



Seoul, Korea: 25-27 April 2007

Plenary Session: State-of-the-Art Lectures

The problem is exaggerated:
Data from "Real World" Registries

15 min

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Research Letters

Late thrombosis in drug-eluting coronary stents after discontinuation of antiplatelet therapy

Eugène P McFadden, Eugenio Stabile, Evelyn Regar, Edouard Cheneau, Andrew T L Ong, Timothy Kinnaird, William O Suddath, Neil J Weissman, Rebecca Torguson, Kenneth M Kent, August D Pichard, Lowell F Satler, Ron Waksman, Patrick W Serruys



Lancet 2004; 364: 1519-21

See [Comment](#) page 1466

4 cases (2 SES and 2 PES) of thrombosis after 300 days



Iakovou et al. JAMA 2005: 9 months FU- SAT 1 months

2229 patients after successful DES implantation
6 month FU available for all patients

Cypher
1062 patients



TAXUS
1167 patients

SAT
4 (0.4%)

LST
5 (0.5%)

P=0.5

P=0.3

SAT
9 (0.8%)

LST
9 (0.8%)

10.2 ± 4.4 m

Cypher

Total : 9 (0.9%)

9.3 ± 5.6 months

Total DES 27/2229 (1.2%)

P=0.2

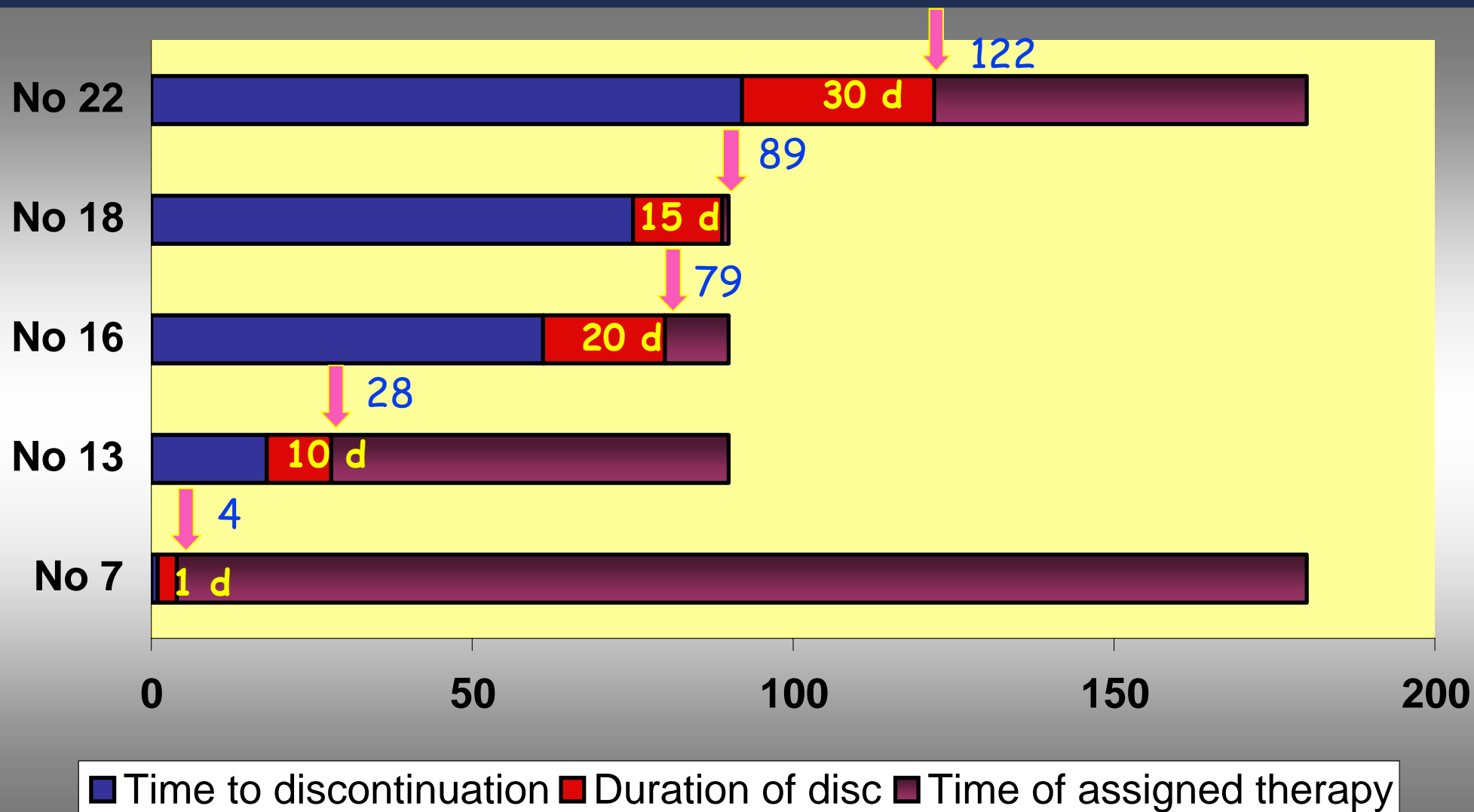
7.9 ± 3.6 m

TAXUS

Total: 18 (1.5%)

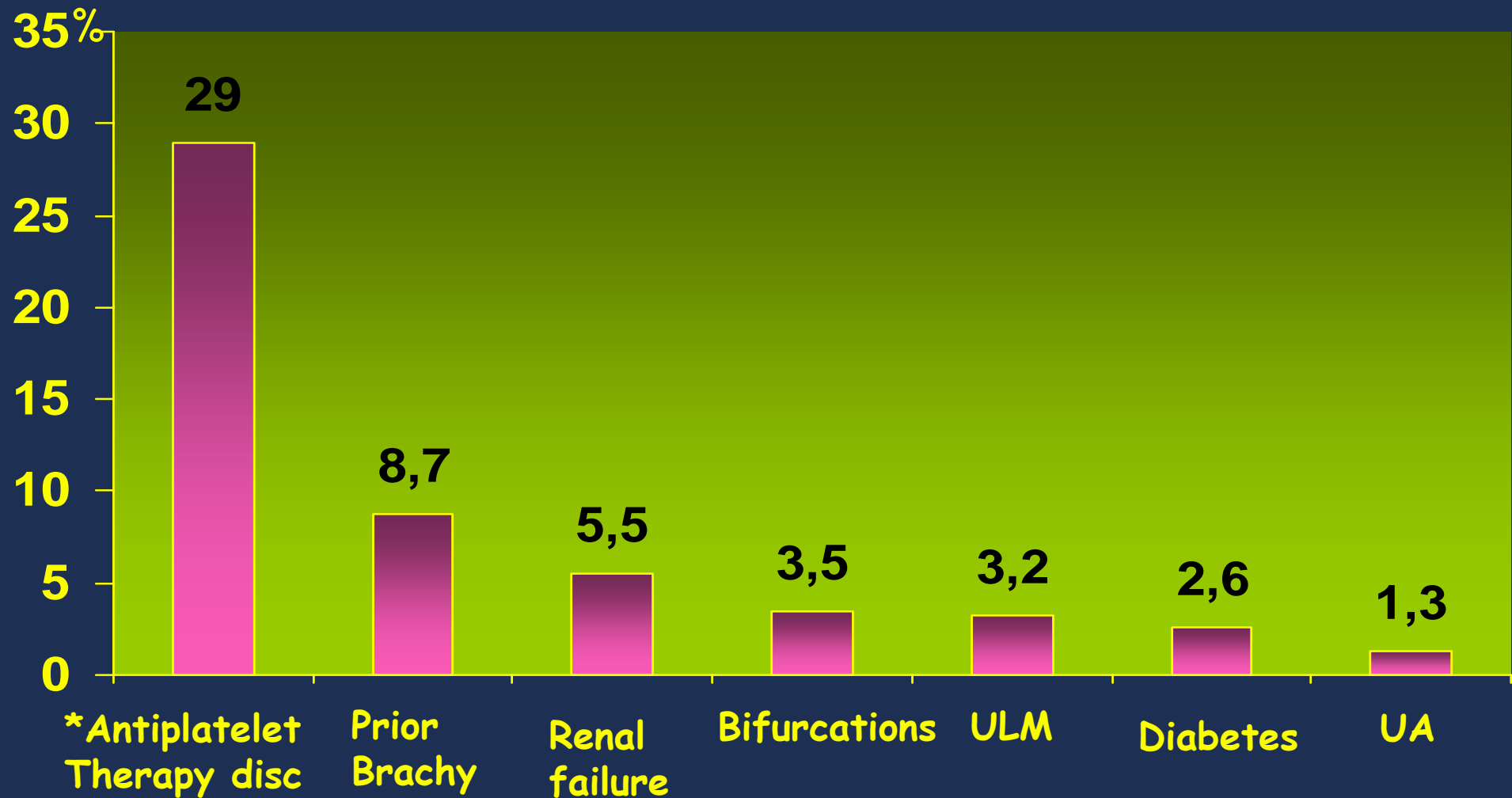


Premature APLT discontinuation





Thrombosis rates according to selected patient characteristics



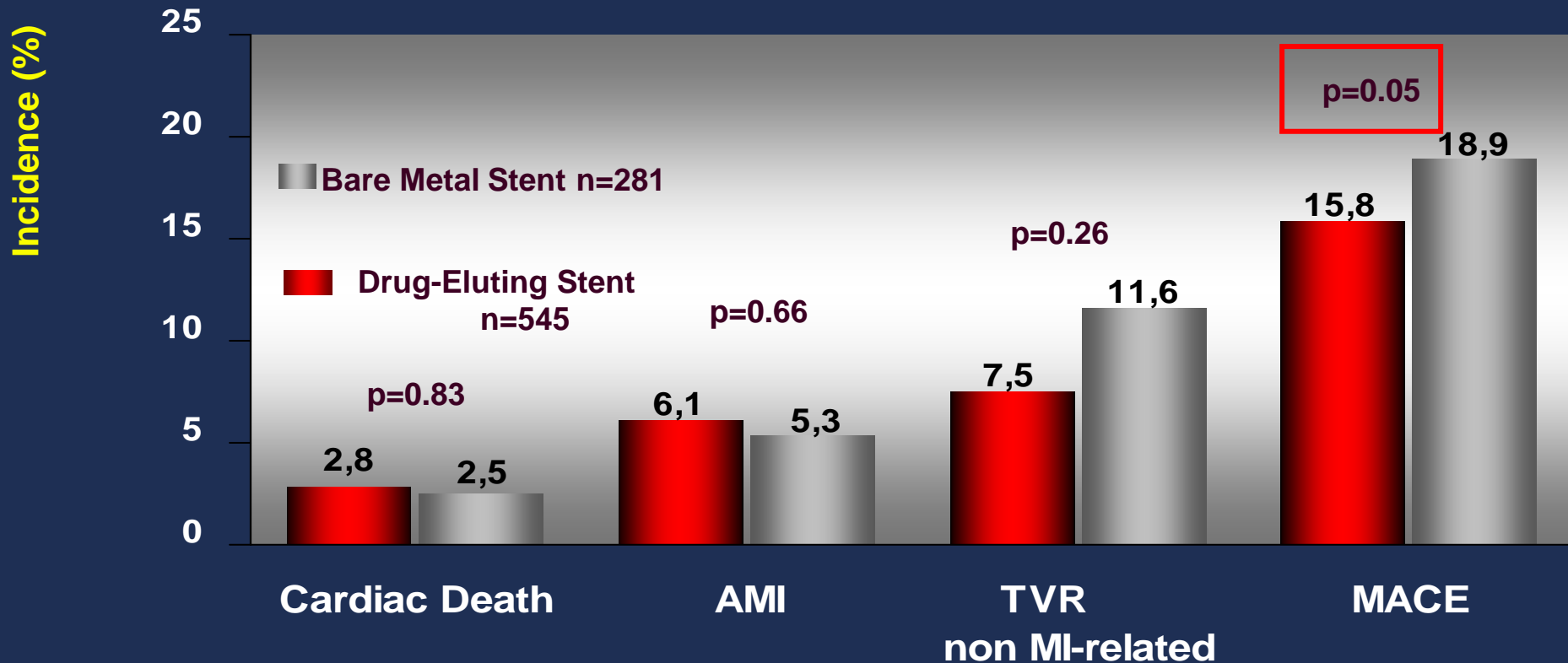
* Premature discontinuation



From 7 till 18 months

	DES	BMS	P
MI %	4.1	1.3	0.04
Death%	1.2	0	0.09

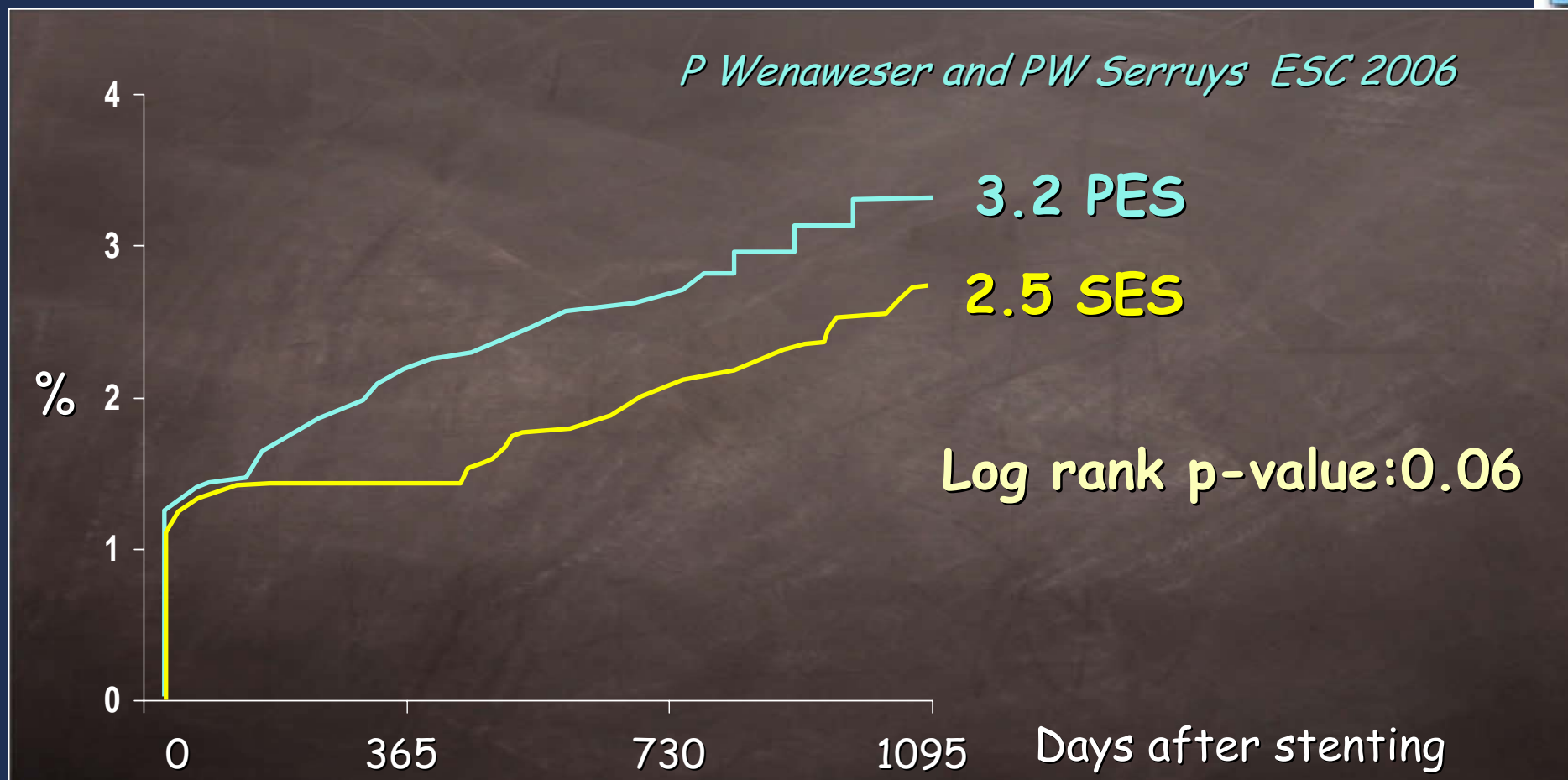
18 Month Death/MI Outcomes no longer significant



Cumulative Incidence of Stent Thrombosis



P Wenaweser and PW Serruys ESC 2006



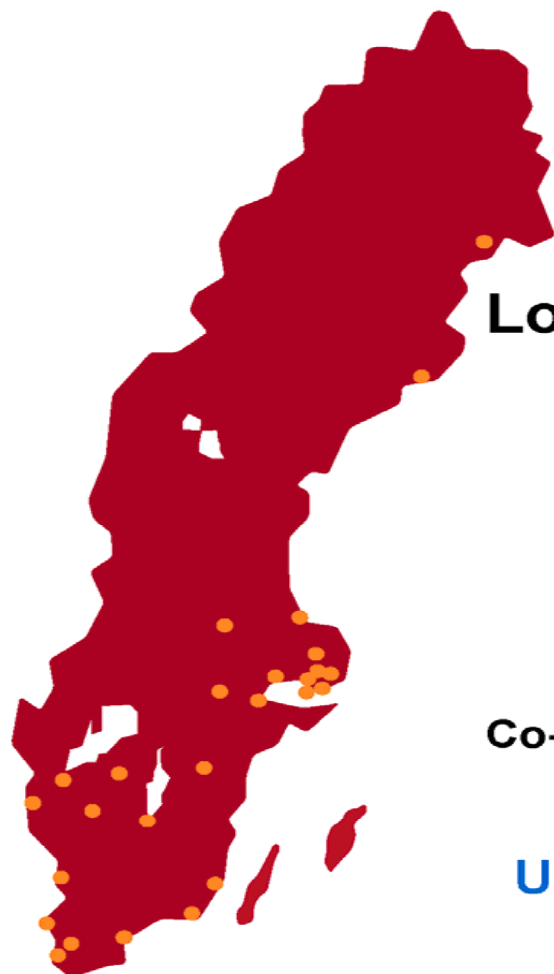
Days after PCI	9	30	365	730	1095
Incidence-SES (%)	1.0	1.1	1.3	1.9	2.5
Incidence-PES (%)	1.2	1.3	2.0	2.7	3.2

Pts at risk	8146	7162	7002	2841	971
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SCAAR-
Swedish Coronary Angiography
and Angioplasty Registry

SCAAR
UCR
SWEDEN
2006



Long-term outcome of DES vs BMS implanted in Sweden 2003 – 2004

Presented at FDA hearing Dec 7, 2006 by
Bo Lagerqvist & Lars Wallentin

Co-authors: Johan Lindbäck, Tage Nilsson, Stefan
James, Ulf Stenestrand

Uppsala Clinical Research Centre, UCR,
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Stent diameter



Long-Term Outcomes with Drug-Eluting Stents versus Bare-Metal Stents in Sweden

Bo Lagerqvist, M.D., Ph.D., Stefan K. James, M.D., Ph.D.,
Ulf Stenestrand, M.D., Ph.D., Johan Lindbäck, M.Sc., Tage Nilsson, M.D., Ph.D.,
and Lars Wallentin, M.D., Ph.D., for the SCAAR Study Group*

N ENGL J MED 356;10 WWW.NEJM.ORG MARCH 8, 2007

	BMS	DES
<2.5 mm	337 (3.3)	328 (9.1)
2.5 to <3.0 mm	2,314 (22.5)	1203 (33.3)
3.0 to <3.5 mm	3,897 (37.9)	1311 (36.2)
3.5 to <4 mm	2,663 (25.9)	744 (20.6)
≥4 mm	1,061 (10.3)	32 (0.9)

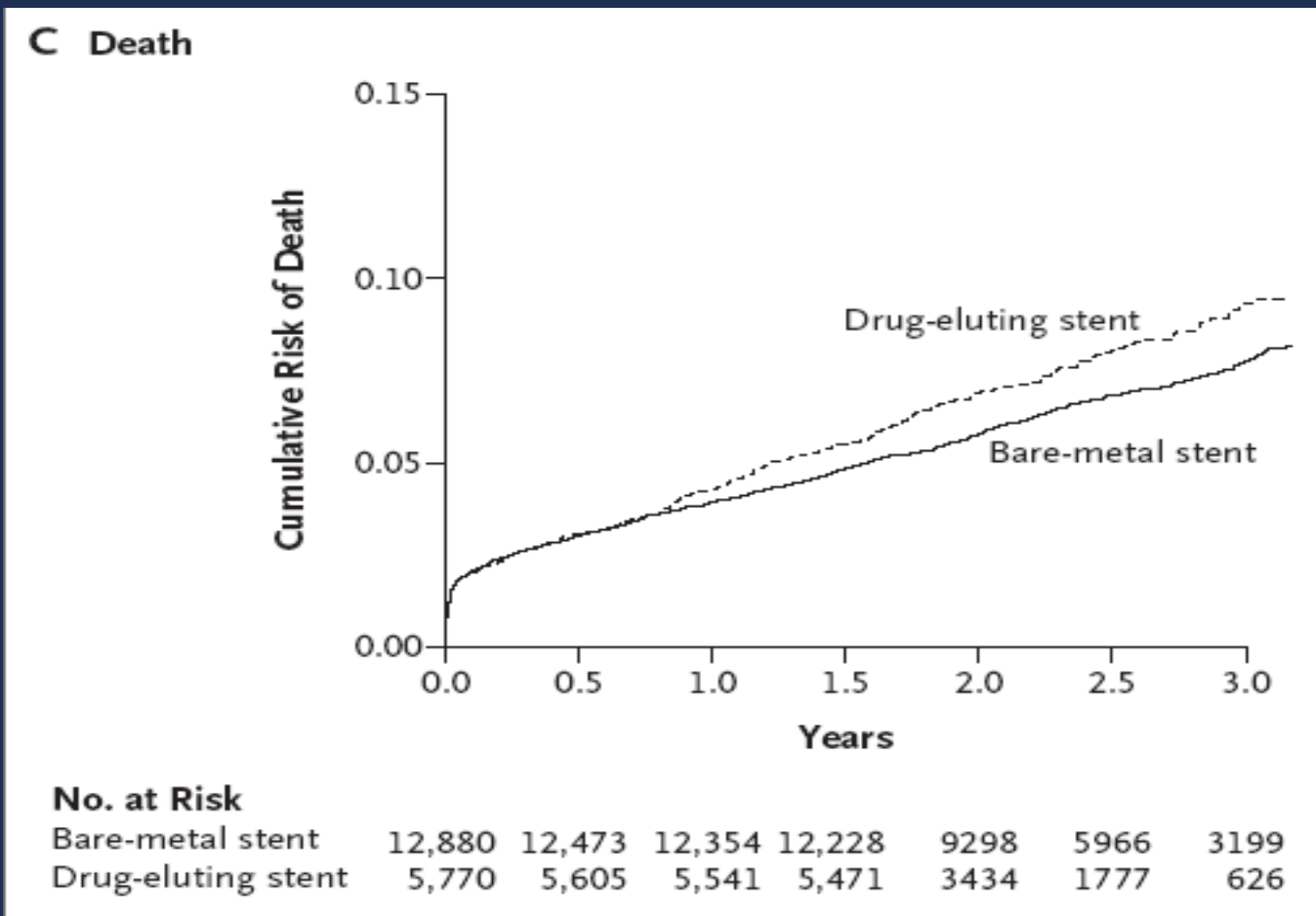


Adverse clinical baseline characteristics

		BMS	DES
Diabetes — no. (%)	19,771	2,140 (15.6)	1421 (23.6)
Previous heart failure — no. (%)	19,771	963 (7.0)	489 (8.1)
Previous stroke — no. (%)	19,771	801 (5.8)	374 (6.2)
Previous renal failure — no. (%)	19,771	124 (0.9)	79 (1.3)
Previous dialysis — no. (%)	19,771	46 (0.3)	40 (0.7)
		29.6%	39.9%



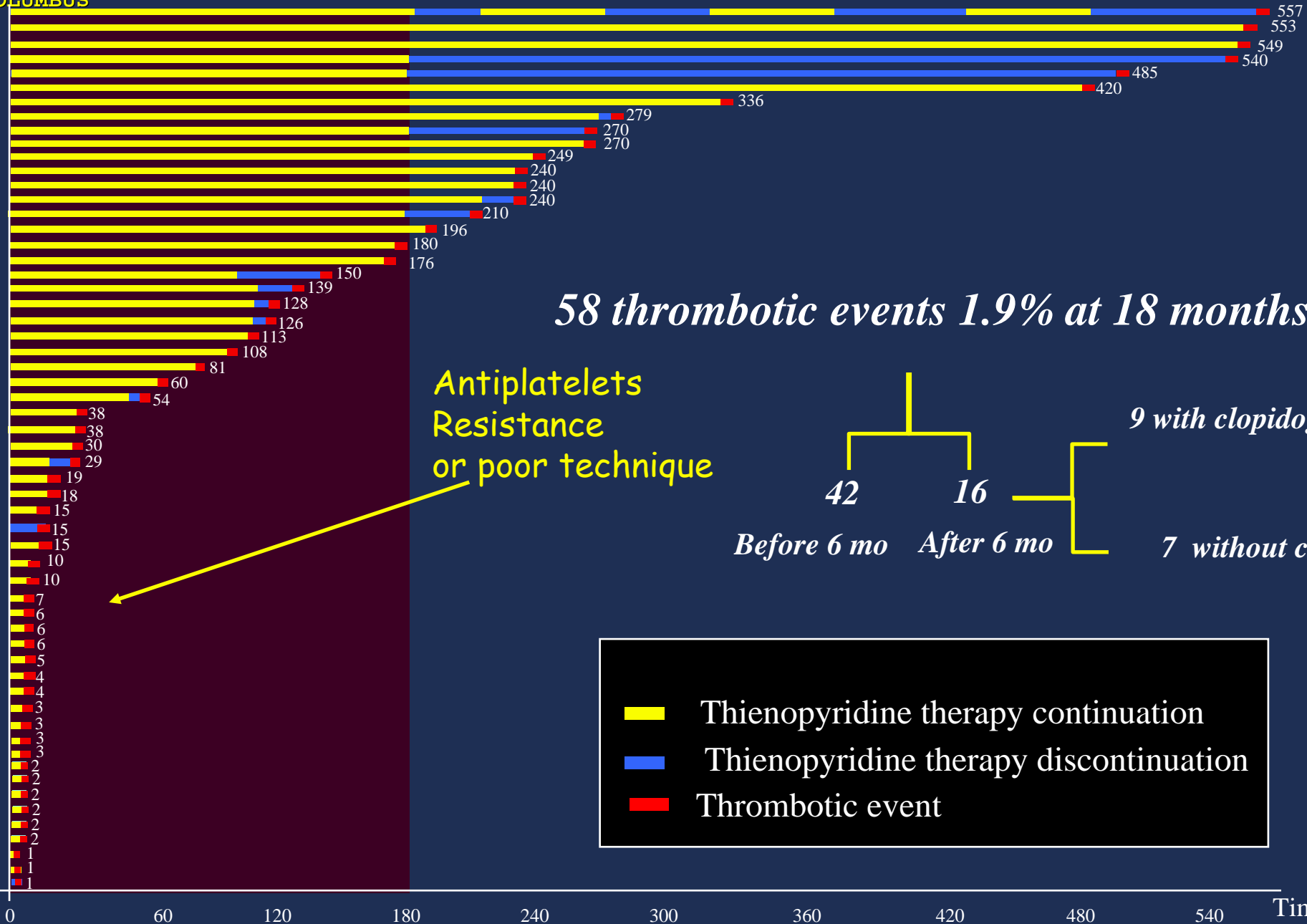
Unadjusted death rates



At 3 years, mortality was significantly higher in patients with drug-eluting stents (adjusted relative risk, 1.18; 95% CI, 1.04 to 1.35), and from 6 months to 3 years, the adjusted relative risk for death in this group was 1.32 (95% CI, 1.11 to 1.57).

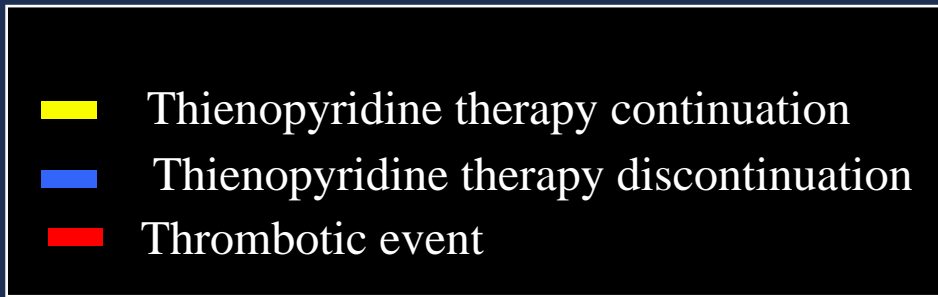
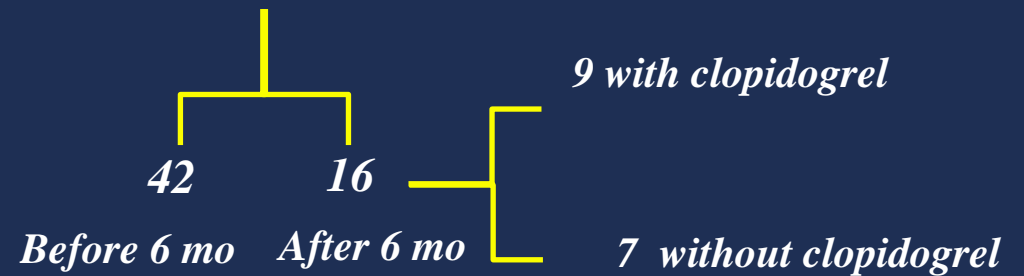


Individual 58 patients (each line bar is a patient)



58 thrombotic events 1.9% at 18 months FU

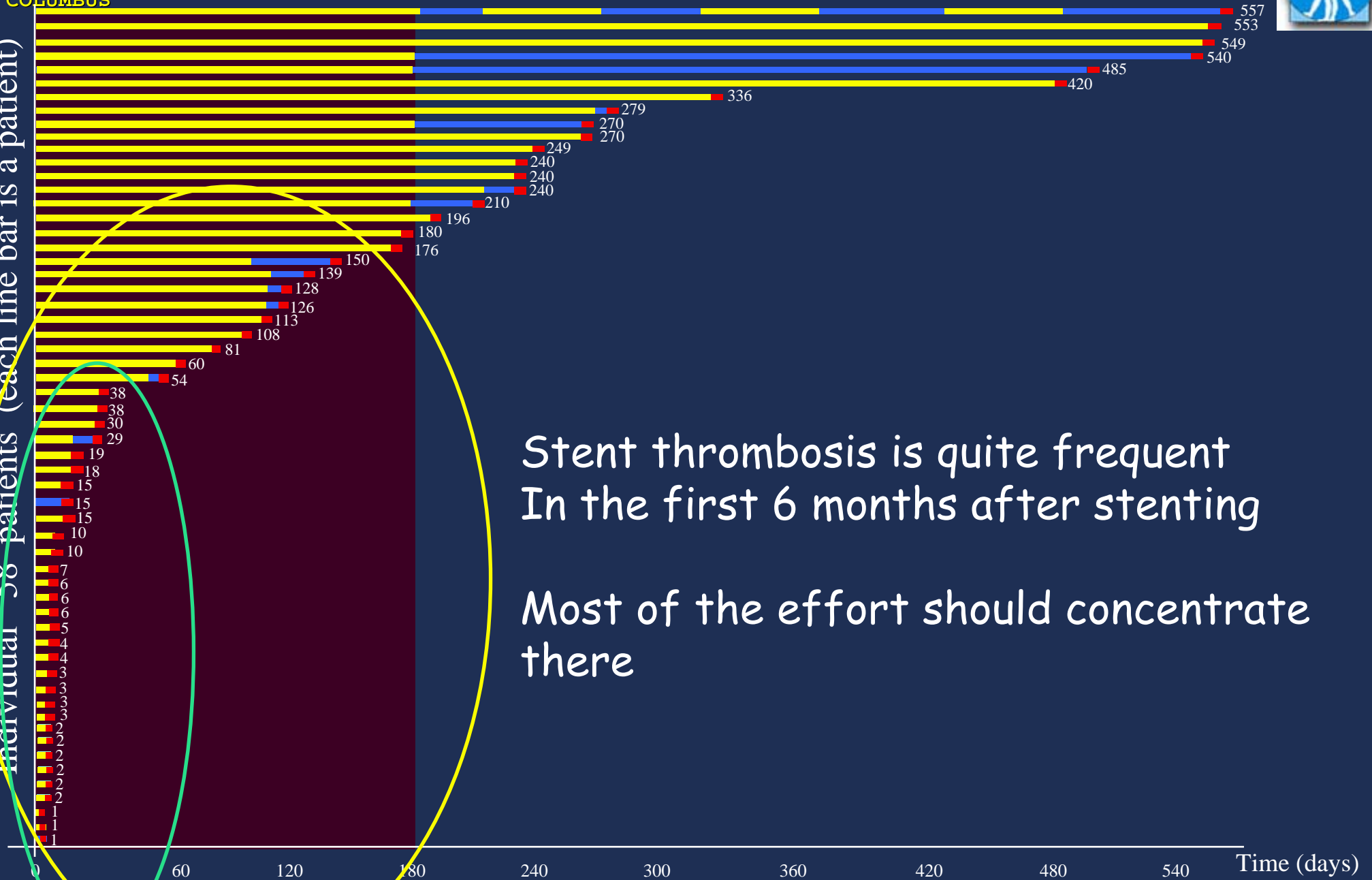
Antiplatelets
Resistance
or poor technique



Occurrence of Stent Thrombosis



Individual 58 patients (each line bar is a patient)



Stent thrombosis is quite frequent
In the first 6 months after stenting

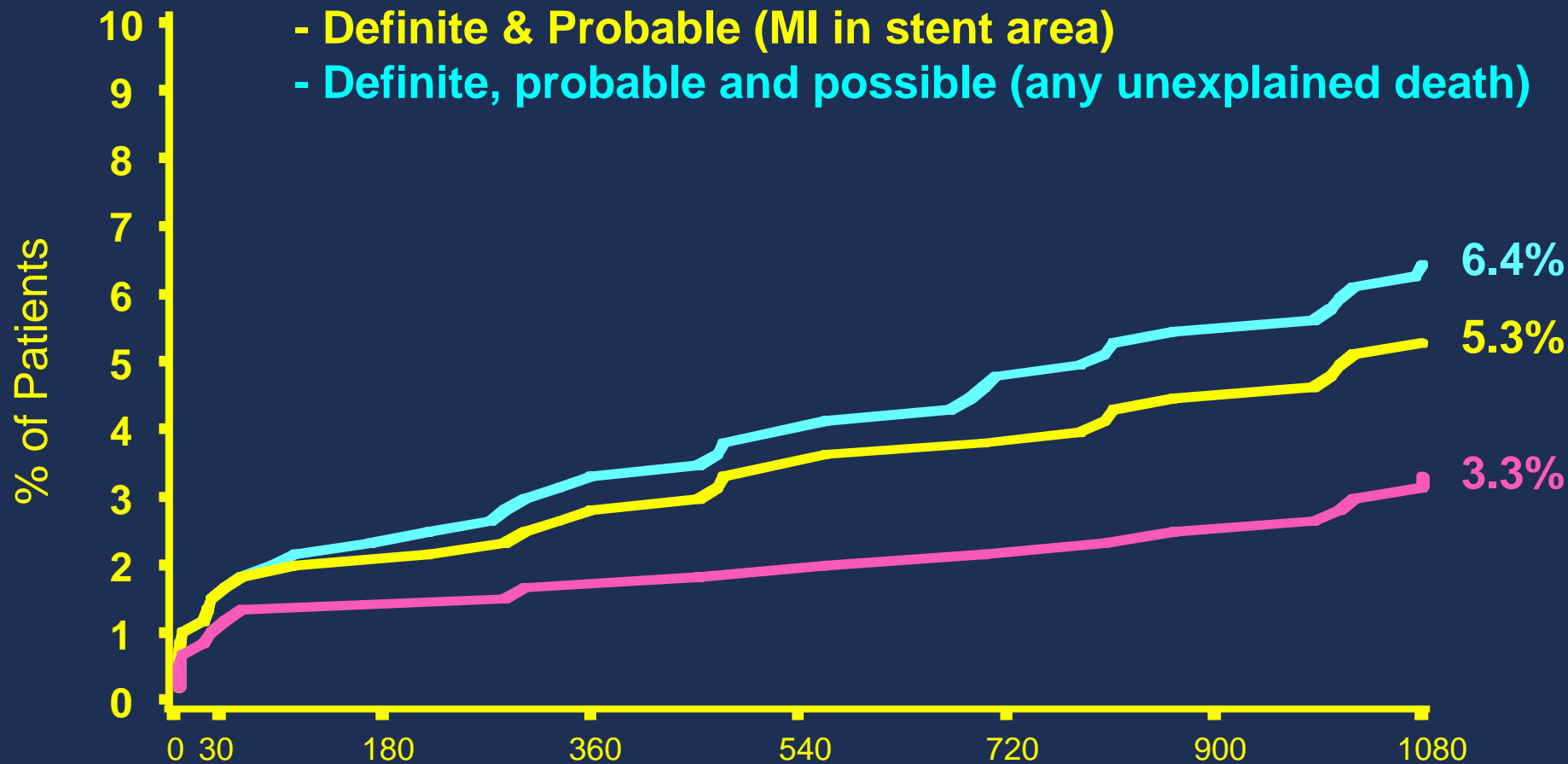
Most of the effort should concentrate
there

ARTS II – Stent thrombosis up to 3 years *



* Re-adjudication according to Dublin definitions

- Definite (angiography pathological confirmation)
- Definite & Probable (MI in stent area)
- Definite, probable and possible (any unexplained death)



ARTS II was performed with SES

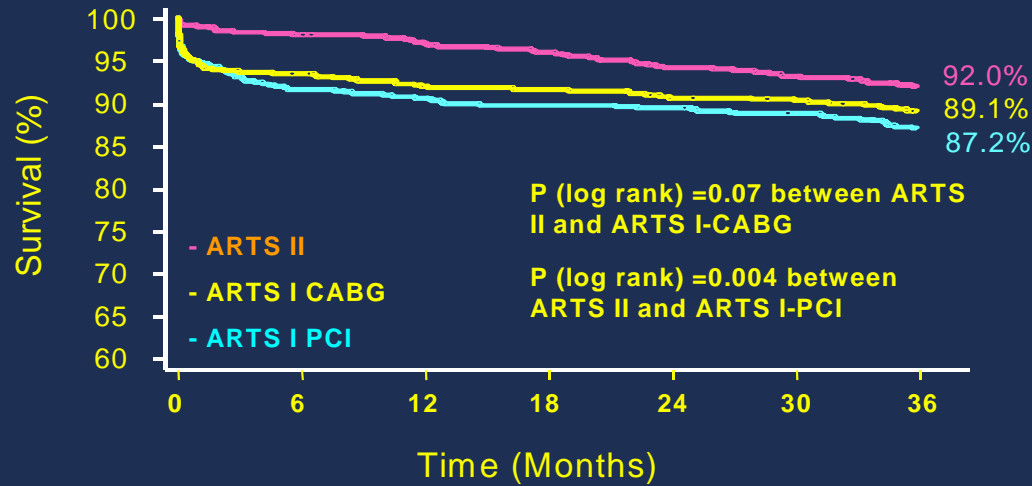


A problem

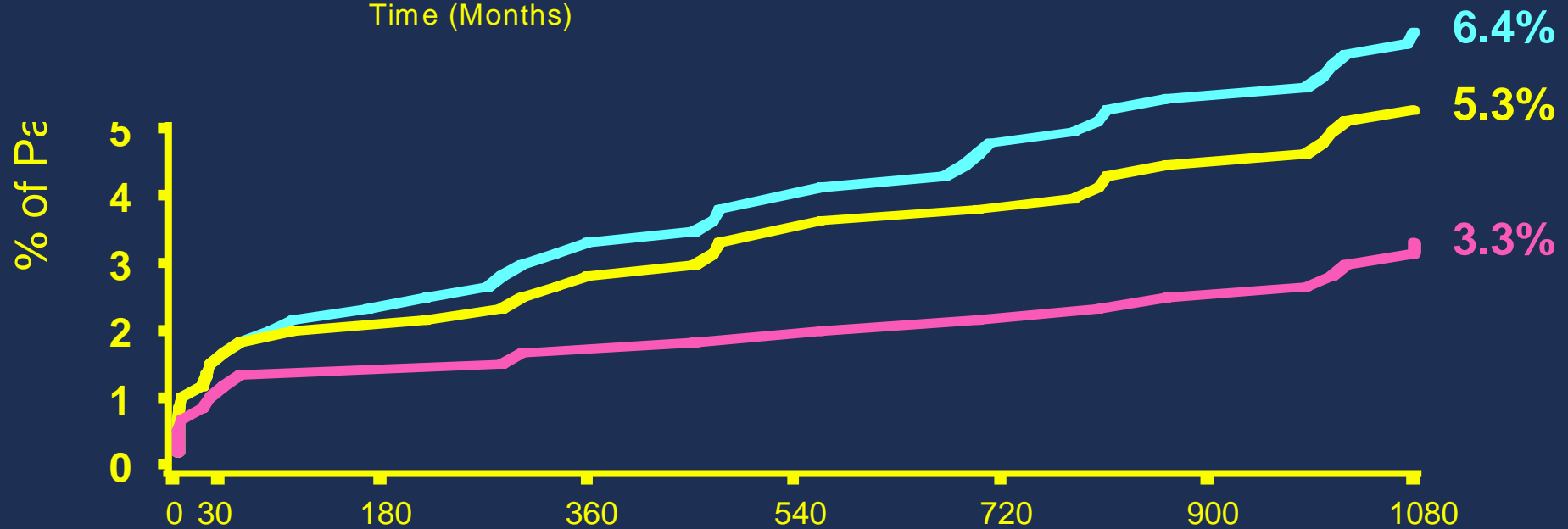
- There is an intrinsic risk for overestimation when we assign the label of “stent thrombosis” to all events which occur in *a stented and diseased coronary segment*. The concept that stents passivate the treated segment has never been proven.
- Treatment of multiple vessels will label any future myocardial infarction as “stent related”.



ARTS II - Death/CVA/MIs up to 3 years



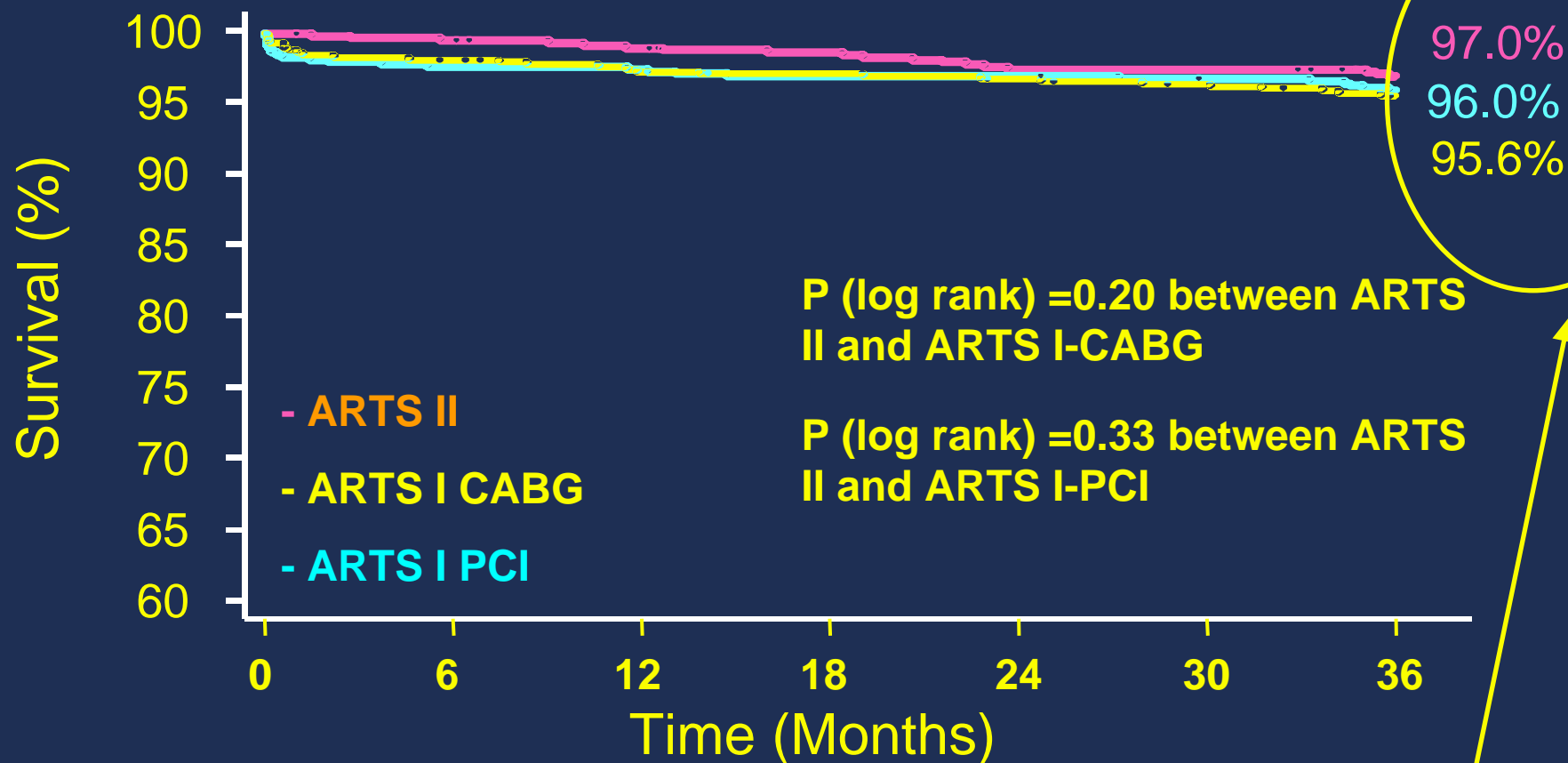
al confirmation)
rea)
any unexplained death)



ARTS II was performed with SES



ARTS II - Deaths up to 3 years



3 to 5% of pts will die at 3 yrs:
In which cohort do you want to die?



Patients with on label and off label indications: Milan experience

Indication	Patients	Percentage of total
On label	364	34.9%
Off label	680	65.1%
Off label Indication		
Bifurcation	339	49.9%
Ostial	246	36.2%
CTO	196	28.8%
Restenosis	152	22.4%
Left Main	44	6.5%
Vein Graft	36	5.3%
EF < 30%	13	1.9%



Baseline Clinical and Procedural Characteristics: Milan Experience

Variable	On Label	Off Label	P Value
Pts	364	680	
Male	325(89.3%)	603(88.7%)	0.84
Age (yrs)	63.8±10.6	63.4±10.6	0.38
EF (%)	54.2±9.1	53.2±9.6	0.56
Diabetes Mellitus	64(17.6%)	137(20.1%)	0.32
Nr Stents per Pt median (range)	2 (1-8)	3 (1-10)	0.0001
Total stent length (mm) Median (IQR)	33 (26-66)	60(36-99)	0.0001
Pts with >1 stent per les	79(21.7%)	192(28.2%)	0.02

In-Hospital And FU clinical Events: Milan Experience



Variable	On Label	Off Label	P Value
Pts	364	680	
Acute Stent Throm	0	0.3%(2)	0.55
Sub-Acute ST	0	0.6%(4)	0.30
Late ST	1.4%(5)	1.2%(8)	0.78
MI	1.9%(7)	2.4%(16)	0.83
Total death	4.9%(18)	4.1%(28)	0.53
Cardiac death	2.7%(10)	2.5%(17)	1.00
MACE	17.6%(64)	28.2%(192)	0.0001



DES represent an unique step forward

- We did not pay sufficient attention to possible complications: *only placebo has almost no complications!*
- Efforts should concentrate to prevent:
 - early thrombosis- technique and antiplatelets
 - late thrombosis- innovative solutions and further understanding

DES allow treatment of more complex lesions with less immediate and late complications

(personal opinion!)