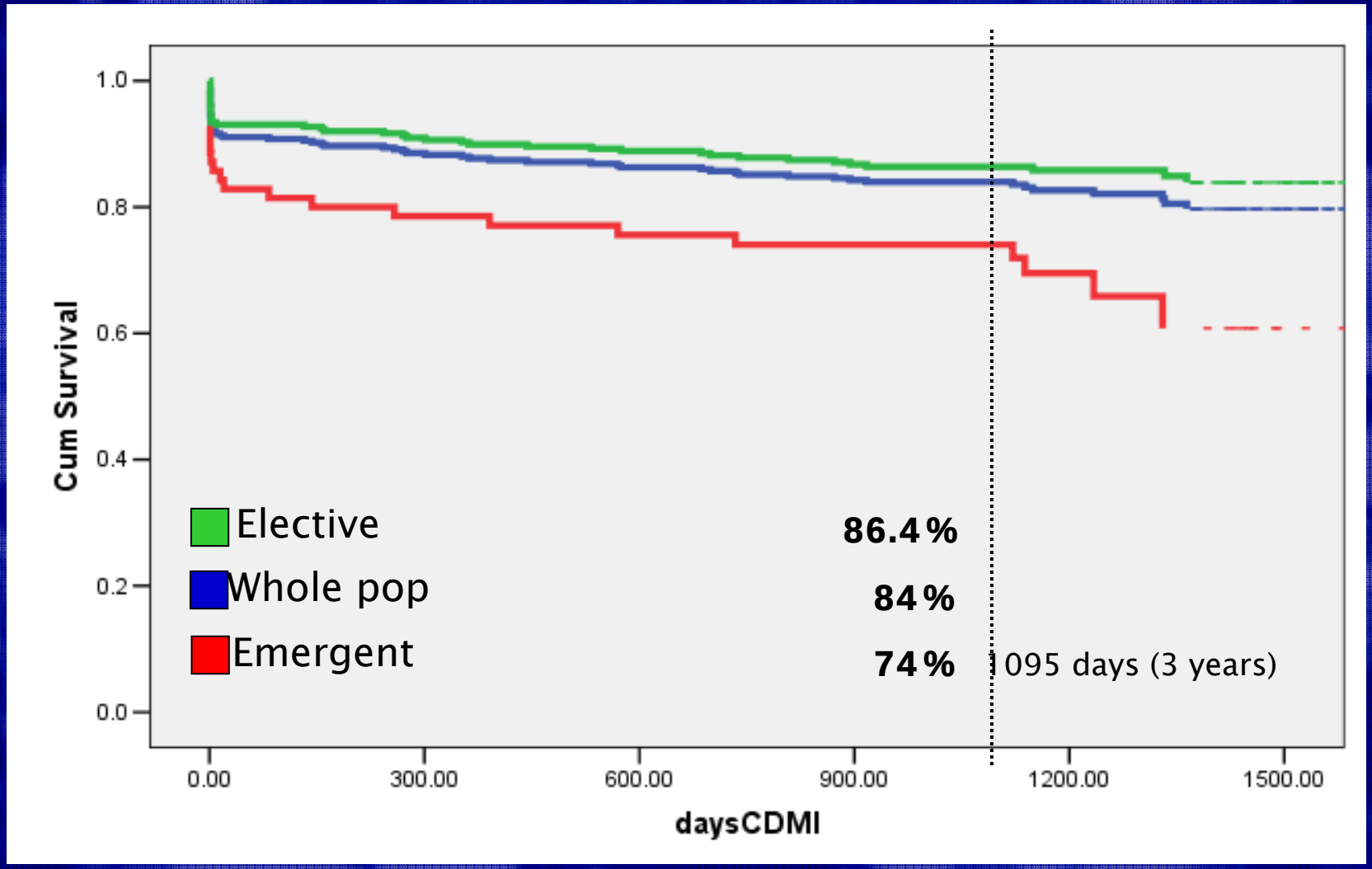
K-M survival analysis – MACE



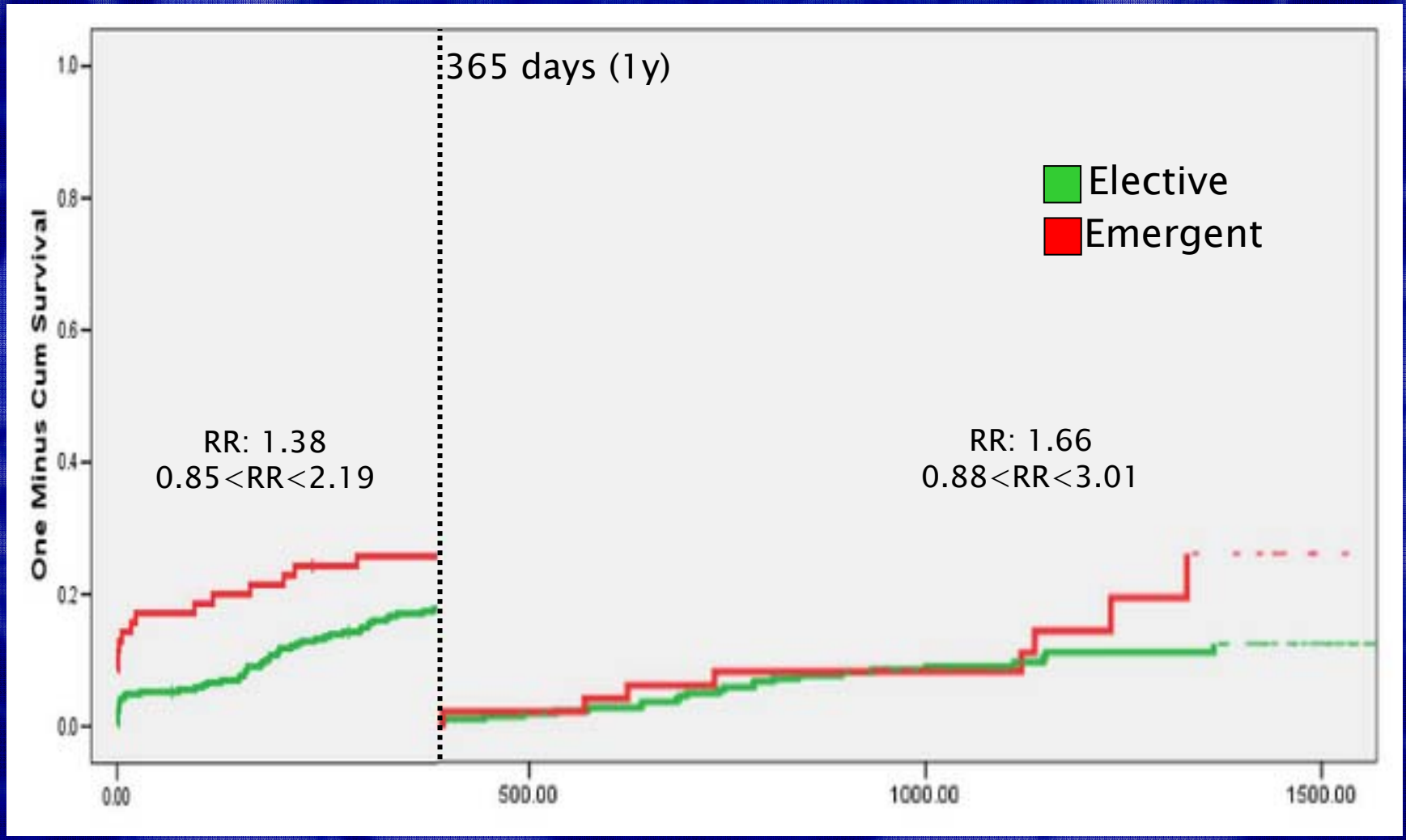
K-M survival analysis - TVR



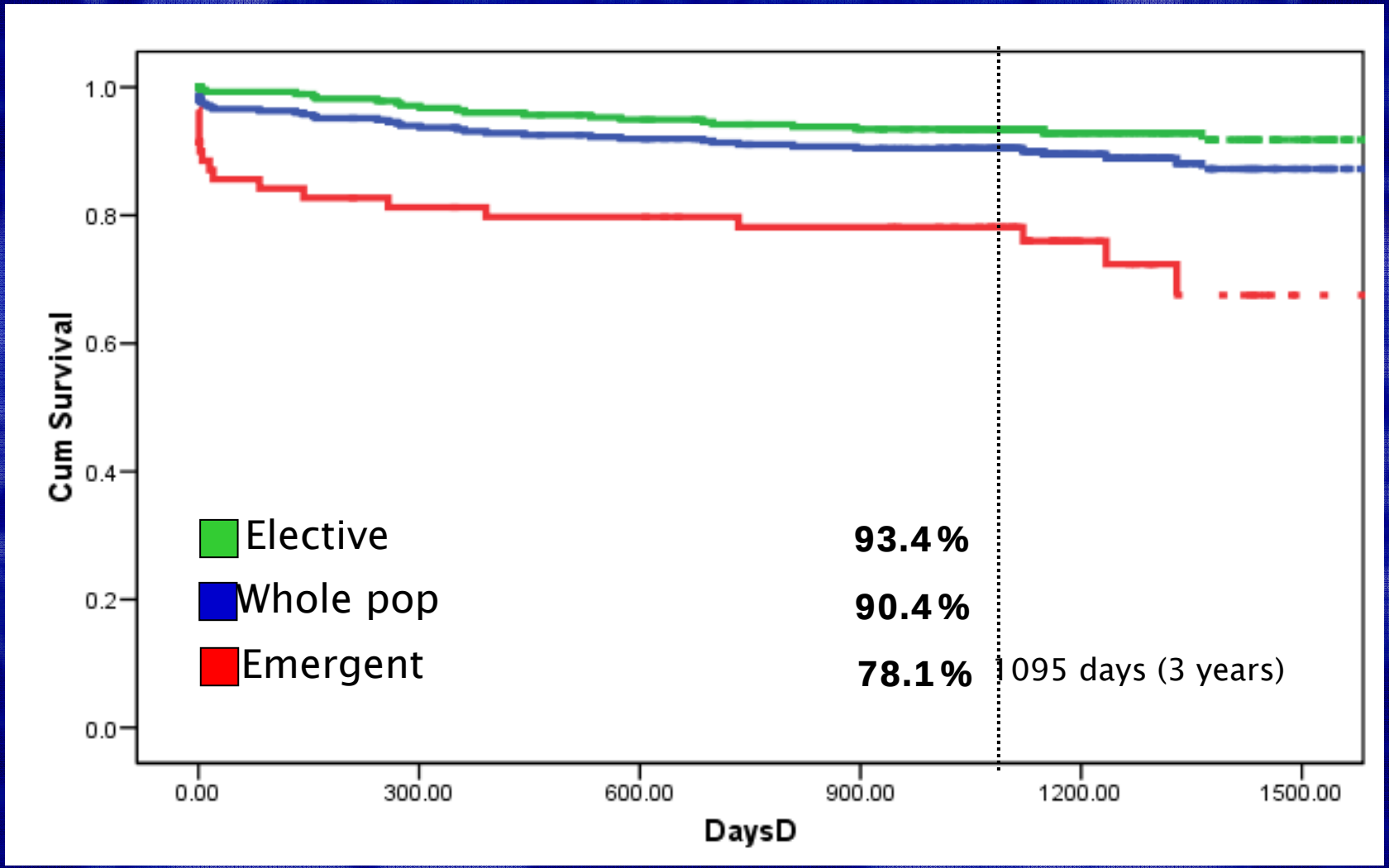
K-M survival analysis – Death + MI



Landmark analysis – MACE



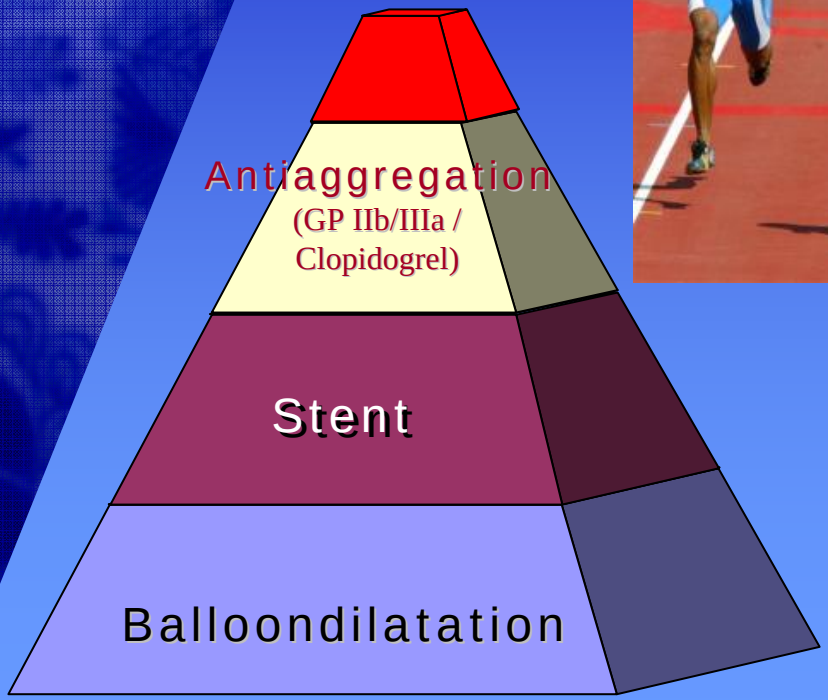
K-M survival analysis - Death

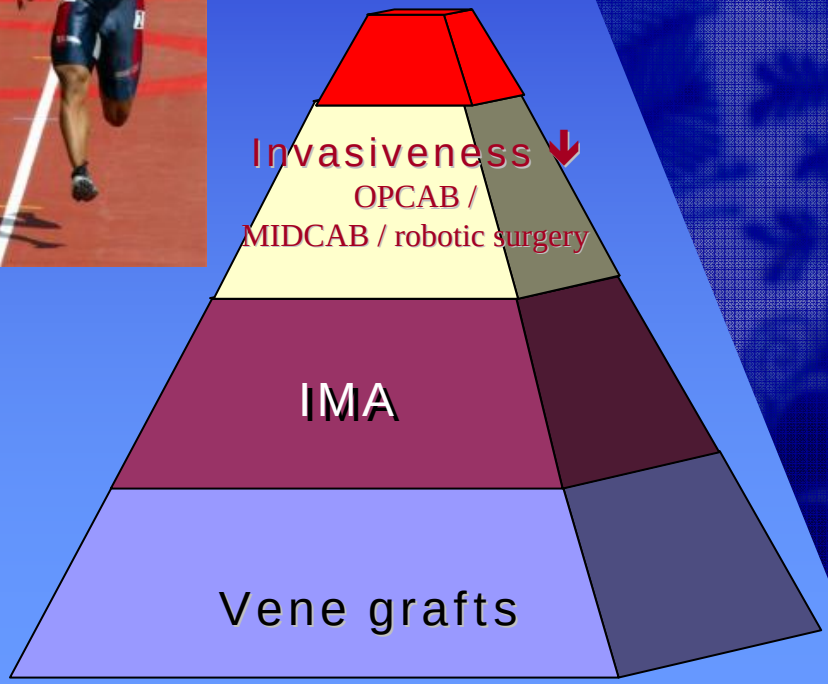


Evolution of revascularization

Drug Eluting stent

Complete arterial revascularization





Major Advisory Guidelines

CABG

- ACC/AHA Guidelines for Coronary Artery Bypass Graft Surgery
- Revised 1999
- Revised Nov 2004

PCI

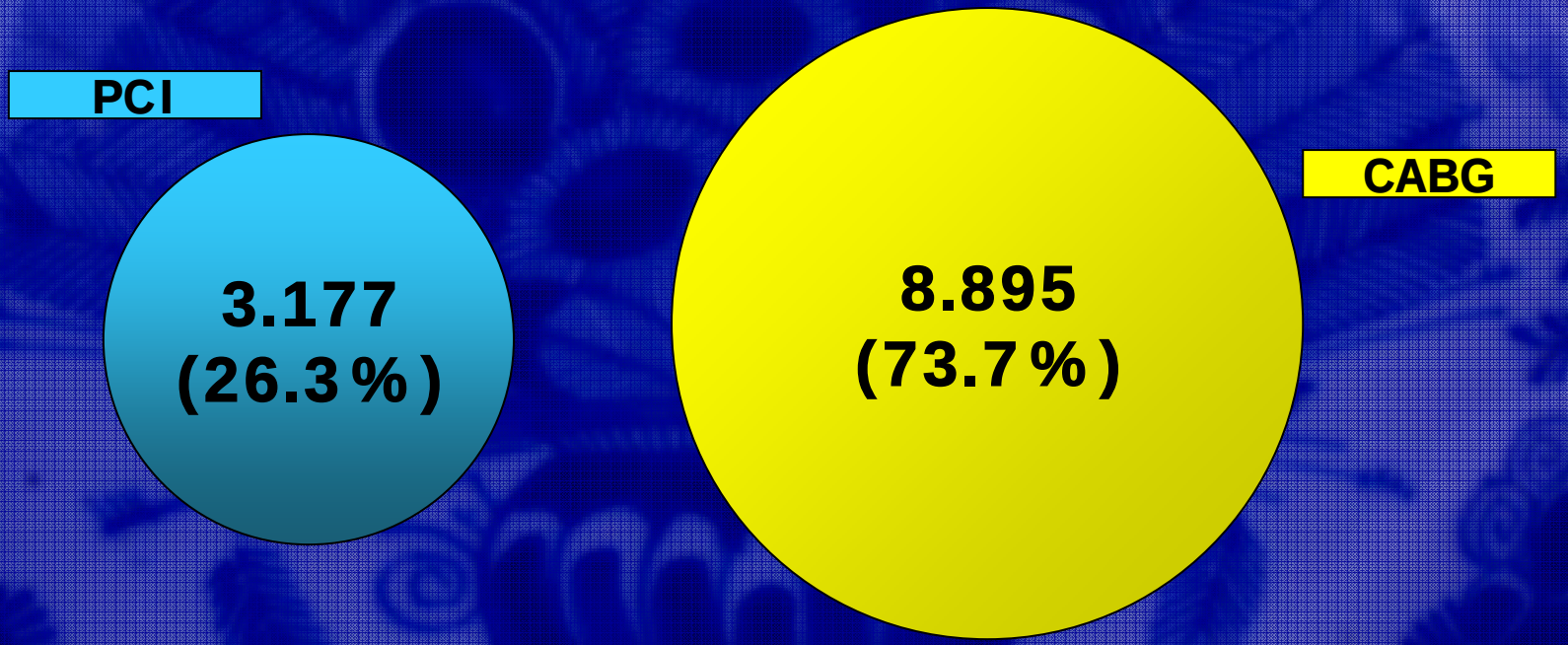
- ACC/AHA Guidelines for Percutaneous Coronary Interventions
- Revised 2005

1 Eagle KA et al. ACC/AHA guidelines for coronary artery bypass graft surgery: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1991 Guidelines for Coronary Artery Bypass Graft Surgery). J Am Coll Cardiol 1999;34:1262–346.

2 Smith SC et al. ACC/AHA guidelines for percutaneous coronary intervention: executive summary and recommendations: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). J Am Coll Cardiol 2001;37:2215–38.

Evolving “wild” DES PCI practice expansion to 3VD and LM

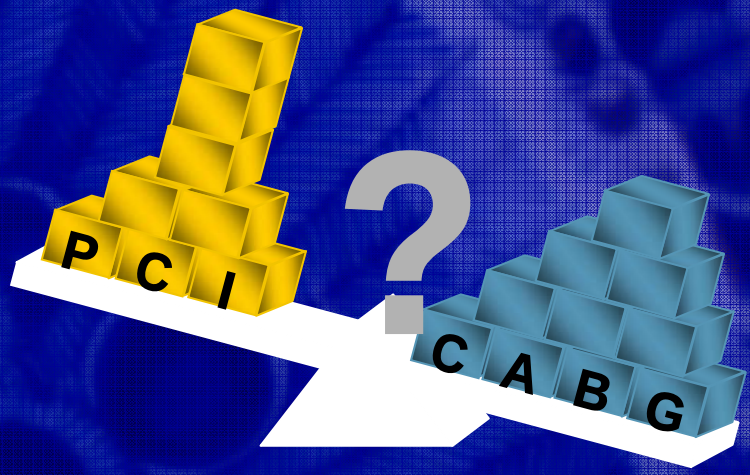
Total n=12.072 pts
104 sites in 2004



the current guidelines no longer reflect the current practice

Kappetein AP et al., EJCTS 2006

Syntax study purpose



- How does modern CABG compare to DES-PCI in high-risk patients eligible for both techniques ? *Randomized Trial*
- Which patient population continues to be solely eligible for CABG (CABG only) ? *CABG Registry*
- What characterizes high-risk patients not eligible for CABG (PCI only) ? *PCI Registry*

Syntax Trial

Question of optimal treatment approach?

Denovo disease

- **Isolated left main**
- **left main + 1-vessel disease**
- **left main + 2-vessel disease**
- **left main + 3-vessel disease**
- **3-vessel disease**

Revascularization in all 3 vascular territories

Exclusion criteria

- Previous interventions (PCI or CABG) excluded
- Acute MI with CK>2x ULN
- Concomitant cardiac surgery

Syntax-Study

All comers design for pts. with 3-VD/LM

Heart Team Conference (surgeon and interventionalist)

amenable for both treatment options

amenable for only one treatment approach

Randomized arm

N=1800 (1:1)

TAXUS *vs.* **CABG**

- **reasonable doubt**
- **Goal: to define the most appropriate treatment through randomized trial methods**

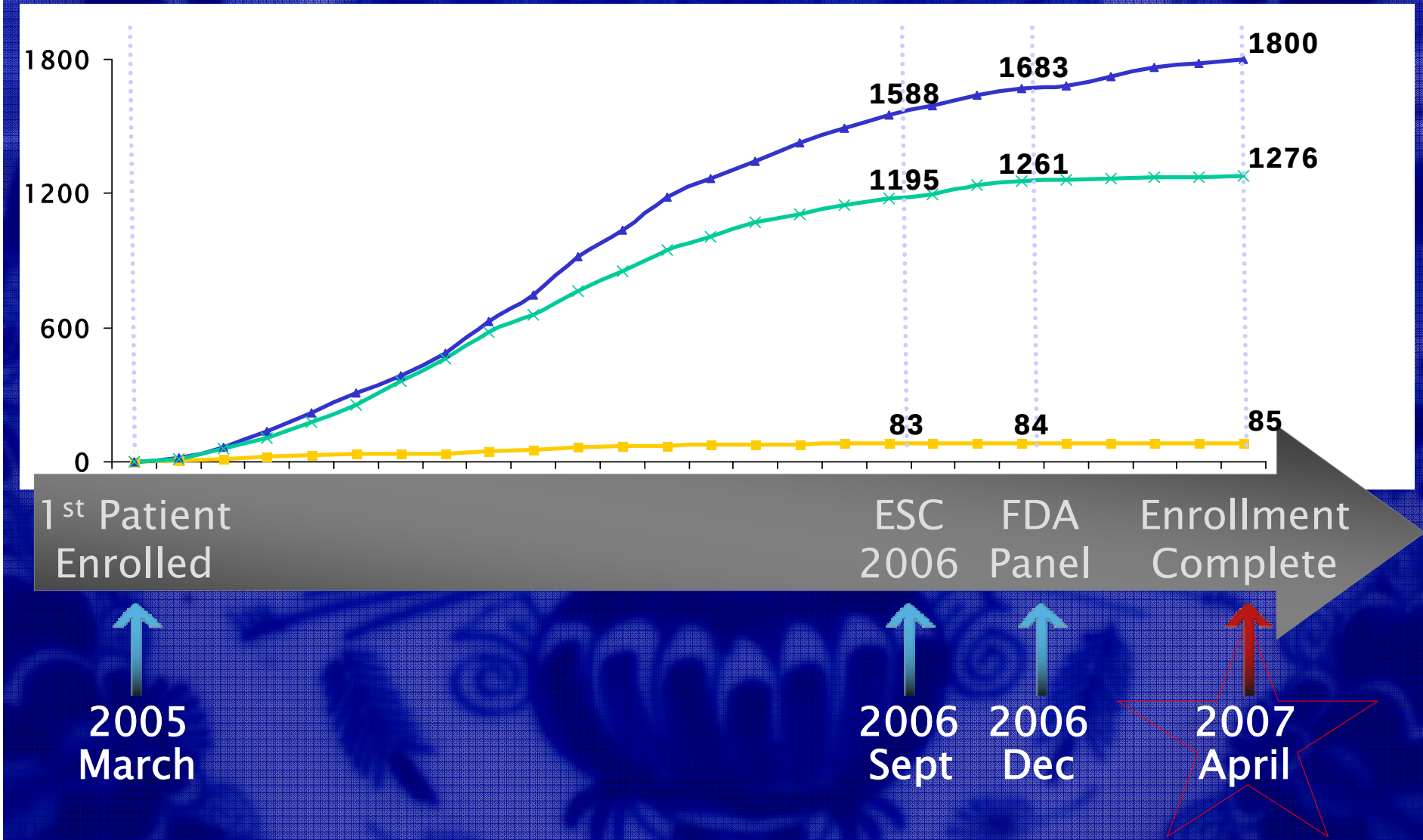
Two registry arms

CABG
All captured (900 followed)

PCI
All captured and followed

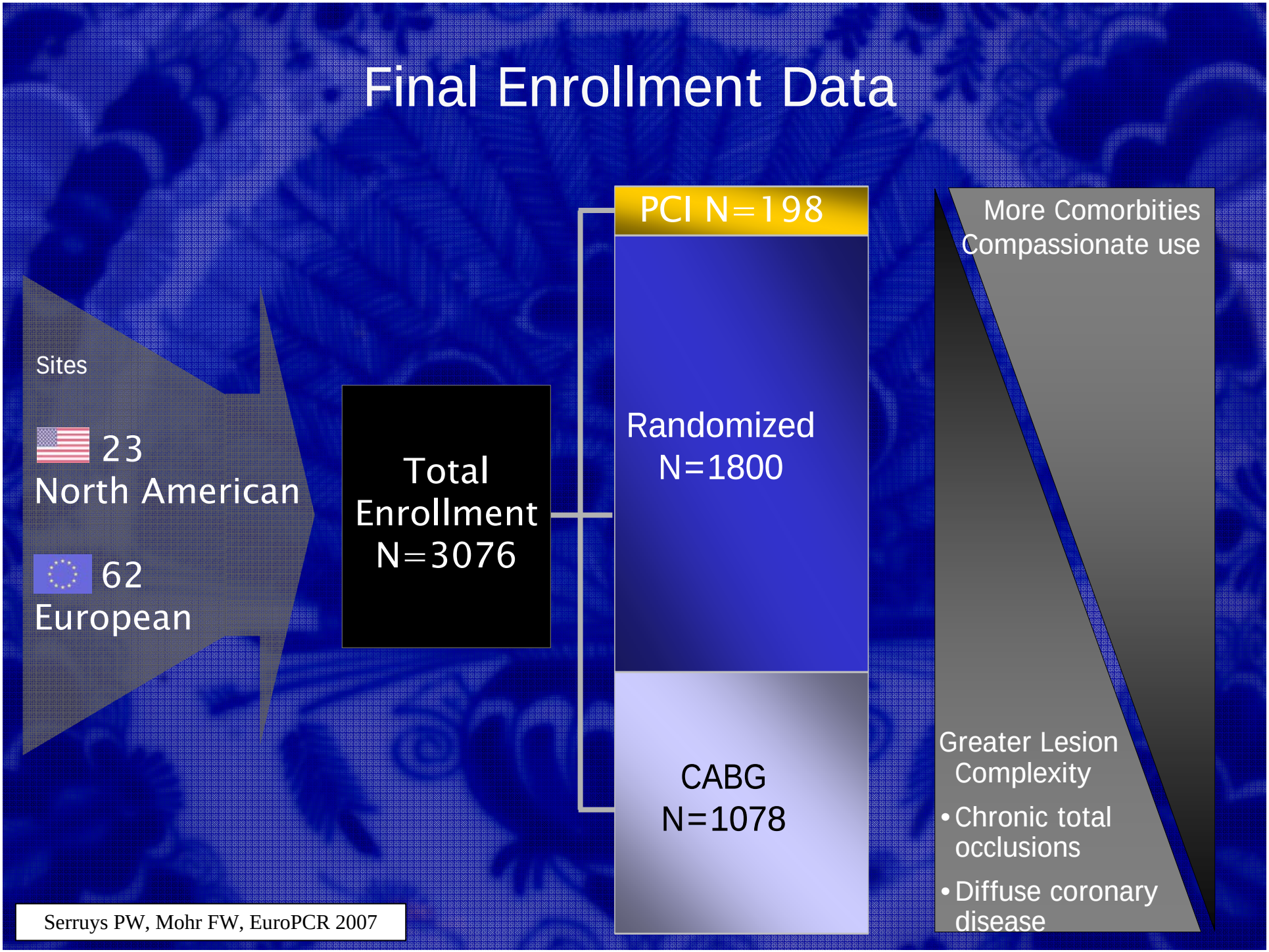
- **consensus that only one treatment option (CABG vs PCI) is appropriate**
- **Goal: to define the pool of non randomizable patients and their outcomes**

2-year SYNTAX enrollment



Serruys PW, Mohr FW, EuroPCR 2007

Final Enrollment Data



Serruys PW, Mohr FW, EuroPCR 2007

Syntax Trial
Endpoints - *Randomized cohorte*

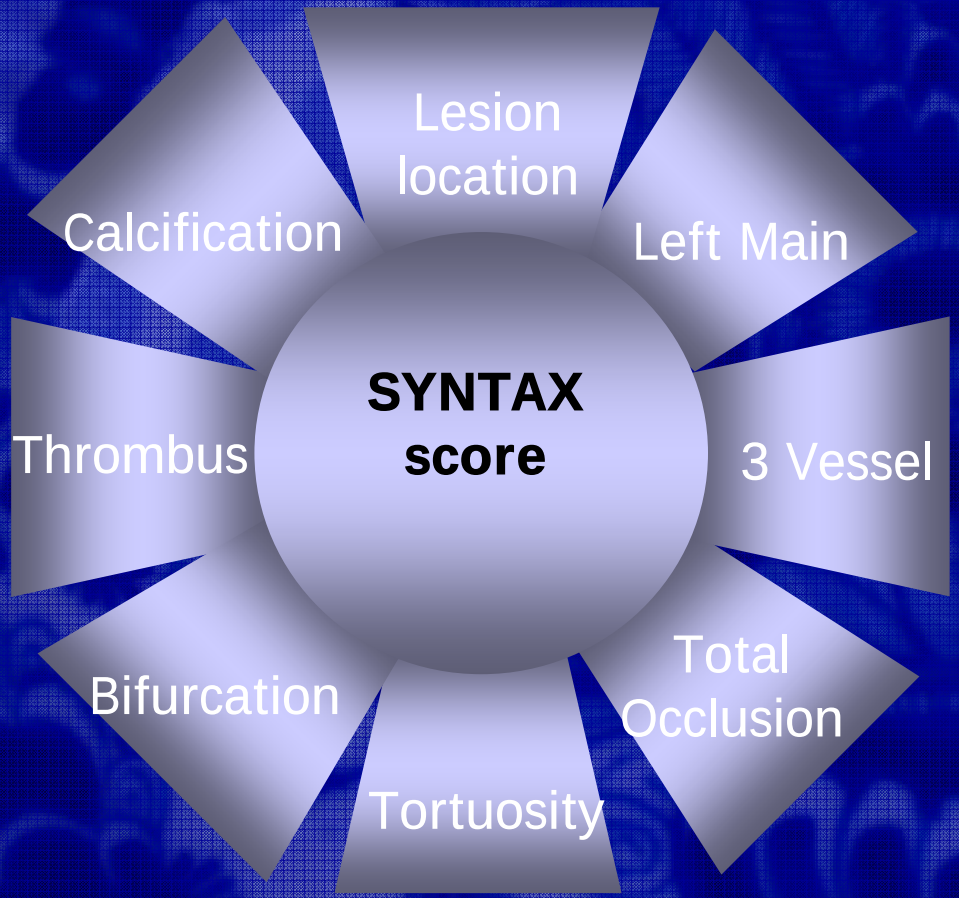
Primary:

- **MACCE rate at 12 months**

Secondary:

- **Overall MACCE rate at 1m post-procedure and at 6m, 3 and 5y post-allocation**
- **Rates of the individual components of MACCE at 1m post-procedure and at 6m, 1, 3, and 5y post-allocation**
- **Freedom from MACCE and its components at 1, 3 and 5y post-allocation**
- **Quality of life at 1m post-procedure and at 6m, 1, 3 and 5y post-allocation**
- **Cost and cost-effectiveness at 1, 3 and 5y post-allocation**

Coronary complexity index
SYNTAX score



- left or right dominance
- number of lesions
- Lumen reduction (<100%, 100%)
- Total occlusion

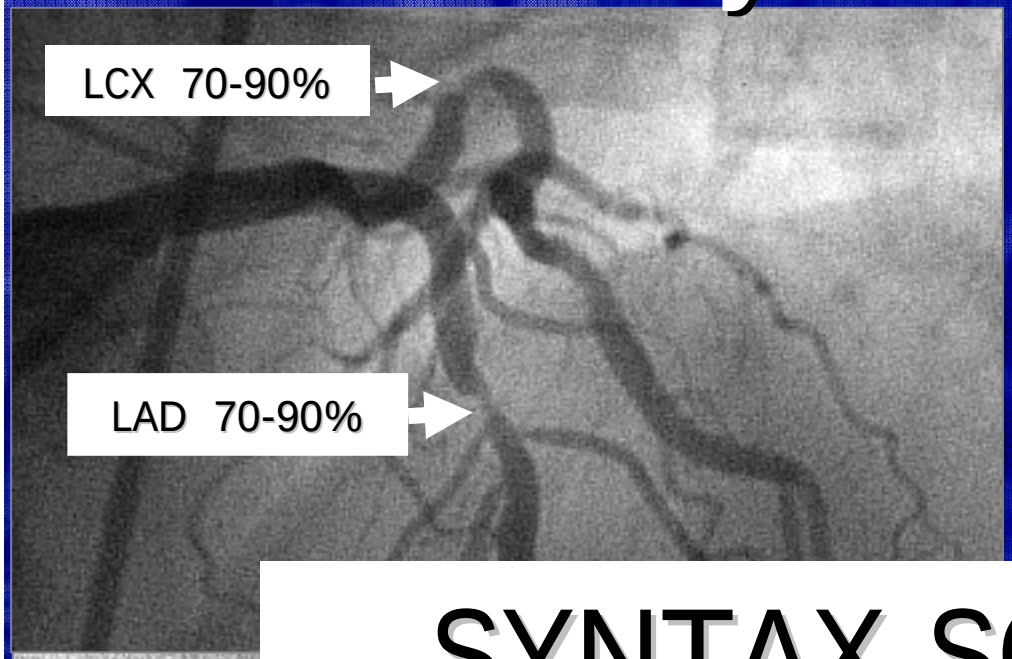
age > 3 months
side branches,
lesion length
collateralization
calcification

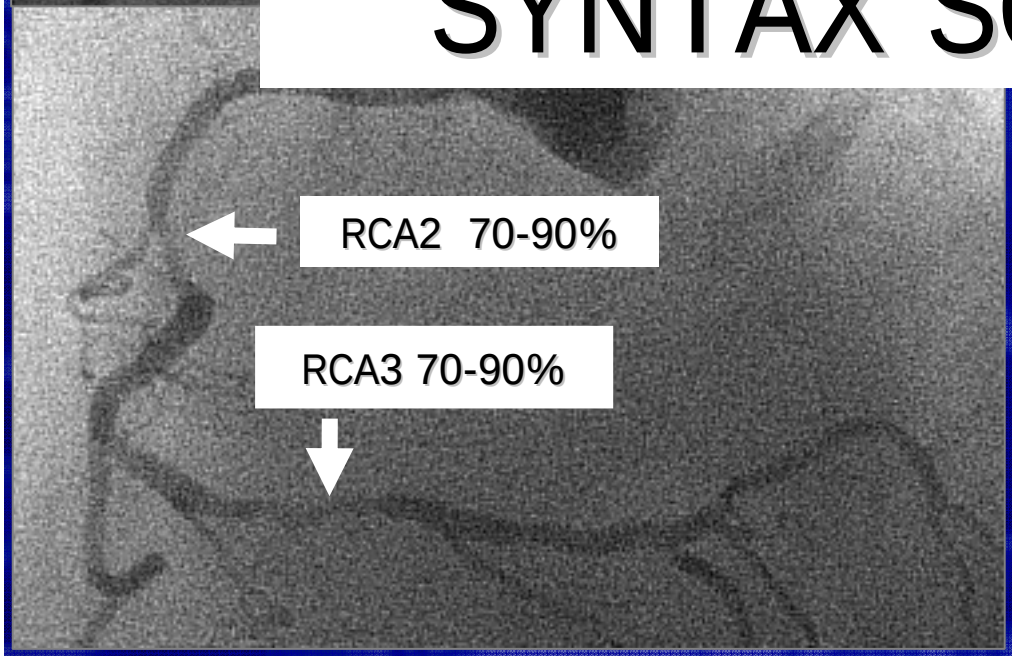
>20mm

- bifurcation
- ostial lesion
- tortuosity
- thrombus

Goal: SYNTAX score to provide guidance on optimal revascularization strategies for patients with high risk lesions

3 VD Syntax Score, pts. 1





SYNTAX SCORE 17

- **Right Dominance**
- **4 lesions**

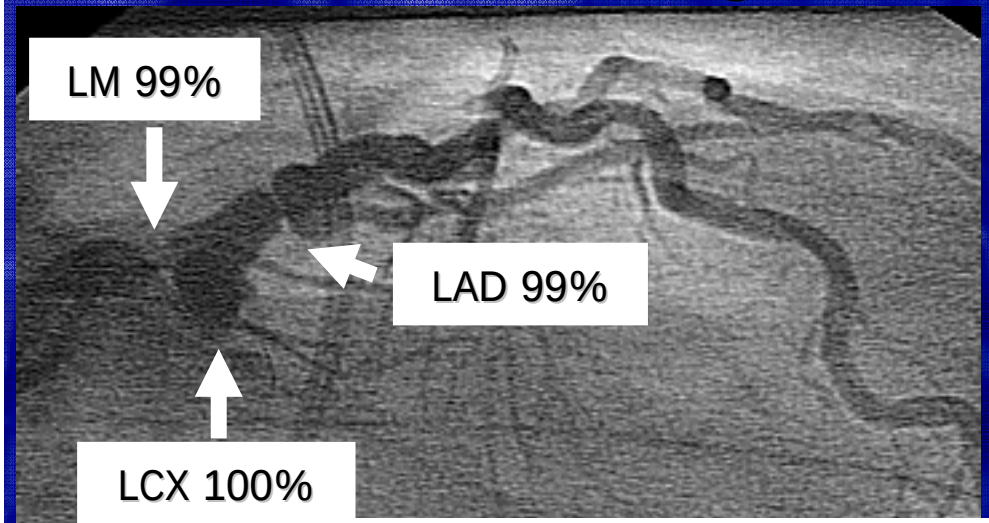
- **Lesion 1 involves segment numbers: 1, 2**

- **Lesion 3 involves segment numbers: 7**

- **Lesion 4 involves segment numbers: 13**

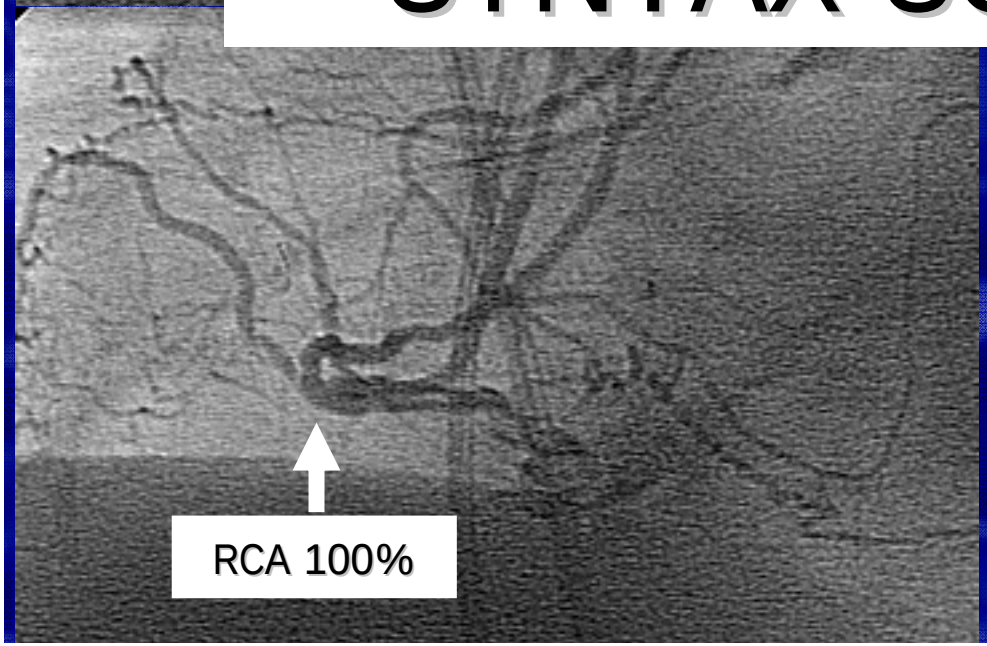
Sianos G et al., Eurointervention 2005

3 VD Syntax Score, pts. 2



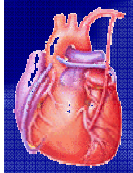
- Right Dominance
- 4 lesions

SYNTAX SCORE 54.5



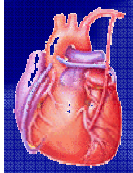
- Lesion 2 involves segment number: 5
- Lesion 3 involves segment number: 11 (total occlusion)
- Lesion 4 involves segment number: 6 (bifurcation)

Sianos G et al., Eurointervention 2005



Top Enrollers

	PCI Investigator	CABG Investigator	Randomized
	Didier Carrie	Gerard Fournial	50
	Patrick Serruys	Pieter Kappetein	48
	Tift Mann	William Killinger	47
	Marie-Claude Morice	Arnaud Farge	47
	Giulio Guagliumi	Paolo Ferrazzi	42
	Adrian Banning	Stephen Westaby	42
	Ezio Bramucci	Andrea d'Armini	41
	Keith G. Oldroyd	Geoff Berg	41
	Michael Aschermann	Jan Tosovsky	40
	Jacques Berland	Jean-Paul Bessou	40
	Gerhard Schuler	Friedrich Mohr	40
	Antonio Colombo	Lucia Torracca	40
	Andrejs Erglis	Romans Lacis	40
	Keith D. Dawkins	Steven Livesey	40
	Ivan G. Horvath	Lajos Papp	39

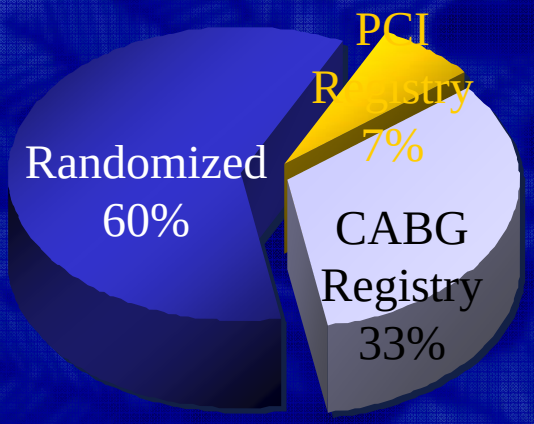


Top Enrollers Continued

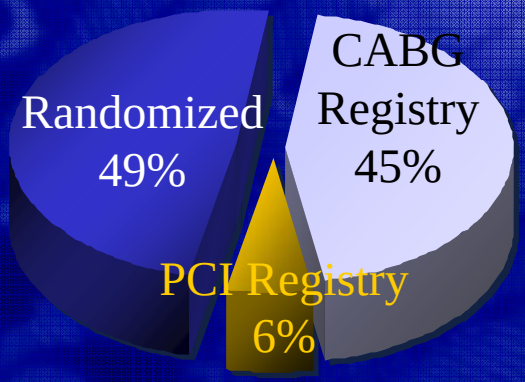
	PCI Investigator	CABG Investigator	Randomized
	Stefan James	Elisabeth Stahle	37
	Sergio Berti	Mattia Glauber	33
	Leif Thuesen	Per Nielsen Hostrup	32
	Jacques Koolen	Jacques Schonberger	32
	Janus Drzewiecki	Andrejs Bochenek	32
	Martyn Thomas	Jatin Desai	32
	Anthony H. Gershlick	Tomasz Spyt	32
	Adam De Belder	Andrew Forsyth	32
	Simon Redwood	Grahm Venn	32
	Peter Boekstegers	Bruno Reichart	31
	Thomas Meinertz	Hermann Reichenspurner	30
	Dietmar Glogar	Paul Simon	28
	Jean Marco	Patrick Soula	28
	Istvan Preda	Ferenc Tarr	28
	David L. Brown	Michael Mack	28

Enrollment Distribution

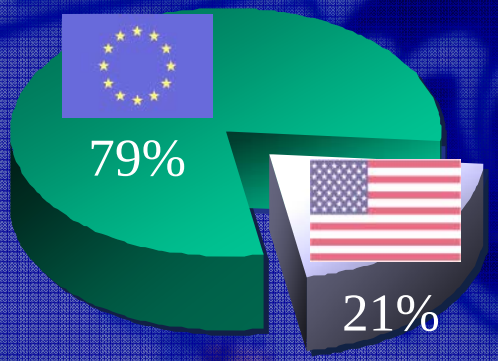
N=2579



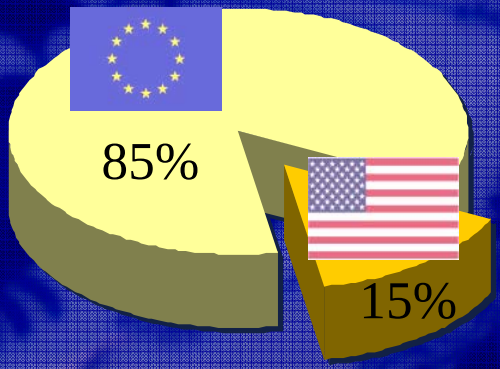
N=497



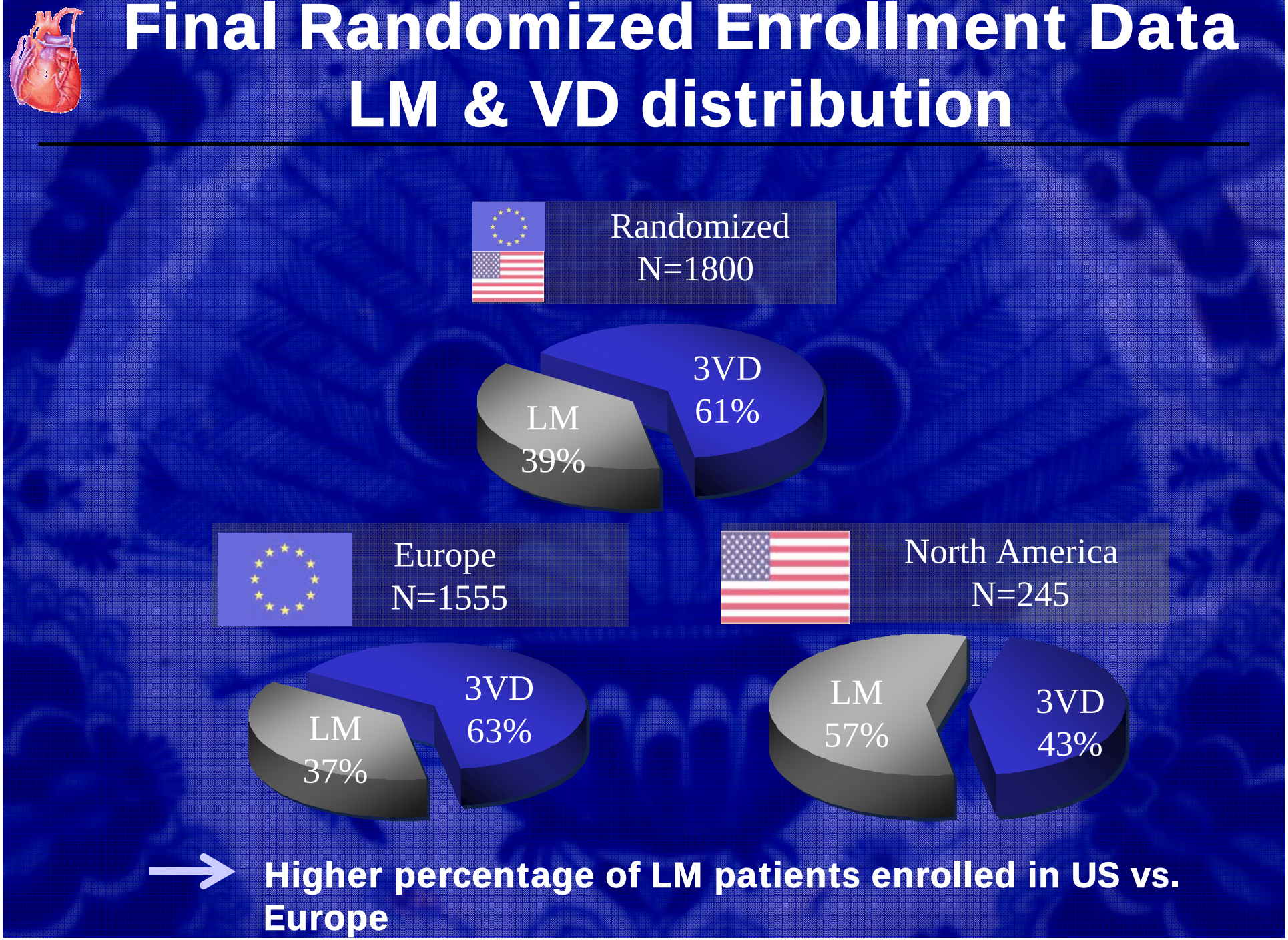
CABG Registry N=1077



PCI Registry N=198



Final Randomized Enrollment Data
LM & VD distribution



Higher percentage of LM patients enrolled in US vs. Europe

Single Centers Enrollment

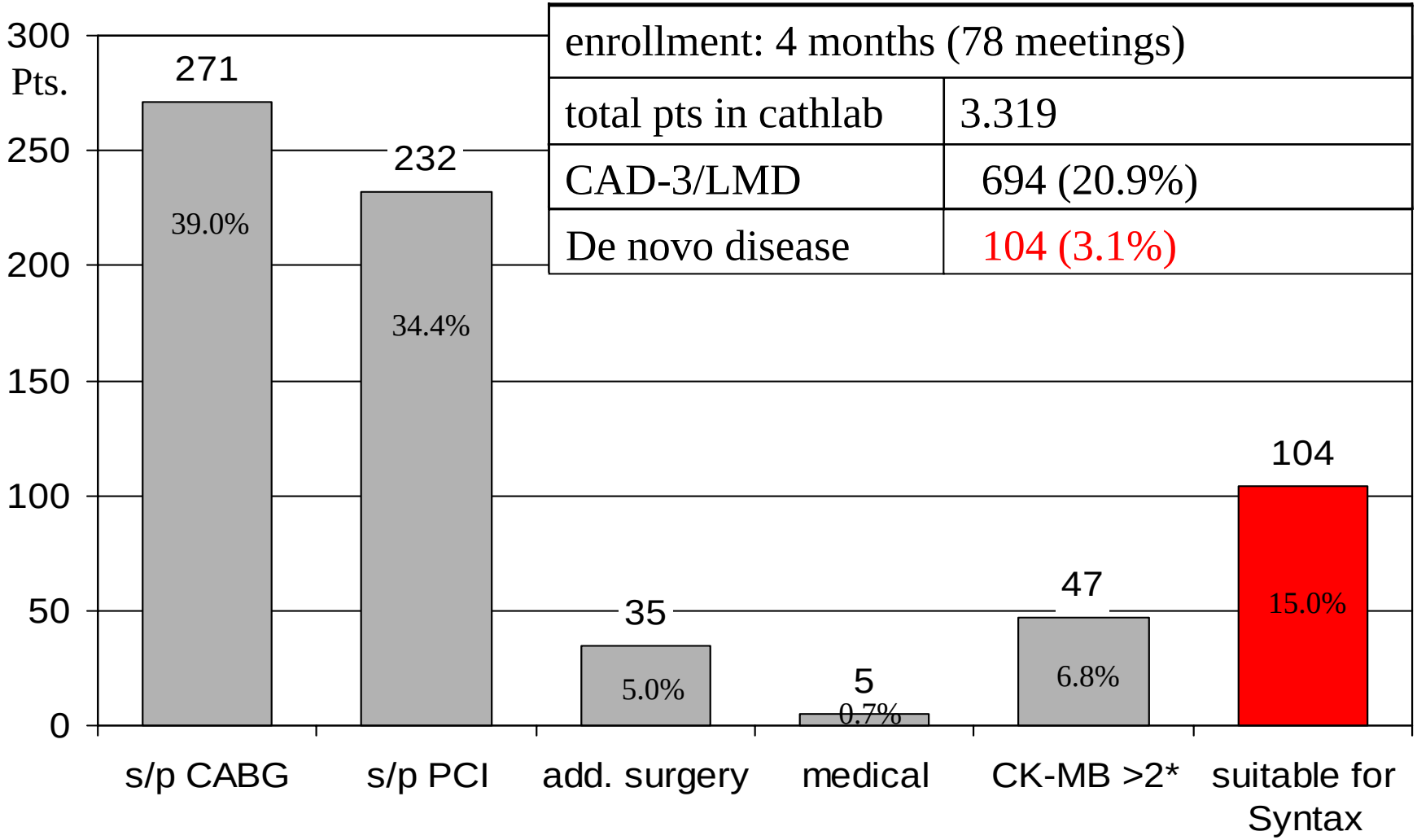
Prospective all comers evaluation with indication for cardiac catheterization during SYNTAX study enrollment.

Goals:

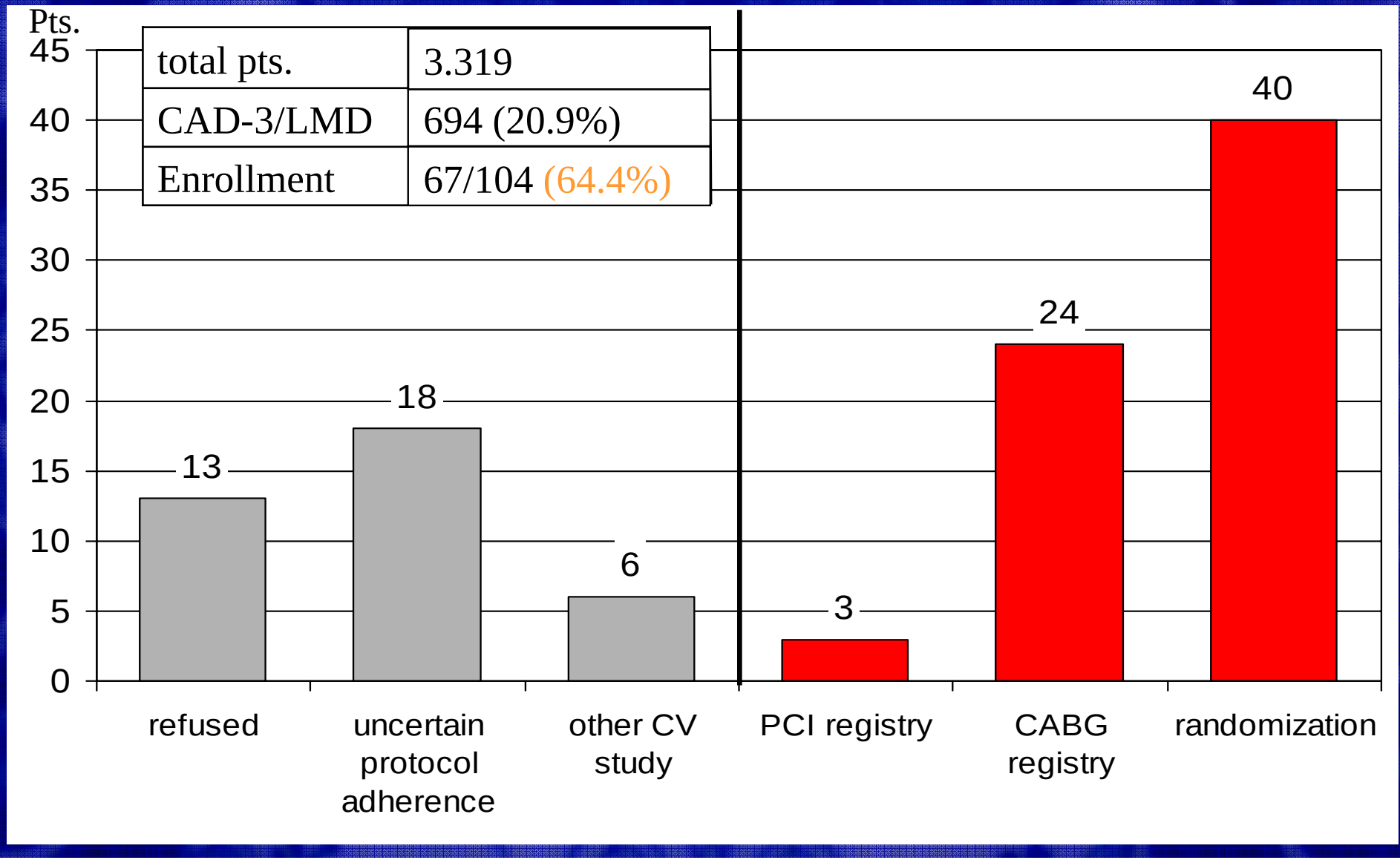
- To evaluate the incidence and study inclusion rate of denovo 3VD/LM in a supraregional cardiac catheterization unit.
- To identify coronary pathologies limiting randomization.

Enrollment results HZL

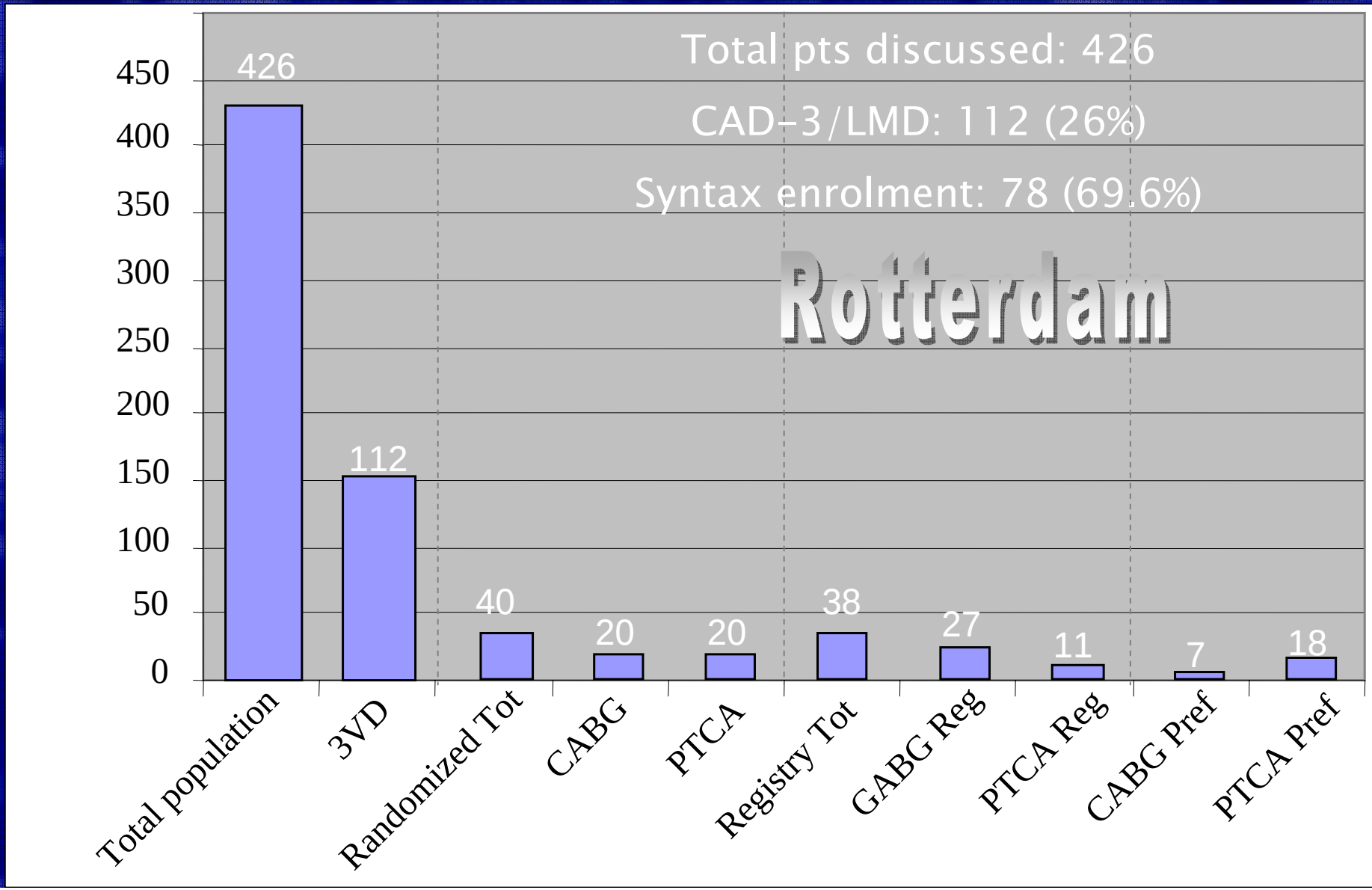
enrollment: 4 months (78 meetings)	
total pts in cathlab	3.319
CAD-3/LMD	694 (20.9%)
De novo disease	104 (3.1%)

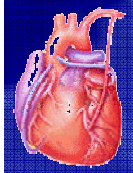


Heart Team Conference HZL



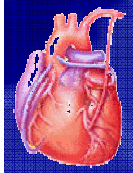
Heart Team Conference





Cut-off / assumptions

- Based on info Leipzig and Rotterdam:
  - 75% pts pre CABG/PCI => 25% cut-off



All Comers Design

	Institution	run in	Expected run in	actual	% of expected actual in trial
		(Pts/M)	(Pts/M)	(Pts/M)	(%)
	1	47	12	10	85%
	2	95	24	17	71%
	3	36	9	4	44%
	4	46	11	9	82%
	5	15	4	2	50%
	6	41	10	7	70%
	7	27	7	5	74%
	8	21	5	1	20%
	9	30	8	1	13%
	10	22	5	3	56%

CABG vs. PCI studies

without Stents / *with Stents* •Trial	•Original Pool	•Screen 1: Clinical Criteria	•Screen 2: Physician Agreement	•Screen 3: Patient Consent	•Randomized	•% Original Pool Randomized
•GABI	•8981	•531		•359	•359	• 4.0 %
•EAST	•5118	•1033	•842	•392	•392	• 7.7 %
•RITA	•27,975	•1011			•1011	• 3.6 %
•ERACI	•1409	•302		•127	•127	• 9.0 %
•CABRI	•42,580	•23,047			•1052	• 2.7 %
•BARI	•25,200	•4100			•1829	• 7.3 %
•MASS-2	•2076	•611			•611	• 7.3 %
•AWESOME	•22,621	•2431	•781	•454	•454	• 2.0 %
•ERACI-2	•5619	•1076		•450	•450	• 8.0 %
•SoS	•~17-30K	•n/a			•998	• ~3-6 %
•ARTS	•~30,000	•n/a			• 1205	• ~ 4 %

Syntax Study randomization 40/104=38.5%

Randomized cohort vs. CABG Registry Baseline data HZL

	Randomized n=40	CABG Registry n=24
Age (y)	68.5 (46-83)	69.5 (53-84)
add EuroScore	4.6	5.0
Ejection fraction	55.2 %	47.4 %
LM disease	47.5 %	41.7 %
Lesions/pt.	4.6 (1-9)	5.3 (4-8)
Syntax Score	**25.5 (11-45)**	**34.5 (22-56) ***
LAD occlusion	5.0 %	16.7 % *
Cx occlusion	5.0 %	29.2 % *
RCA occlusion	20.0 %	41.7 % *

* $p<0.05$

PCI vs. CABG randomized pts. Baseline data HZL

	Taxus PCI (n=21)	CABG (n=19)
Age (y)	69.7	67.2
add EuroScore	**5.0**	**4.1**
Ejection fraction	57.8 %	52.4 %
Syntax Score	**24.0**	**27.2**
Lesions /pt.	4.5	4.6
LM disease	42.9 %	52.6 %
LAD occlusion	4.8 %	5.3 %
Cx occlusion	4.8 %	5.3 %
RCA occlusion	19.0 %	21.1 %
Abd. girth (cm)	99.0	106.0

n.s.

PCI vs. CABG randomized patients Treatment HZL

	Taxus PCI (n=21)	CABG (n=19)
Δt randomization/therapy (d)	1.4 (1-4)	4.5 (1-15) *
CABG		
BIMA		**52.6 %**
Radial Artery		42.1 %
Complete art. grafting		**58.8 %**
OPCAB		63.2 %
grafts /pts.		3.3 (2-5)
PCI		
staged procedure	**23.8 %**	
stents /pts.	6.0 (1-11)	
Grafts or stents /lesion	1.4 (0.8-3.0)	0.8 (0.4-1.0)
Complete revascularization	**100 %**	**100 %**
Hospital stay (d) post	6.1	12.4 *
Hospital stay > 14 d post	9.5 %	31.6 % *

* $p<0.05$

CABG Registry - Treatment

	CABG (n=24)
7 Surgeons	
BIMA	58.3%
Radial artery	41.7%
Complete arterial grafting	66.7%
OPCAB	66.7%
Grafts /pts.	3.3
Graft /lesion	0.7 (0.3-1.0)
Complete revasc.	100%
Hospital stay (d) post	12.1 d
Hospital stay > 14d post	12.5%

Events (pts.) HZL

	Randomized cohort		Registry	
	PCI n=21	CABG n=19	CABG n=24	PCI n=3
MACCE	1	2	0	1
Death	0	0		1
Myocardial infarction	0	0		
Cerebrovascular event	0	1		
Repeated revasc.	1	1		
Serious adverse events	7	6	4	2
Serious ad. device events	1	-	-	1
Adverse events	7	11	12	1

Lesion and Patient Complexity
Randomized vs. Registry Cohorts

		Randomized N=1800	CABG Registry N=649	PCI Registry N=198
Patient	3 Vessel Disease (%)	60.6%	54.5%	65.2%
	LM (%)	39.4%	45.5%	34.8%
	Diabetics (%)	24.6%	29.4%	35.5%
PCI	Bifurcation (% pts)*	62.7%	n/a	58.6%
	Total Occlusion (% pts)*	27.2%	n/a	39.6%
	Total stent length >100mm (% pts)	34.2%	n/a	11.2%
	Number of stents (per pt)	4.7	n/a	3.1
CABG	Arterial grafts (%)	94.9%	91.5%	n/a
	Complete arterial revascularization (%)	18.6%	12.5%	n/a
	Double IMA grafts (%)	26.9%	16.0%	n/a
	Conduits used to LAD (%)	95.2%	92.5%	n/a

Data is site reported. *Based on baseline SYNTAX score

Conclusions

- 3-CAD/LM disease represented 20% of all patients in a superregional cardiac catheterization unit.
- 15% of them, i.e. 3.1% of all, were candidates for Syntax study enrollment presenting denovo disease without study exclusion criteria.
- Study inclusion rate was 64.4%, randomization 38.5% of all screened pts.
- Chronic total vessel occlusion associated with higher Syntax Score was the major pathology limiting randomization.

Randomized Cohort

	PCI n=21		CABG n=19	
MACCE	1 # 1	stent thrombosis PLA	2 # 1 # 2	stroke (preoperative !) postop LCO - repeated revascularization

Randomized Cohort

	PCI n=21		CABG n=19	
SAEs	13/7		7/6	
	# 1	stent thrombosis	# 1	groin bleeding (pre-op)
	# 2	groin bleeding	# 2	AV-II/III block (ICD impl.)
	# 3	cath site infection, bradycardia	# 3	sternal wound infection
			# 4	ventricular tachycardia
	# 4	renal insufficiency, erysipela		ICD pocket hematoma
			# 5	transitional syndrome
	# 5	angina CCS II, cath site infection	# 6	acute renal failure
	# 6	acute renal failure		
	# 7	acute renal failure, venous thrombosis, cath site infection,		
	33.3%	groin bleeding	31.6%	

Randomized Cohort

	PCI n=15		CABG n=17	
AEs	9/6		21/11	
	# 1	acute ischuria	# 1	local wound infection, muscle pain
	# 2	angina-equivalent	# 2	transient AV-block, fever, hypertension
	# 3	nausea, wound infection	# 3	pleural effusion
	# 4	Claudicatio intermittens ↓	# 4	AFib, pleural effusion, hematuria
			# 5	collapse, anaemia, pleura effusion
	# 5	renal dysfunction ↓	# 6	dysphonia, anaemia, hematuria
	# 6	hyponatriaemia, exanthem,anaemia	# 7	pleural effusion
			# 8	epiglottitis
			# 9	AFib
			# 10	pleural effusion
			# 11	intestinal atony, transitional syndrome
	40.0%		64.7%	

CABG registry
Perioperative adverse events

	CABG Registry n=24 (12* Follow-Up)	
MACCE	0	
SAEs	4 pts. (16.7%) Pt. # 1 Pt. # 2 Pt. # 3 Pt. # 4	 transitional syndrome, AFib,hematothorax laryngitis, sepsis hematothorax LCO (IABP), transitional syndrome

CABG registry

	CABG Registry n=24	
AEs	12 pts. (50.0%)	
	# 1	atrial fibrillation
	# 2	pleural effusion, anaemia
	# 3	minor sternal instability (conservative)
	# 4	atrial fibrillation
	# 5	atrial fibrillation
	# 6	atrial fibrillation
	# 7	pleural effusion, pneumothorax
	# 8	pleural effusion
	# 9	pneumothorax
	# 10	recurrent fever (unclear)
	# 11	syncope of unclear reason
	# 12	acute ischuria, pneumothorax

Syntax overall study results

For patients with denovo 3VD and/or LM disease:

1) will define those patients best treated by CABG

2) will define those patients maybe/can be treated by PCI

3) define best technical strategies in surgery and PCI

4) Le Mans results will focus on LM

One year results maybe similar outcome, but if not?

Syntax Trial
Inclusion Criteria

- 3 vessel disease and/or left main disease
- Total occlusion without time limitation
- Previous cerebrovascular events >1 months
- Renal and respiratory insufficiency
- Decreased pump function
- Myocardial ischemia (unstable-silent-stable)
- Patients with cardiac or extra-cardiac comorbidities

Real world patient population

Syntax-Trial Exclusion Criteria

- Prior CABG or PCI procedure
- AMI with CK (>2xCK upper limit of normal)
- Planned need for major surgery
- Age < 21
- Uncertainty study adherence
- Pregnancy

Limited exclusion criteria to ensure real-world patient population

The Syntax-Score includes:

- BARI classification of the coronary tree segments modified for the ARTS study (*Semin Interv Cardiol. 1999 Dec;4(4):209-19)*.
- Modified Leaman score (*Circulation 1981; 63(2): 285-292).*
- ACC/AHA lesions classification system *(Circulation, 2001;103:3019-3041).*
- Combination of the Duke and ICPS classification of Bifurcation *(Cathet. Cardiovasc. Intervent, 2000; 49:274-283)*
- Total occlusion classification *(JACC,1997;30:649-56*