

# « L' Histoire du stent actif »

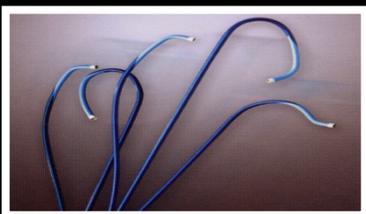
DR Renaud VIDAL

Unité Cardiovasculaire Interventionnelle  
Clinique Saint George - NICE



De 1970...

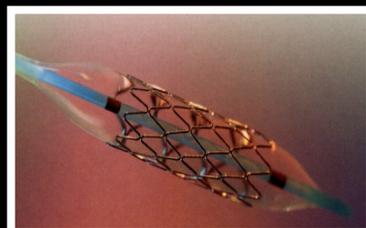
...2010



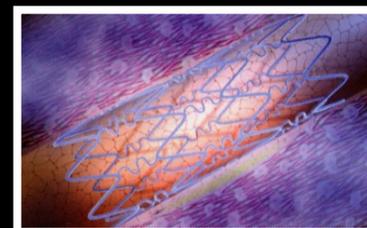
1ère Thrombolyse  
Intracoronaire



1er ATC



1987 1er stent



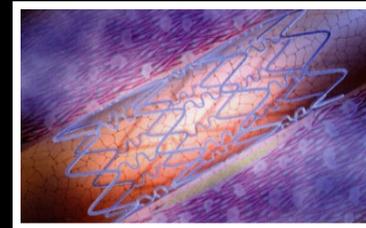
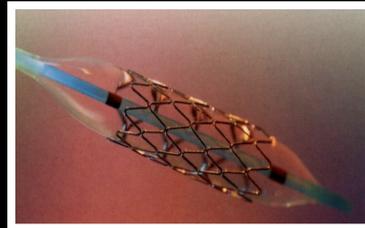
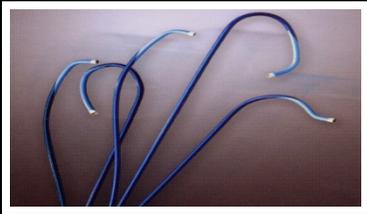
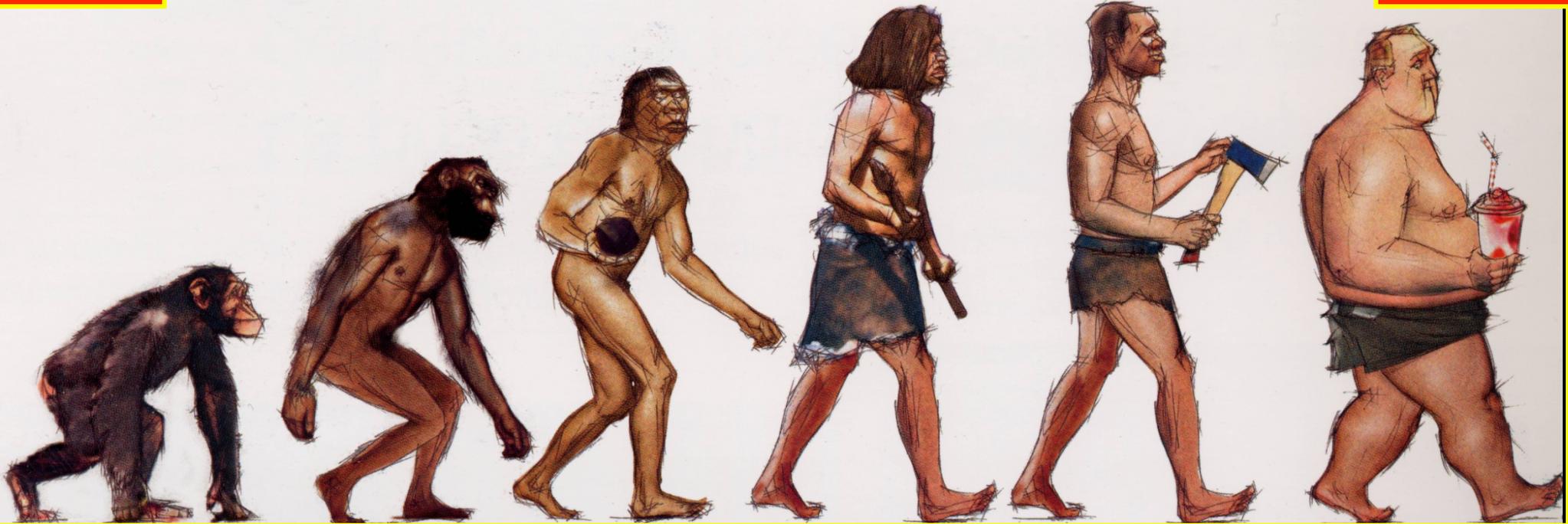
1998 1er stent  
« ACTIF »



2008 ?  
« Actif Résorbable »

1970...

2010



1ère Thrombolyse  
Intracoronaire

1er ATC

1987 1er stent

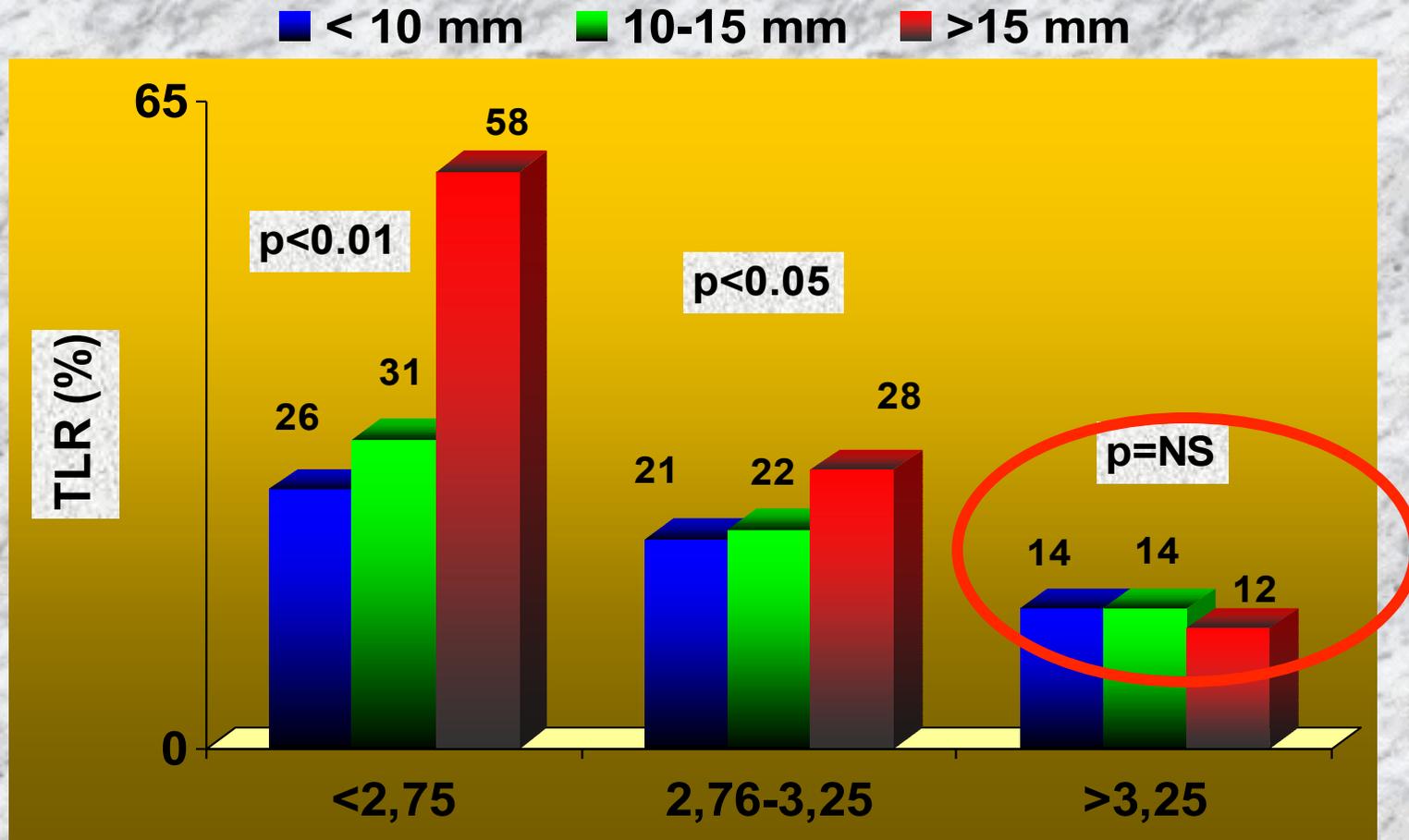
1998 1er stent  
« ACTIF »

2008 ?  
« Actif Résorbable »



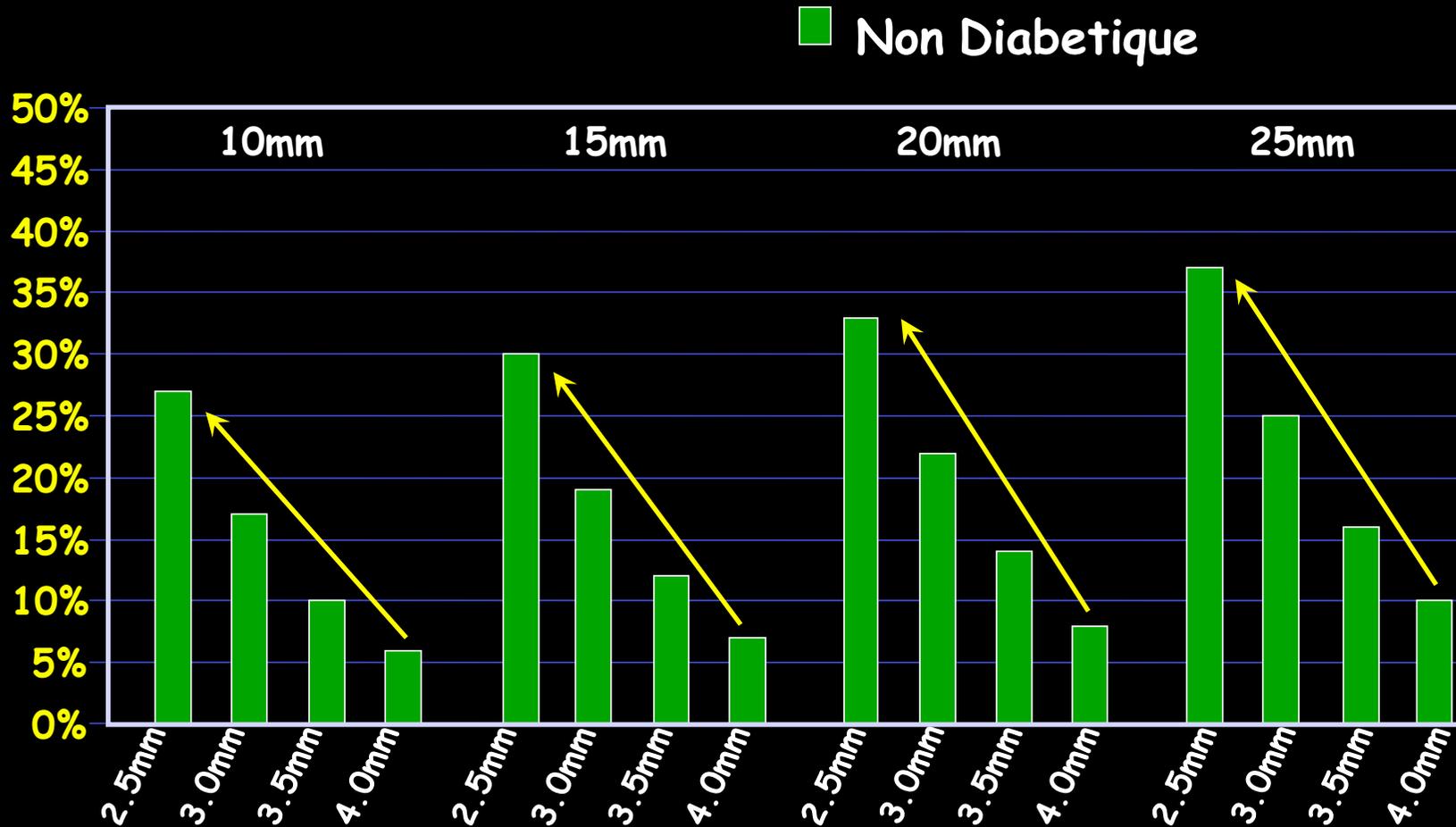
# Stent « conventionnels » :

% de resténose selon diamètre et longueur



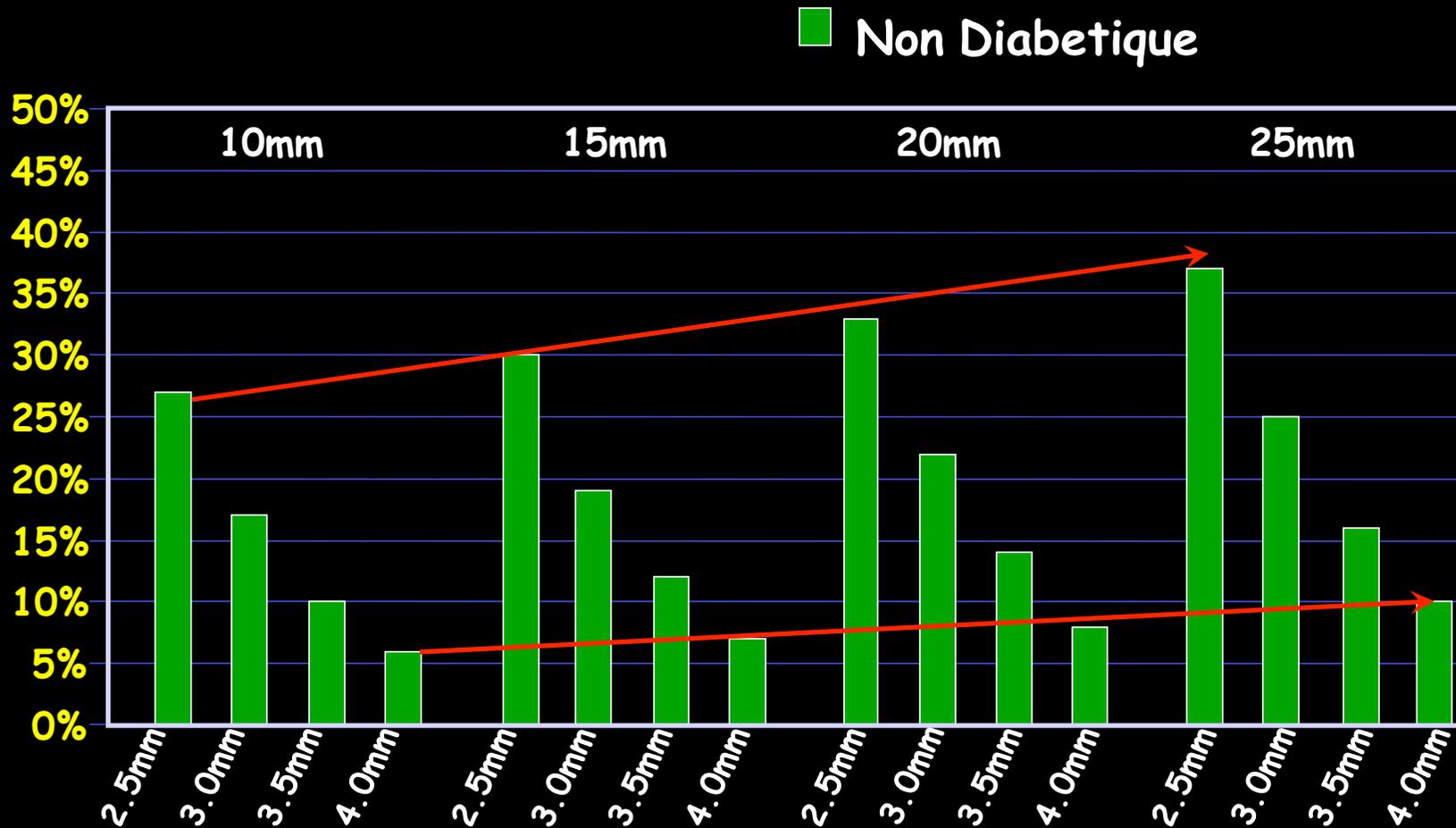
# Resténose Intra Stent

Longueur lésion, Diamètre Vaisseau, Diabète



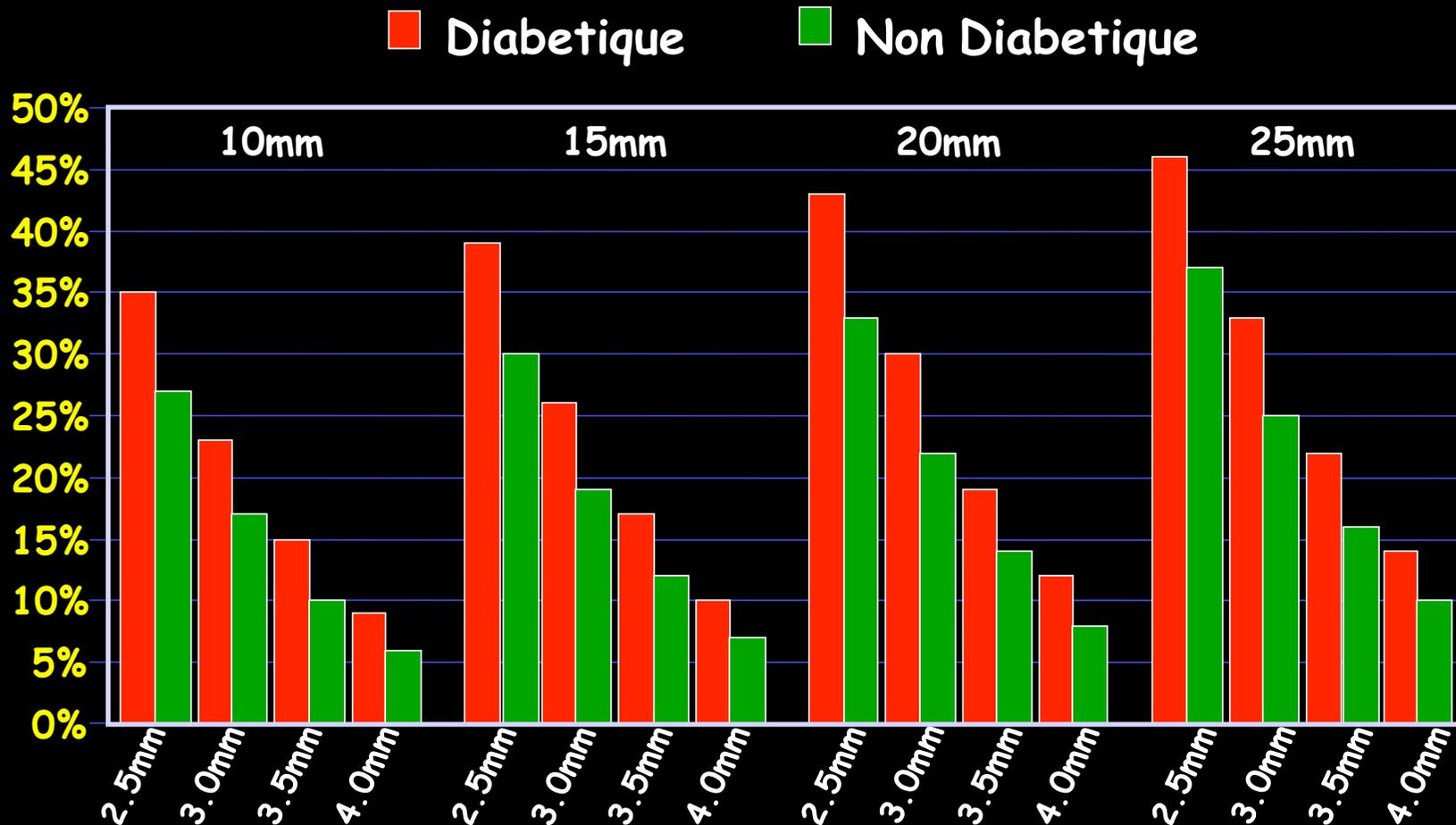
# Resténose Intra Stent

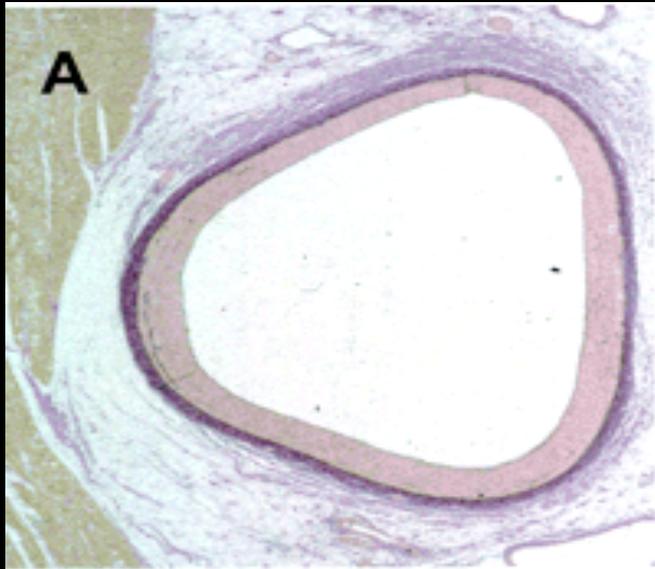
Longueur lésion, Diamètre Vaisseau, Diabète



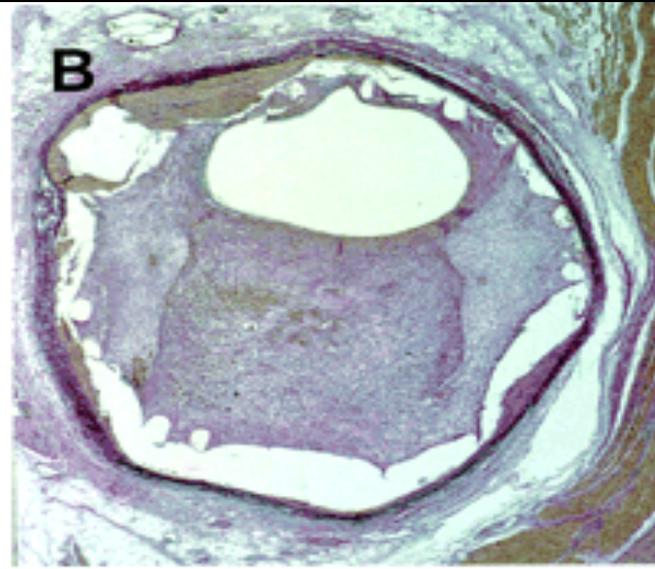
# Resténose Intra Stent

Longueur lésion, Diamètre Vaisseau, Diabète

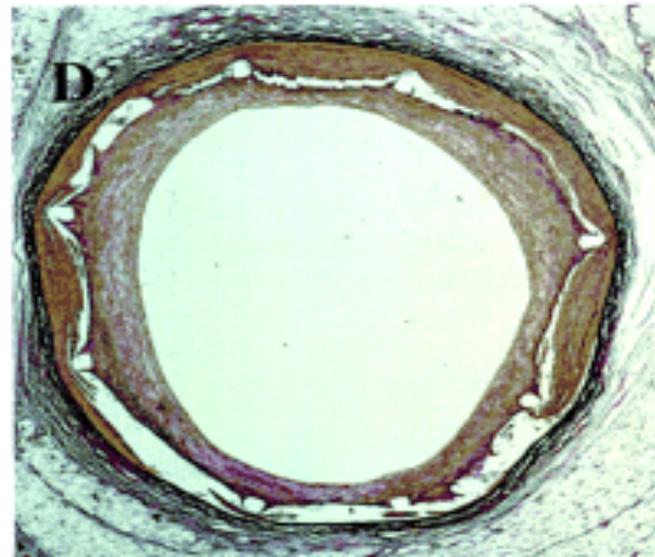
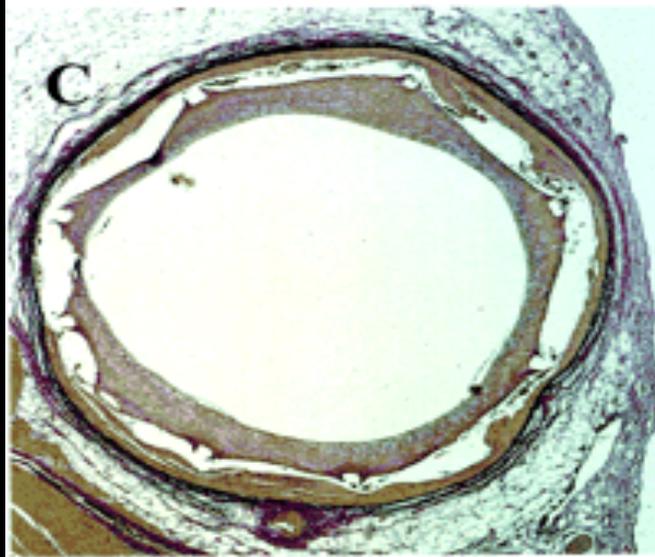




Control Vessel

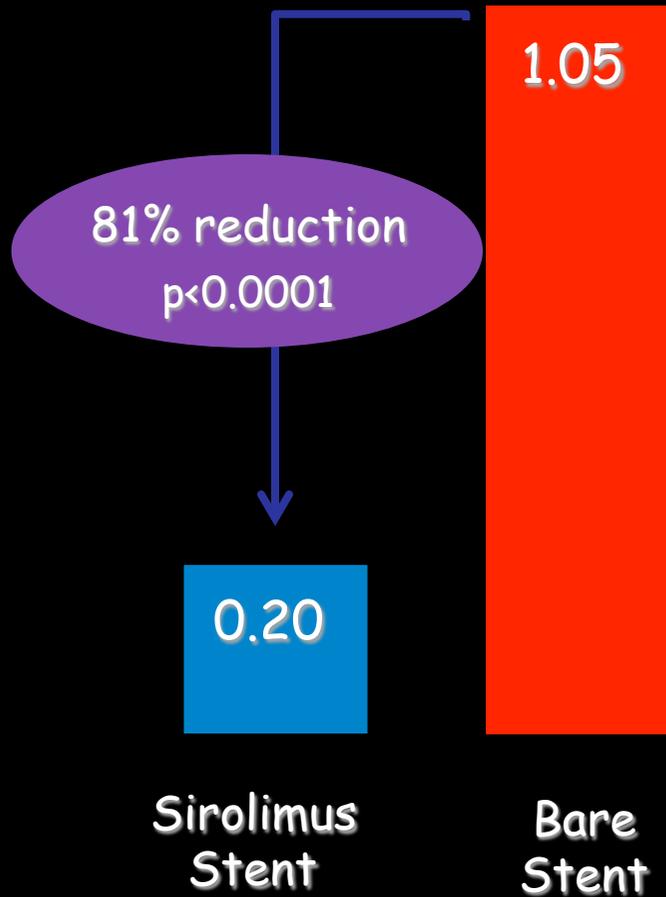


Control Stent



# E-SIRIUS : Restenosis Rates / 8 Month FU Angiographic

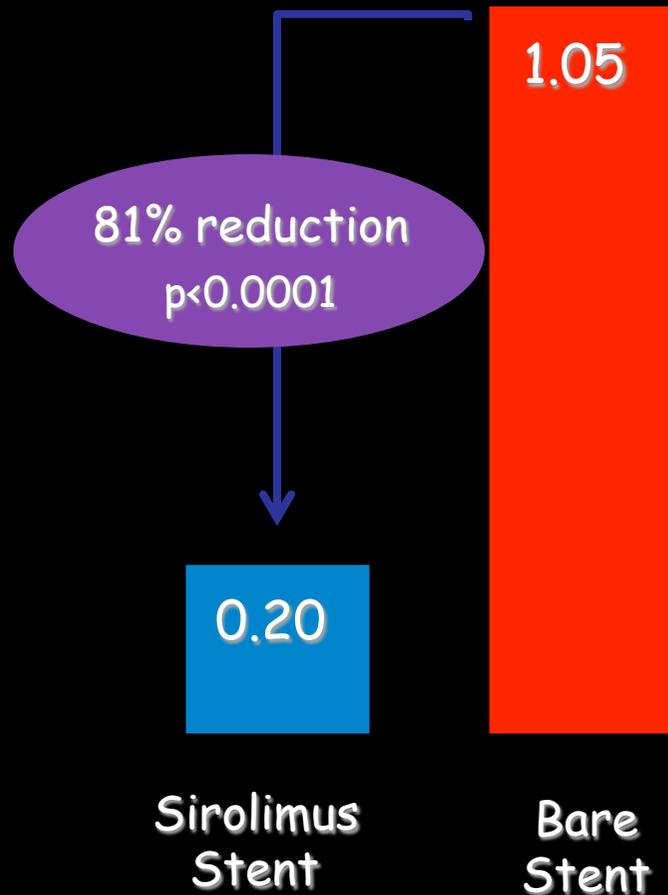
In-stent Late Loss (mm)



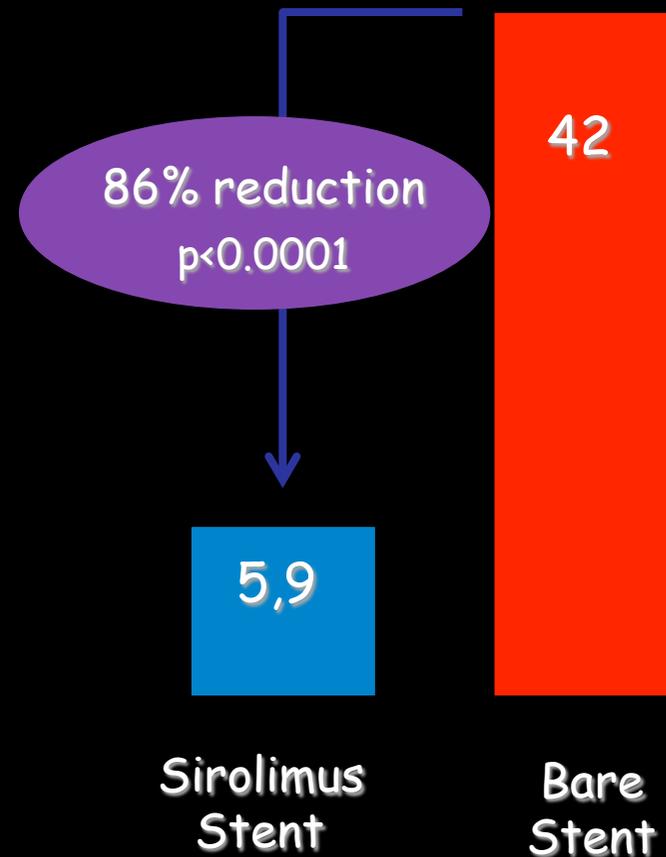
SIRIUS - TCT 2002

# E-SIRIUS : Restenosis Rates / 8 Month FU Angiographic

## In-stent Late Loss (mm)

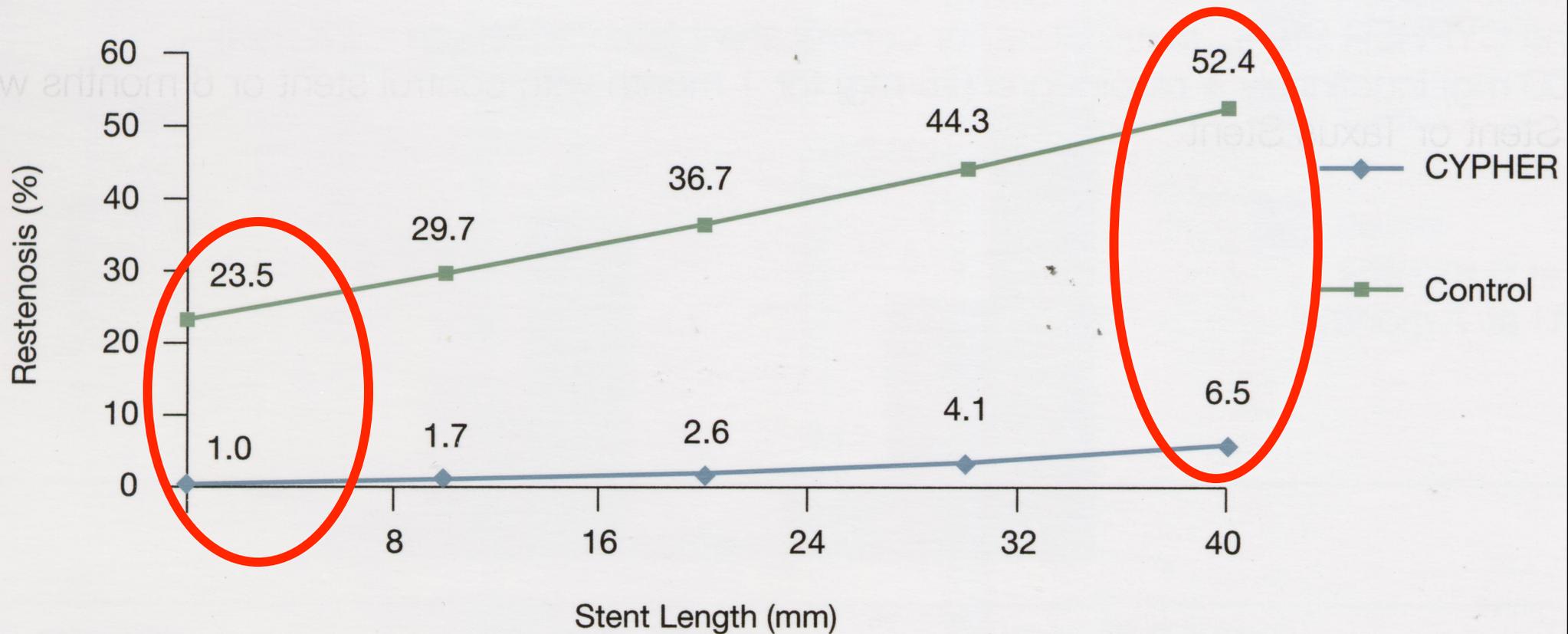


## In-segment Restenosis

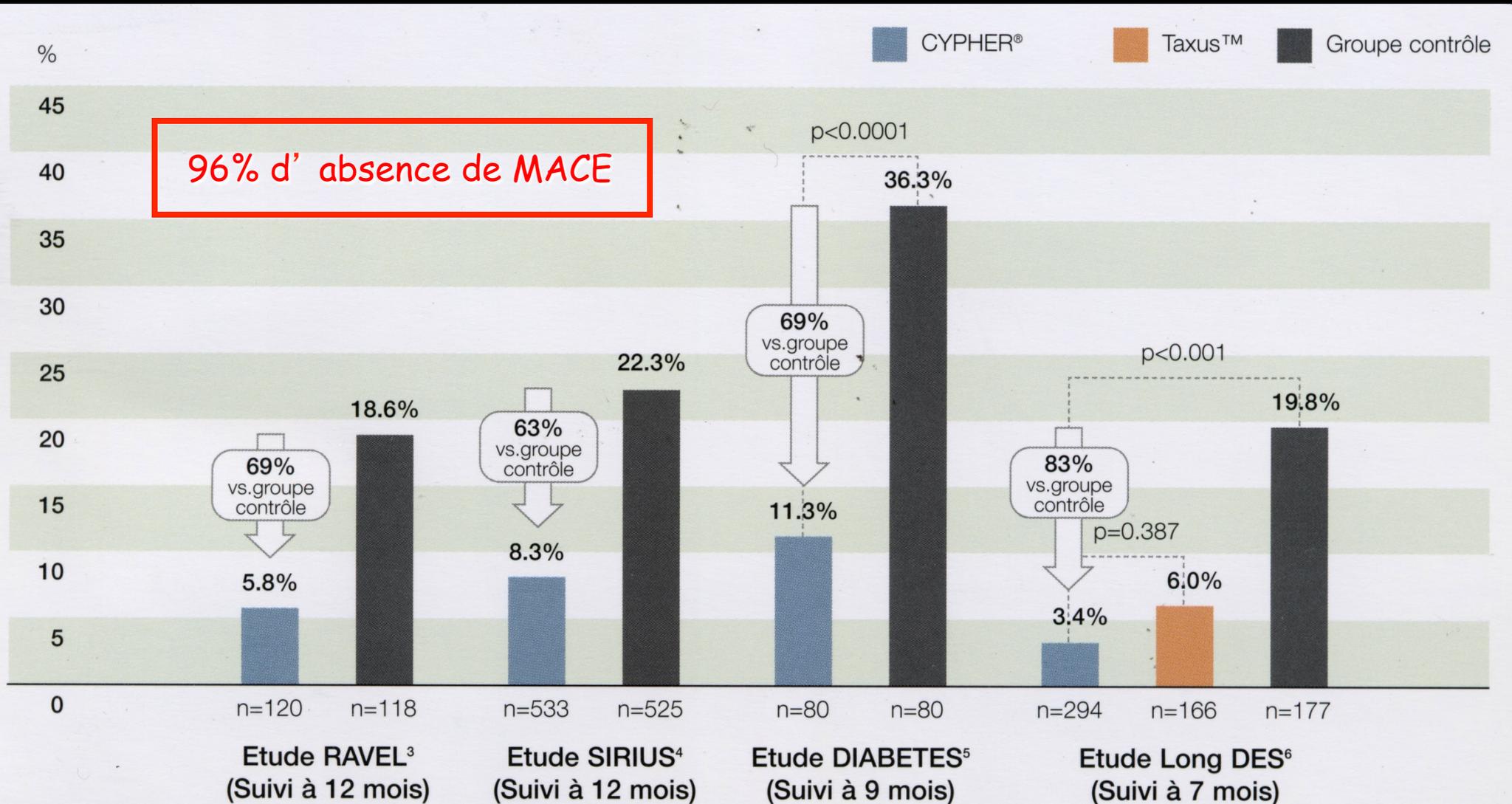


# Stent « ACTIF » :

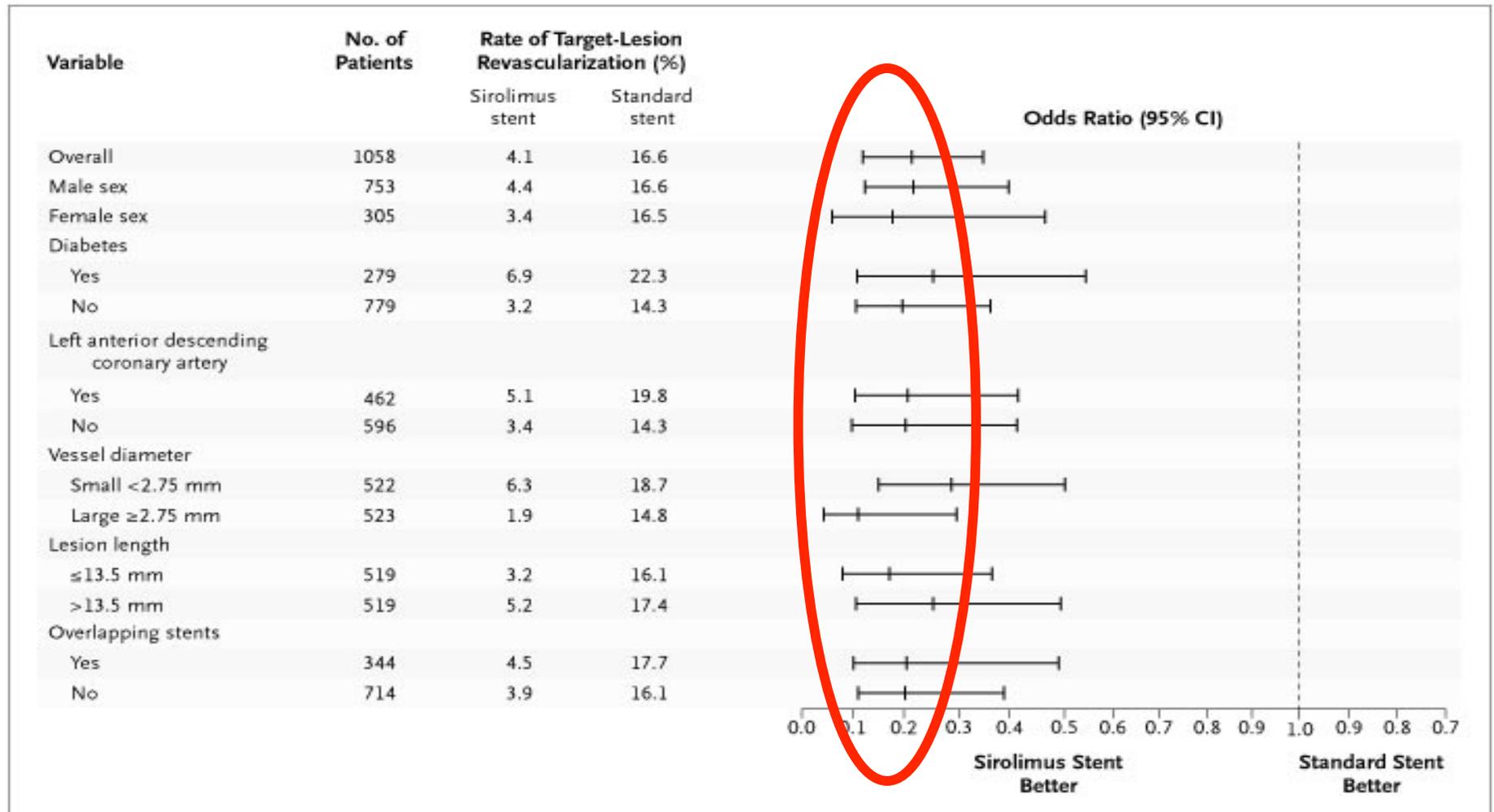
% de resténose selon diamètre et longueur



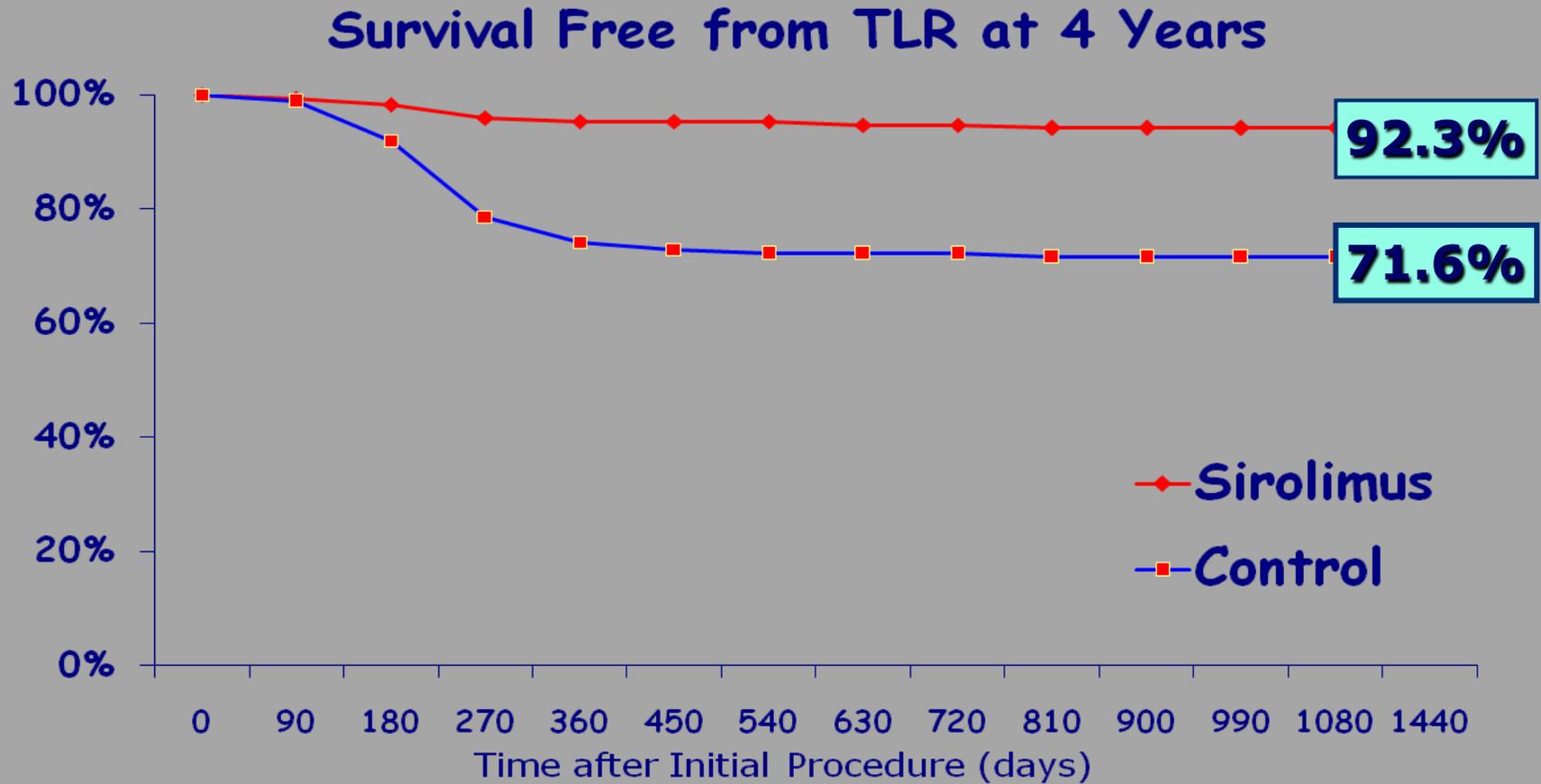
# Lésion / patients complexes : Ne pas rester « Passif »



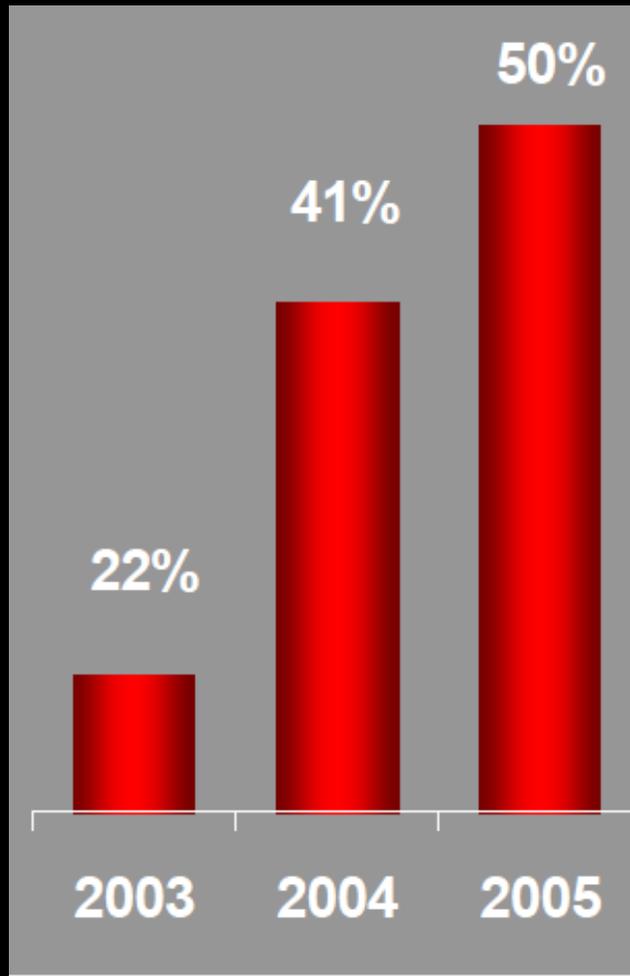
# SIRIUS : Bénéfice et sous groupe



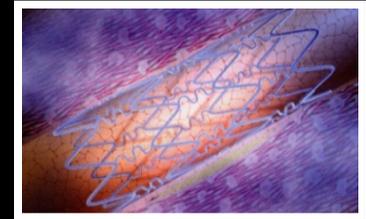
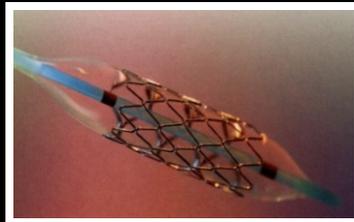
# E-SIRIUS : Survival Free from TLR 4 years



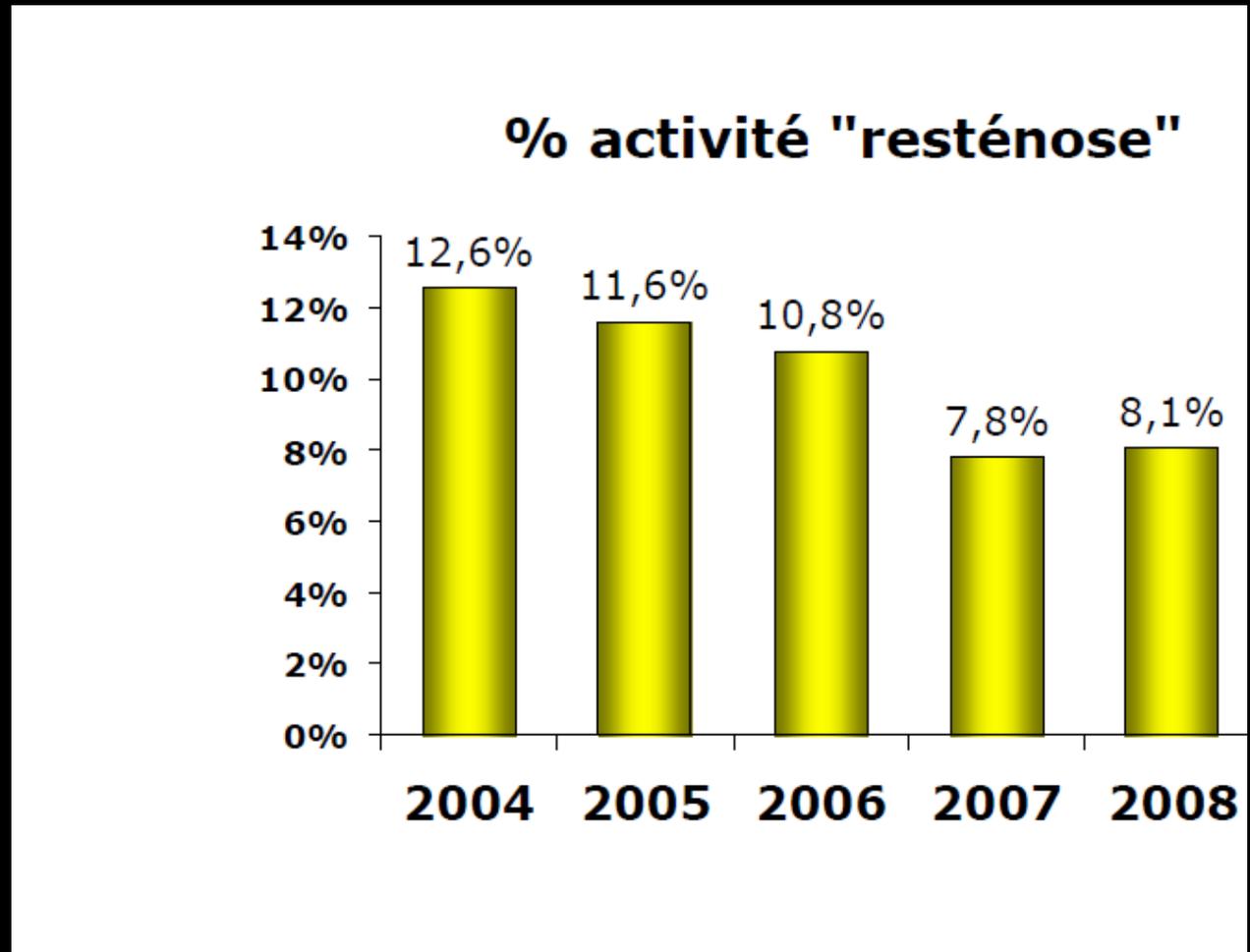
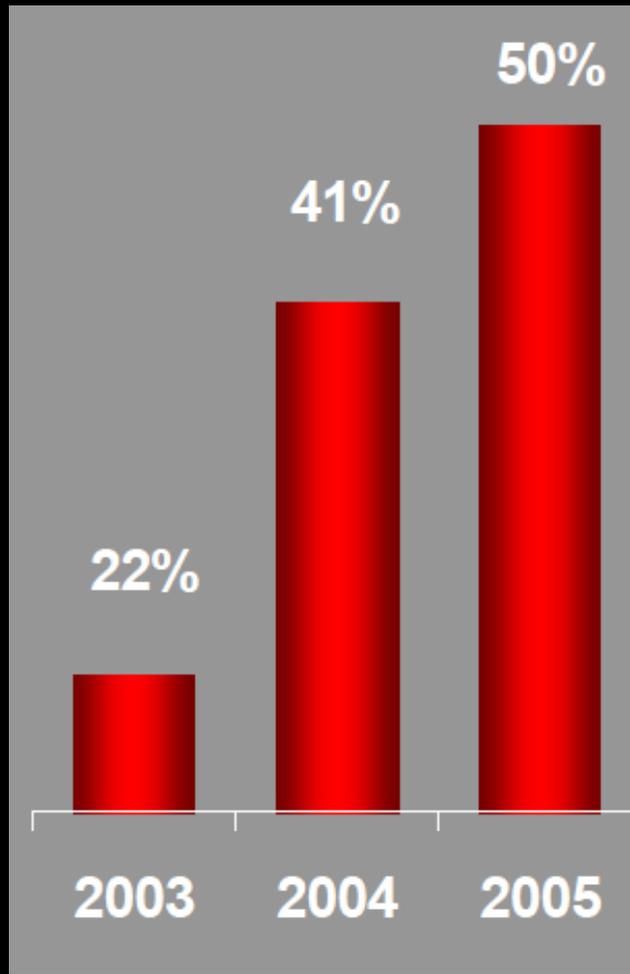
# Utilisation stent "ACTIF" (FRANCE)



Implantation « exponentielle »



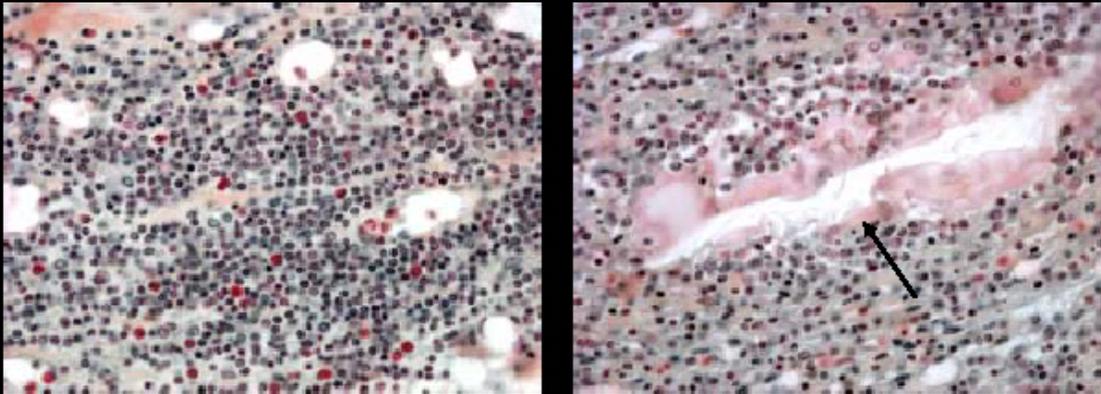
# Utilisation stent "ACTIF" (FRANCE)



« Baisse du nombre ATC pour resténose »

« DES : La resténose est vaincue...

# « DES : La resténose est vaincue... Mais la thrombose vous tue !!! »



Localized Hypersensitivity and Late Coronary Thrombosis  
Secondary to a Sirolimus-Eluting Stent.  
Should We Be Cautious?

Virmani R. *Circulation*. 2004 ; 109 : 701-5.

Guagliumi G.

*Circulation* 2003 ; 107 : 1340-1.



*Sirolimus 16 Months after Deployment*

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

We report 4 cases of angiographically confirmed stent thrombosis that occurred **late after** elective implantation of polymer-based Paclitaxel eluting (343 and 442 days) or Sirolimus-eluting (335 and 375 days) stents and resulted in myocardial infarction.

All cases arose **soon after** antiplatelet therapy was interrupted.

If confirmed in systematic long-term follow-up studies, our findings **have potentially serious clinical implications**

# Prédicteurs de thrombose de stent actif

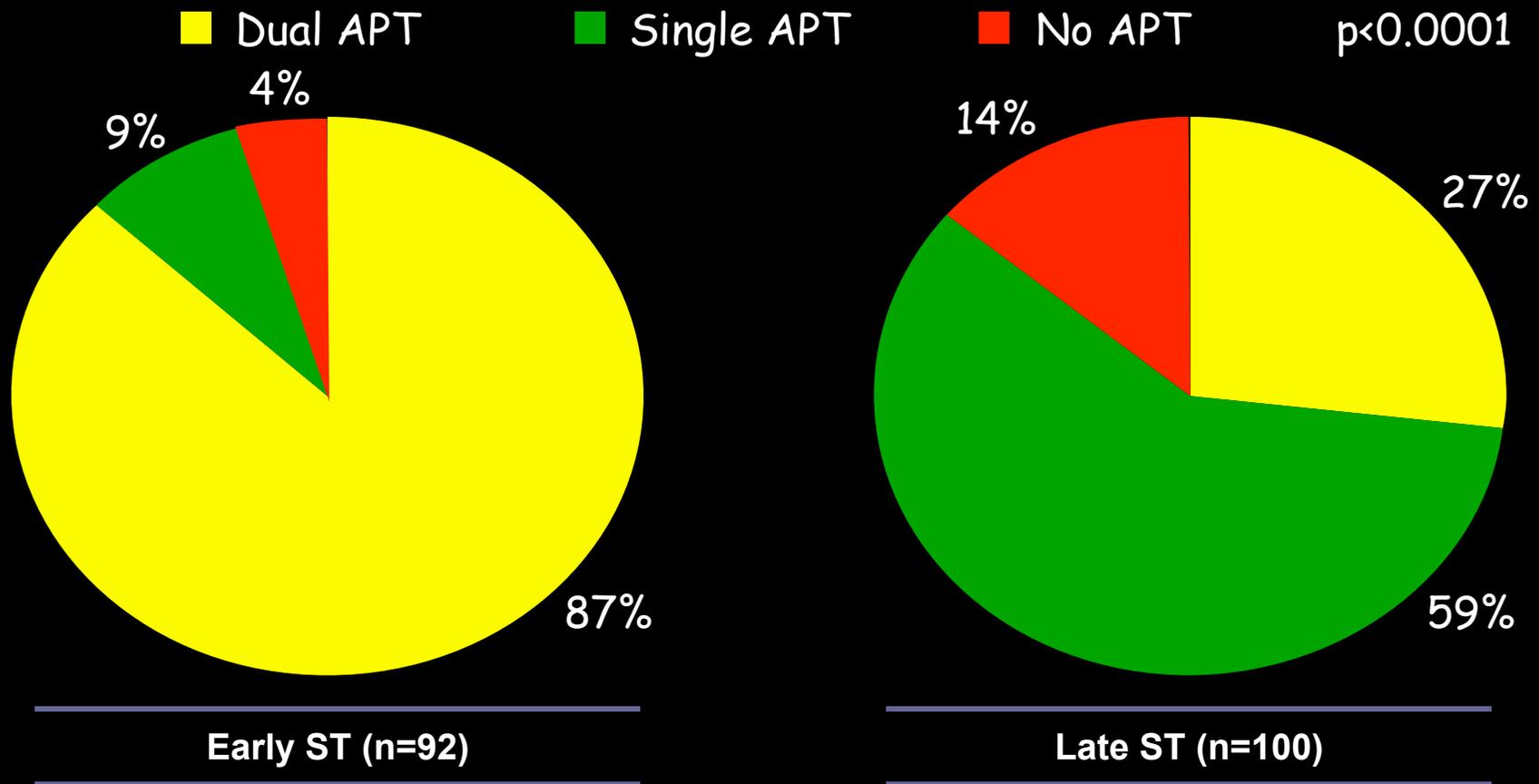
Variables	HR (IC 95%)	P
Arrêt antiagrégant	89.78 (29.9-269.6)	<.001
Insuffisance rénale	6.49 (2.6-16.1)	<.001
Bifurcation	6.42 (2.9-14.1)	<.001
Diabète	3.71 (1.7-7.9)	<.001
Dysfonction VG	1.1 (1.1-1.13)	<.001

N=2 229 DES PCI

JAMA. 2005 ; 293:2126-2130.

# Results from the Bern/Rotterdam Registry : FU 4 ans

## Antiplatelet Treatment at the Time of Stent Thrombosis



# Late thrombosis of DES :

a meta-analysis of randomized clinical trials.

14 clinical trials in which a total of 6 675 patients were randomized to either a **bare-metal stent** or a **sirolimus** - or **paclitaxel-eluting stent**

There was **no statistically significant difference** in the overall rate of stent thrombosis between the DES and BMS (9.3/1000 vs 9.0/1000).

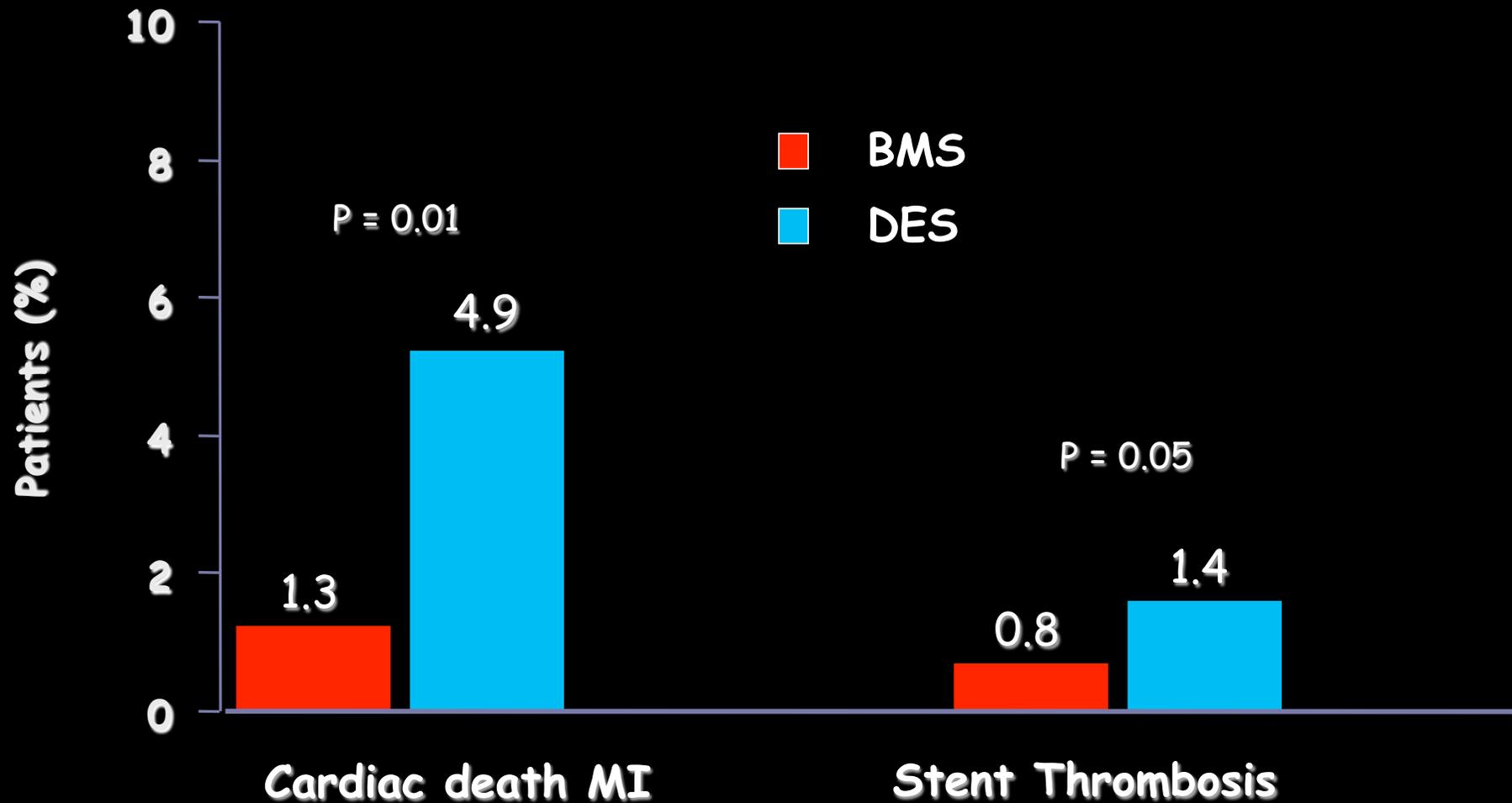
**However, the risk of very late stent thrombosis was significantly different**

**Very late stent thrombosis rates  
(>1 year postimplantation)**

Group	Event rate, per 100 pts	Risk ratio*	95% CI	p
All DES	0.5	5.02	1.29-19.52	0.02
Sirolimus	0.36	3.99	0.45-35.62	0.22
Paclitaxel	0.59	5.72	1.08-32.45	0.049

\* no late bare metal stent thrombosis occurred

# BASQUET Late : Outcome between 7 and 18 months



# Drug Eluting stent : a new serial killer ?

"What kills a patient, I think, is a large vessel with a drug-eluting stent"

Renu Virmani. ESC 2006

"DES use should be restricted to patients at the highest risk for restenosis"

Lars Wallentin

**"epidemic of madness"**

"As clinicians we seem to have lost our clinical judgment, let alone our ability to view data and evidence" Salim Yusuf. ESC 2006

most important presentations to come out of this year's meeting.

"Six million people in the world have been implanted with DES, yet their long-term safety and efficacy is unknown," said Yusuf. "I've a feeling the data we're seeing today is only the tip of the iceberg. We need to encourage more public access to the data."



he said. The use of PCI was established in MI, high-risk unstable angina and cardiogenic shock. However, its use in stable disease was a totally different question.

"There's no beneficial influence on mortality - PCI does nothing to prevent heart attack. All we are doing is providing short-term relief of chest pain. It's not re-stenosis that kills but the

27 Novembre 2006 ←

**GOOGLE VS. MICROSOFT**  
THE RACE TO REV UP THE SEARCH ENGINE

America's Largest Private Companies  
Howard Stern—Is Anyone Listening?  
*SCORE!* Hockey Is Hot Again

NOVEMBER 27, 2006 | WWW.FORBES.COM

# Forbes

DES : Have we implanted  
“a million ticking time bombs” ?

STENTS  
DEFIBRILLATORS  
SPINAL DISCS  
ARTIFICIAL KNEES

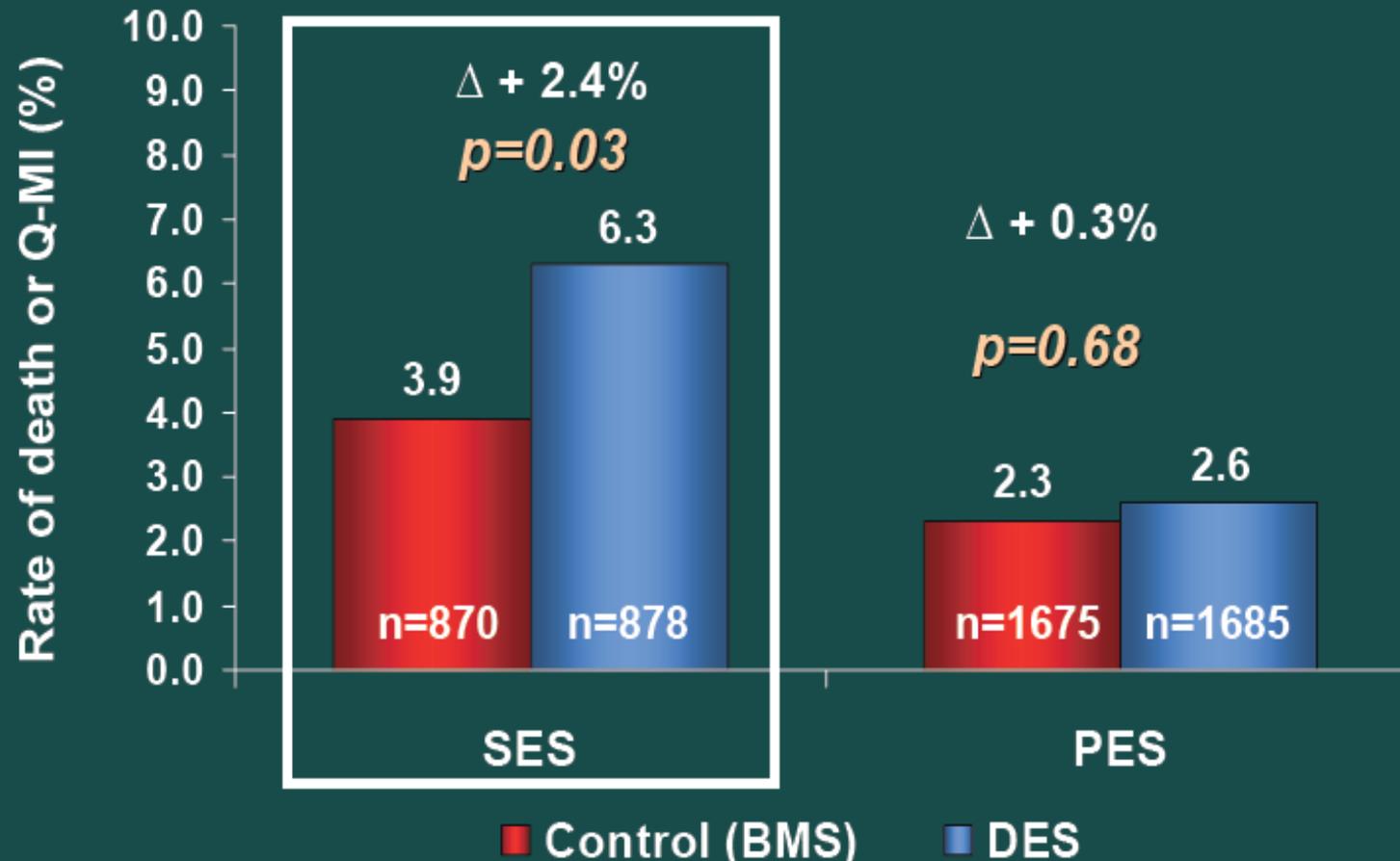
**Are These  
As Safe As  
You Think?**

\$4.99 | CANADA \$6.99

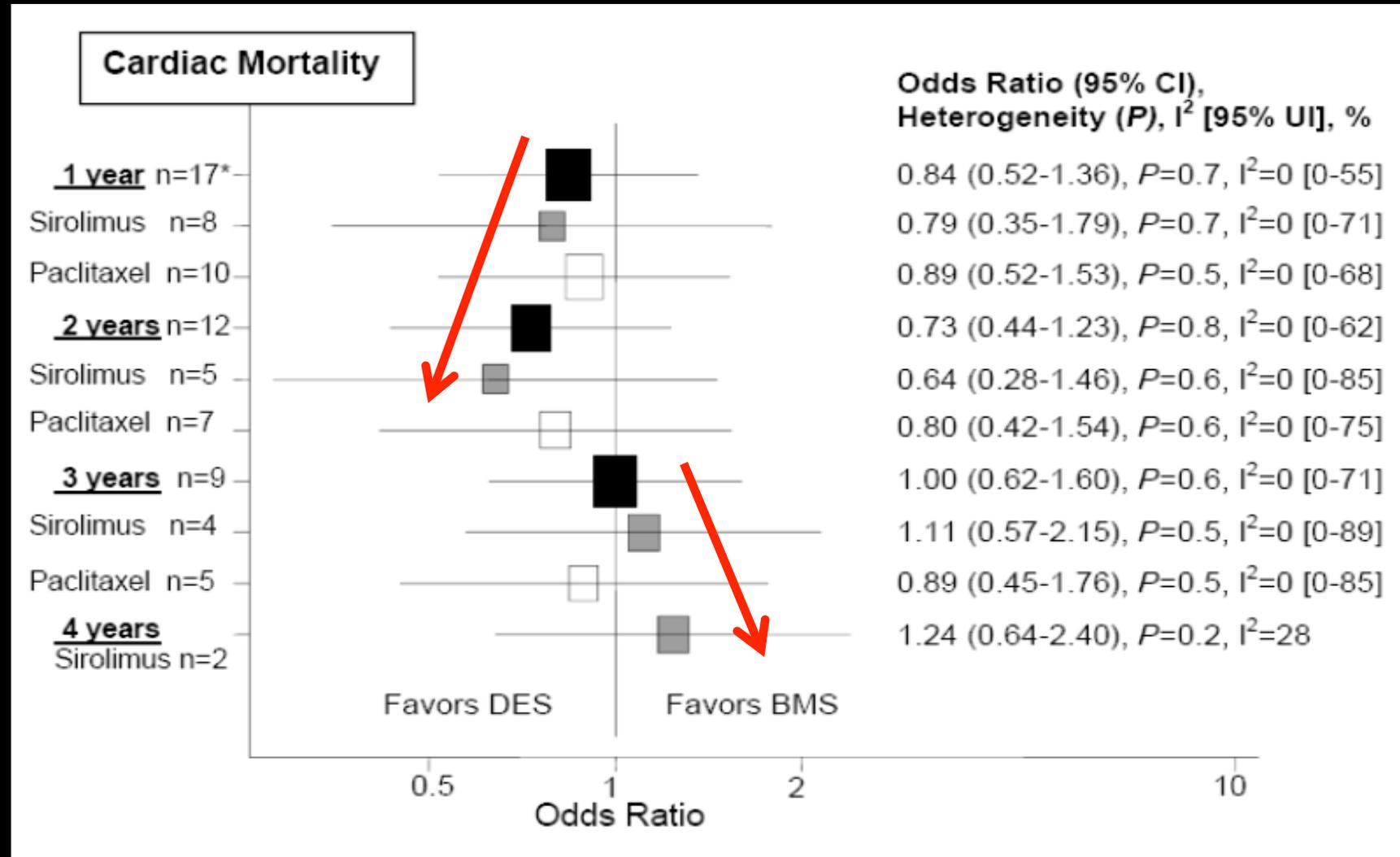


# Incidence of Serious Adverse Events (Death or MI)

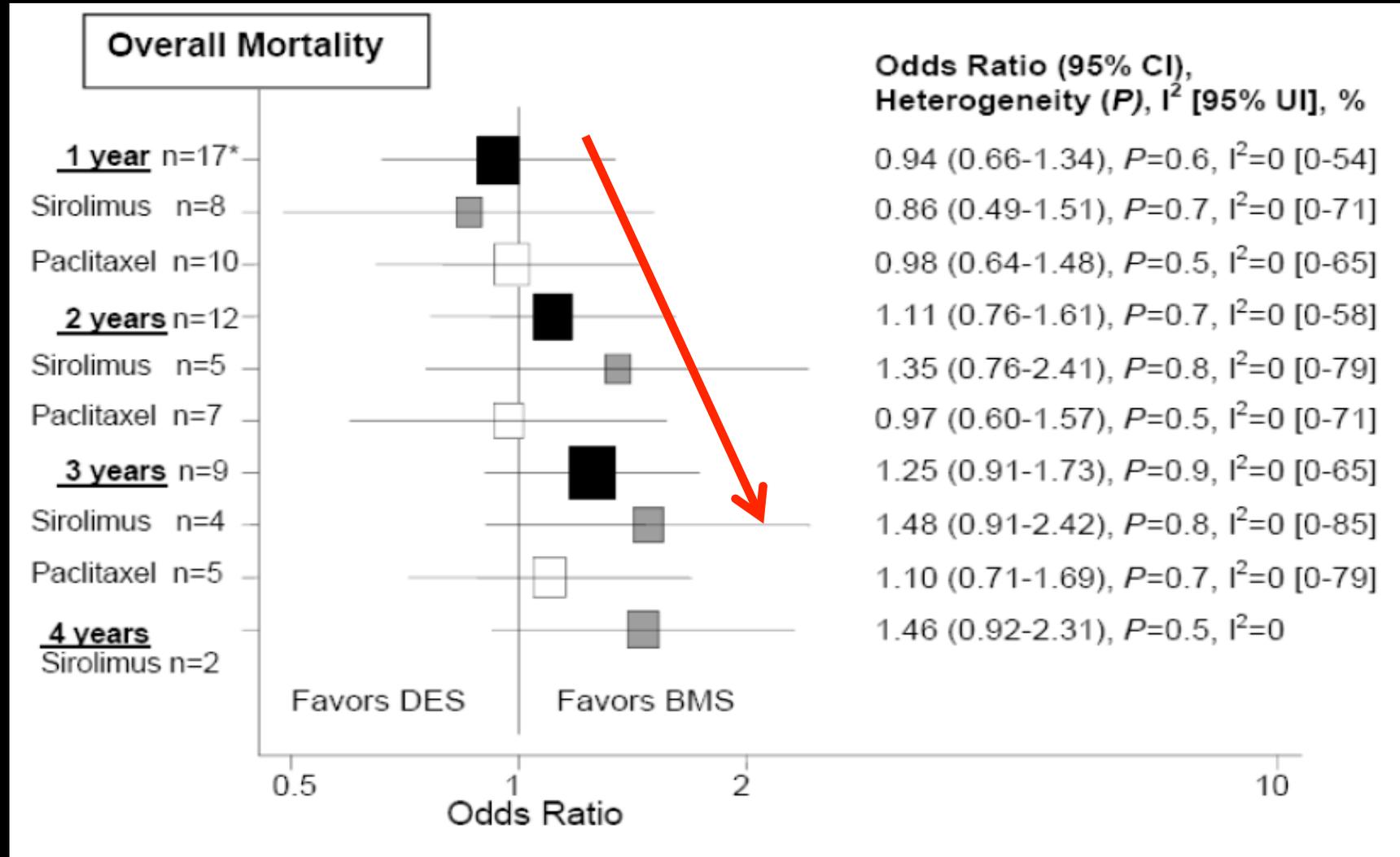
All randomized studies up to latest available follow-up



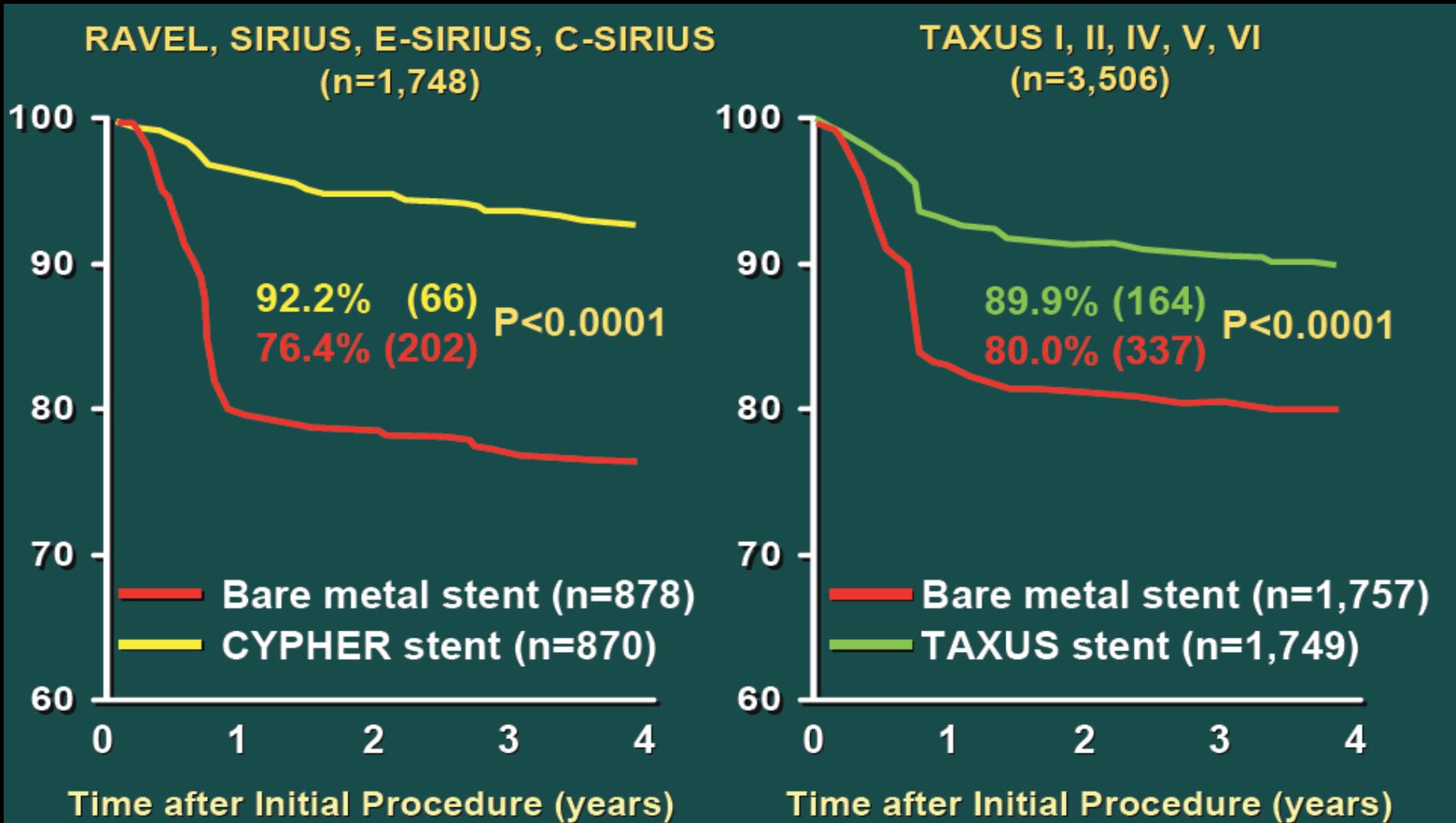
# Meta analysis of 17 RCT



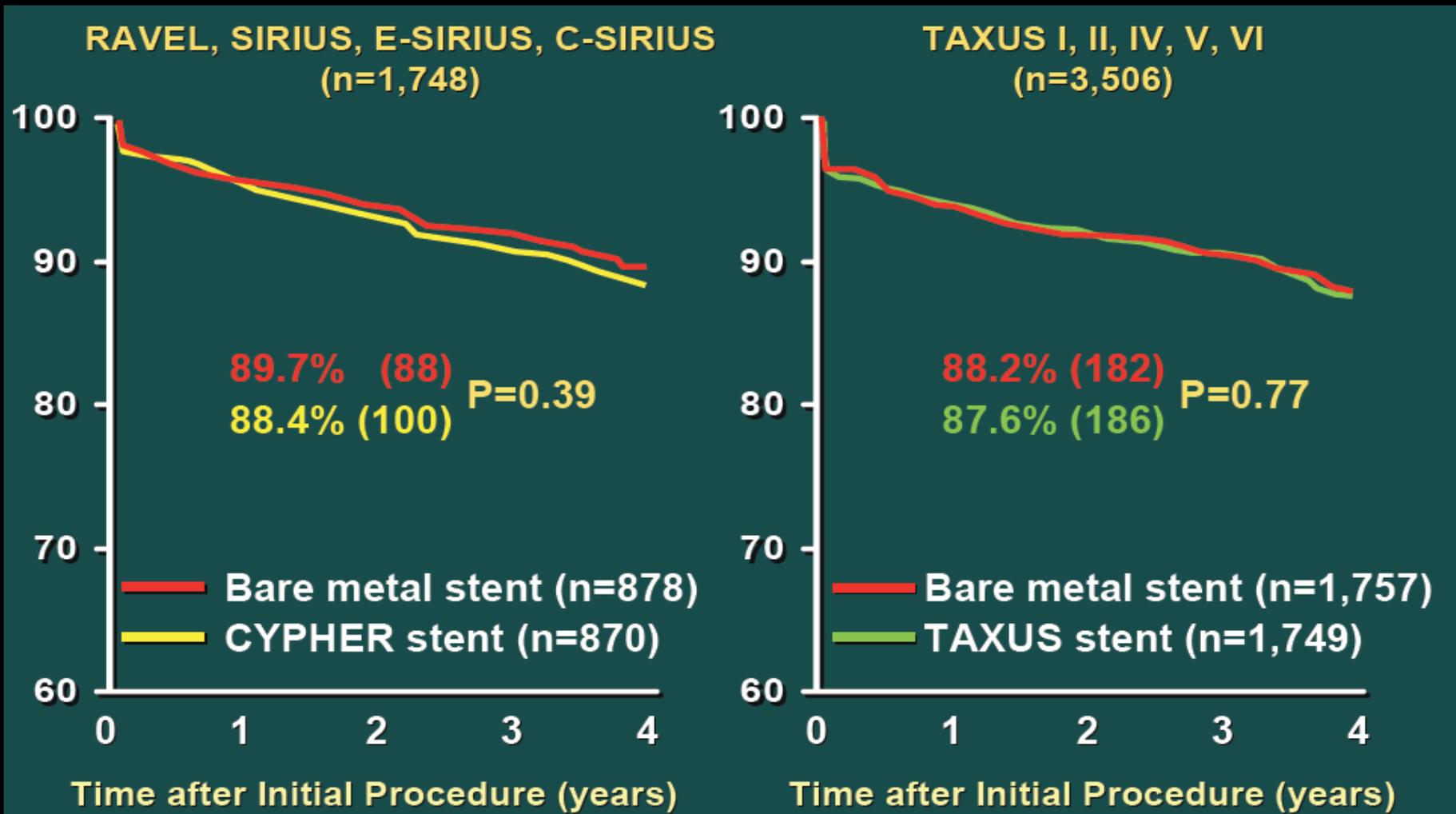
# Meta analysis of 17 RCT



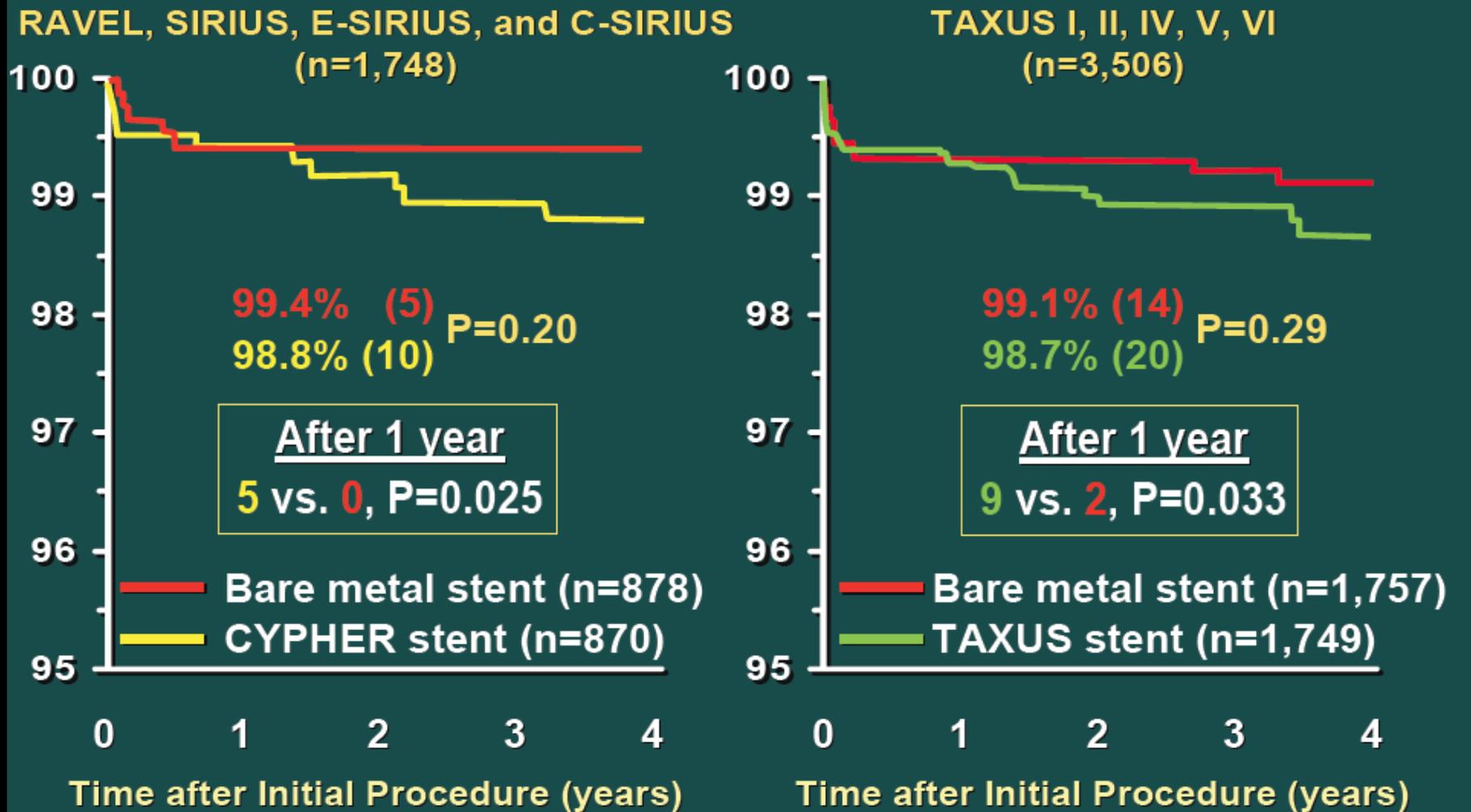
Meta analysis including 9 Prospective, Double-Blind, RT :  
Freedom from ischemic target lesion revascularization



# Meta analysis including 9 Prospective, Double-Blind, RT : Freedom from Death or myocardial Infarction



# Meta analysis including 9 Prospective, Double-Blind, RT : Freedom from Stent Thrombosis



# The Swiss Network Meta-Analysis : 38 RCT's Comparing 1st generation DES with BMS

Meta-Analyse : **38** études randomisées, **18 023** patients, Suivi jusqu'à **4 ans**

Critères primaires : Mortalité, Mortalité Cardiaque, causes de décès et d'IDM,  
Thromboses de Stents (ARC Confirmées)

## SES vs BMS

RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS, SES-SMART,  
DIABETES, Pache et al, PRISON II, SCANDSTENT, TYPHOON  
SESAMI, DECODE, SCORPIUS, RRISC, MISSION, Ortolani et al

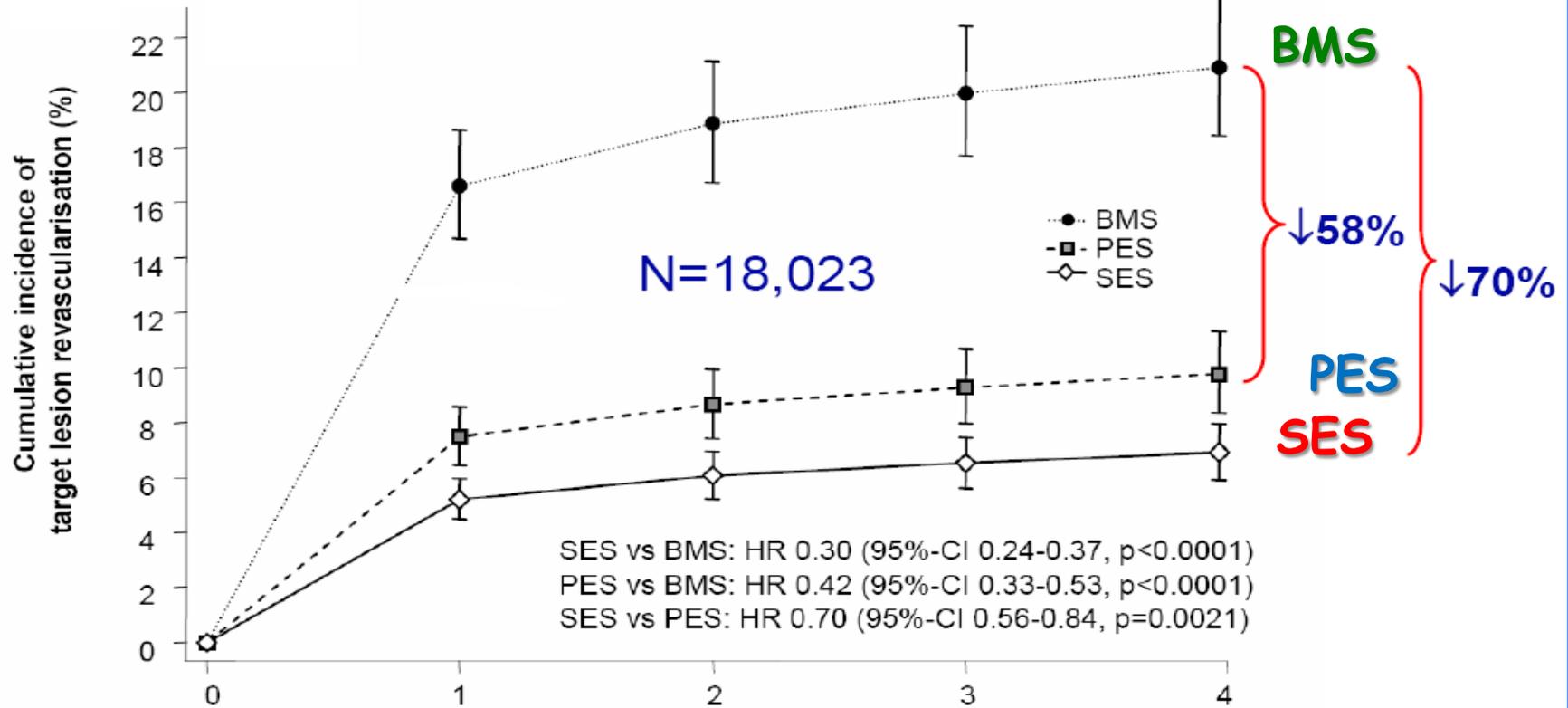
## PES vs BMS

TAXUS I, II, IV, V, VI / PASSION / HAAMU-STENT

## SES vs PES

TAXi, ISAR-DESIRE, ISAR-DIABETES, SIRTAX, CORPAL, REALITY, PROSIT,  
ISAR-SMART 3, Zhang et al, Han et al, LONG DES II,, SORT OUT II,  
Cervinka et al, Petronio et al, BASKET

# SES vs BMS vs PES : TLR (critère secondaire)

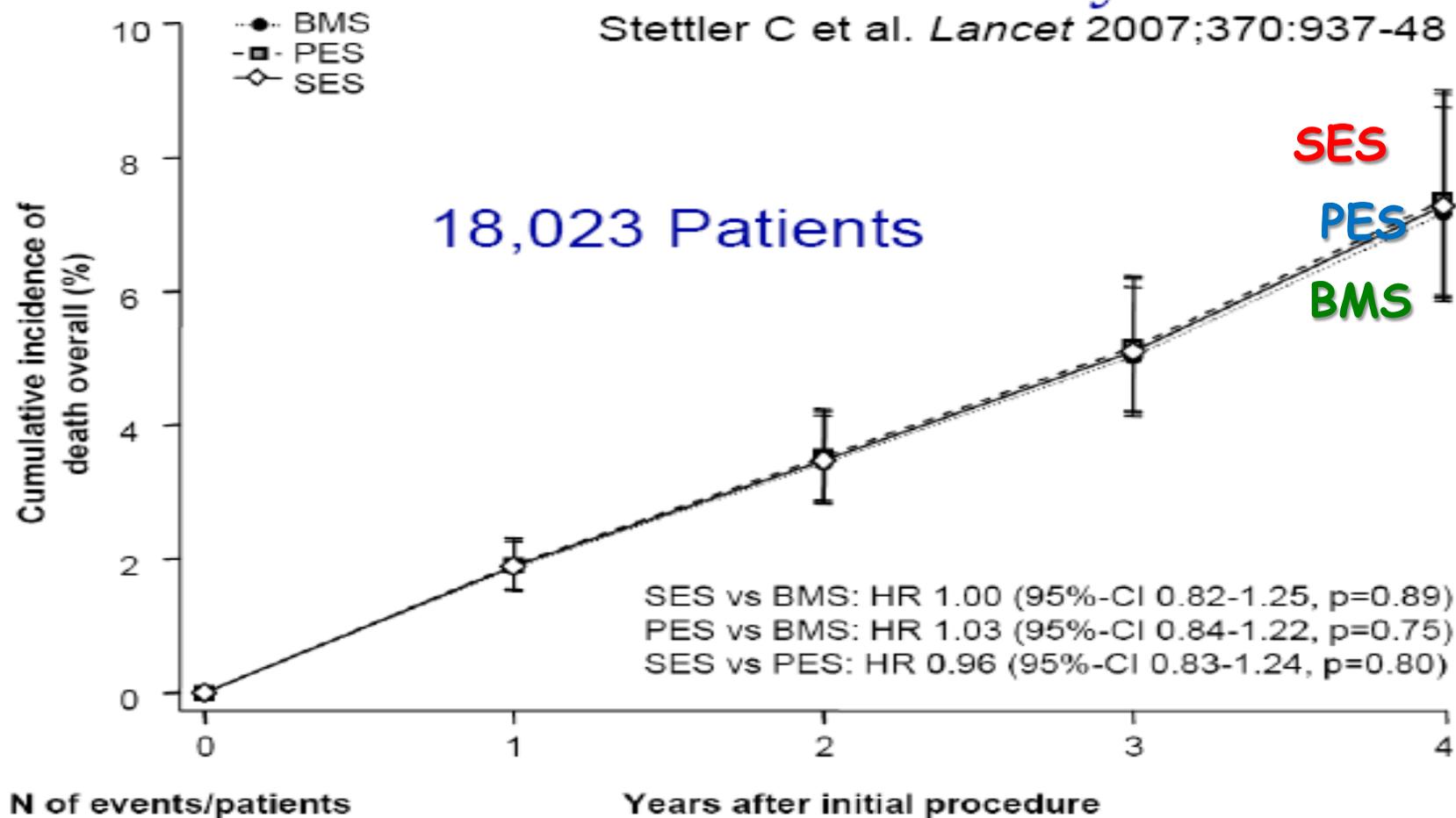


N of events/patients

Years after initial procedure

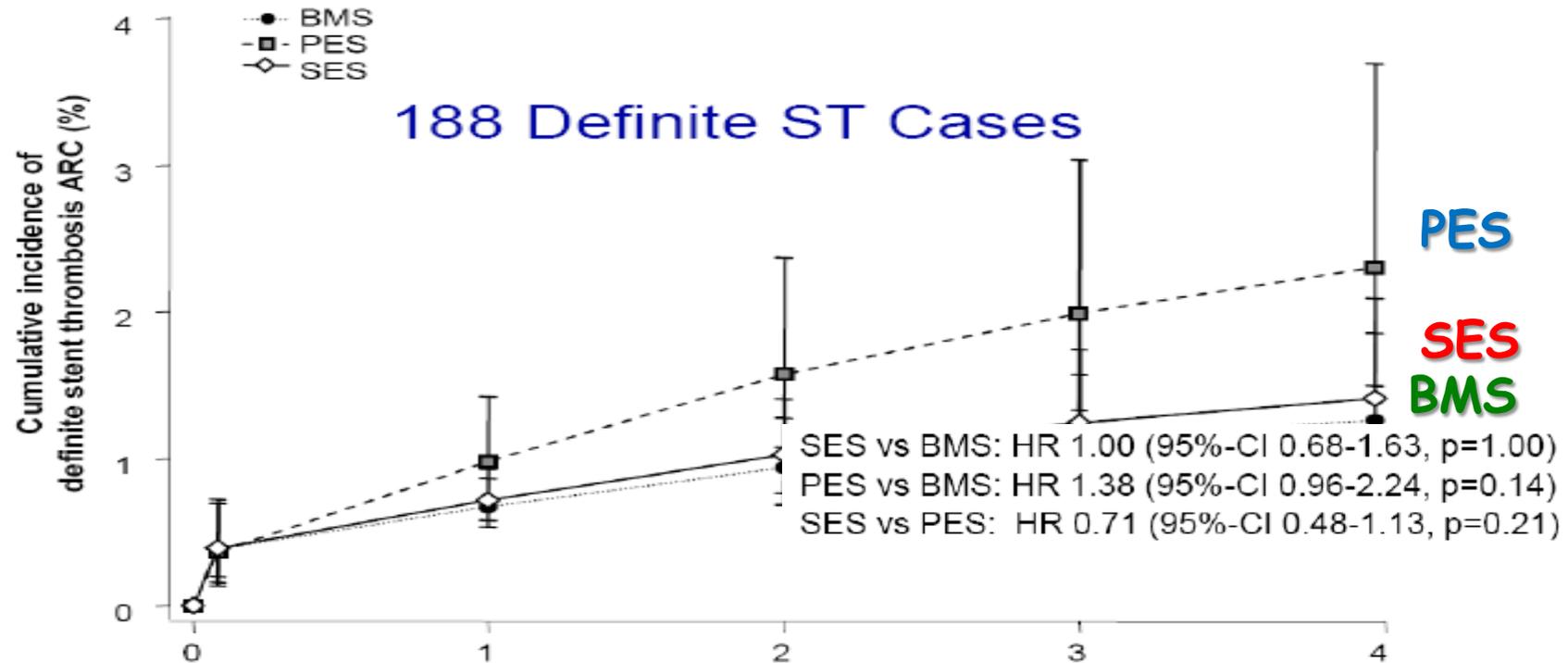
BMS	4763	820/4746	53/2795	22/1871	10/1543
PES	6328	448/6280	98/3950	15/1999	6/832
SES	6621	356/6580	68/3801	16/2153	14/999

# SES vs BMS vs PES : Mortalité „toute cause“



BMS	4921	109/4904	48/3340	31/2264	44/1875
PES	6331	138/6283	78/4263	32/2187	15/869
SES	6771	139/6730	72/4041	38/2340	24/1081

# SES vs BMS vs PES : Thrombose Stent (ARC critères)

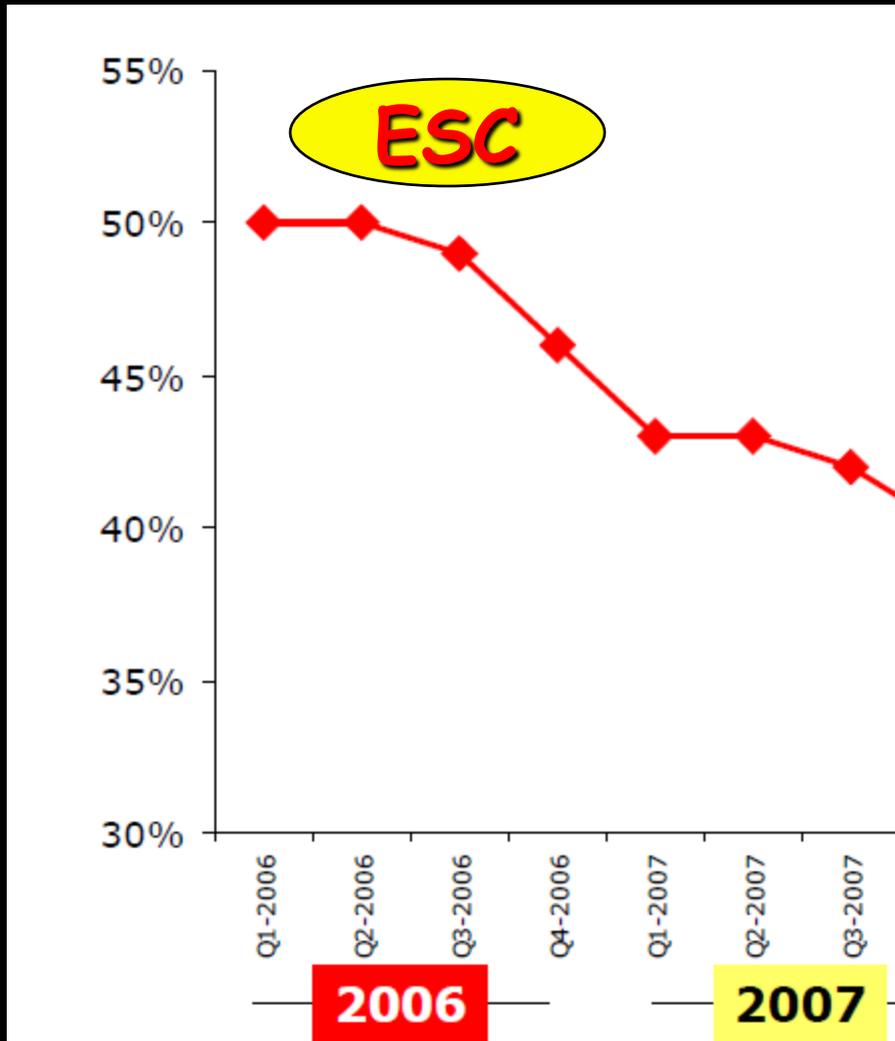


N of events/patients

Years after initial procedure

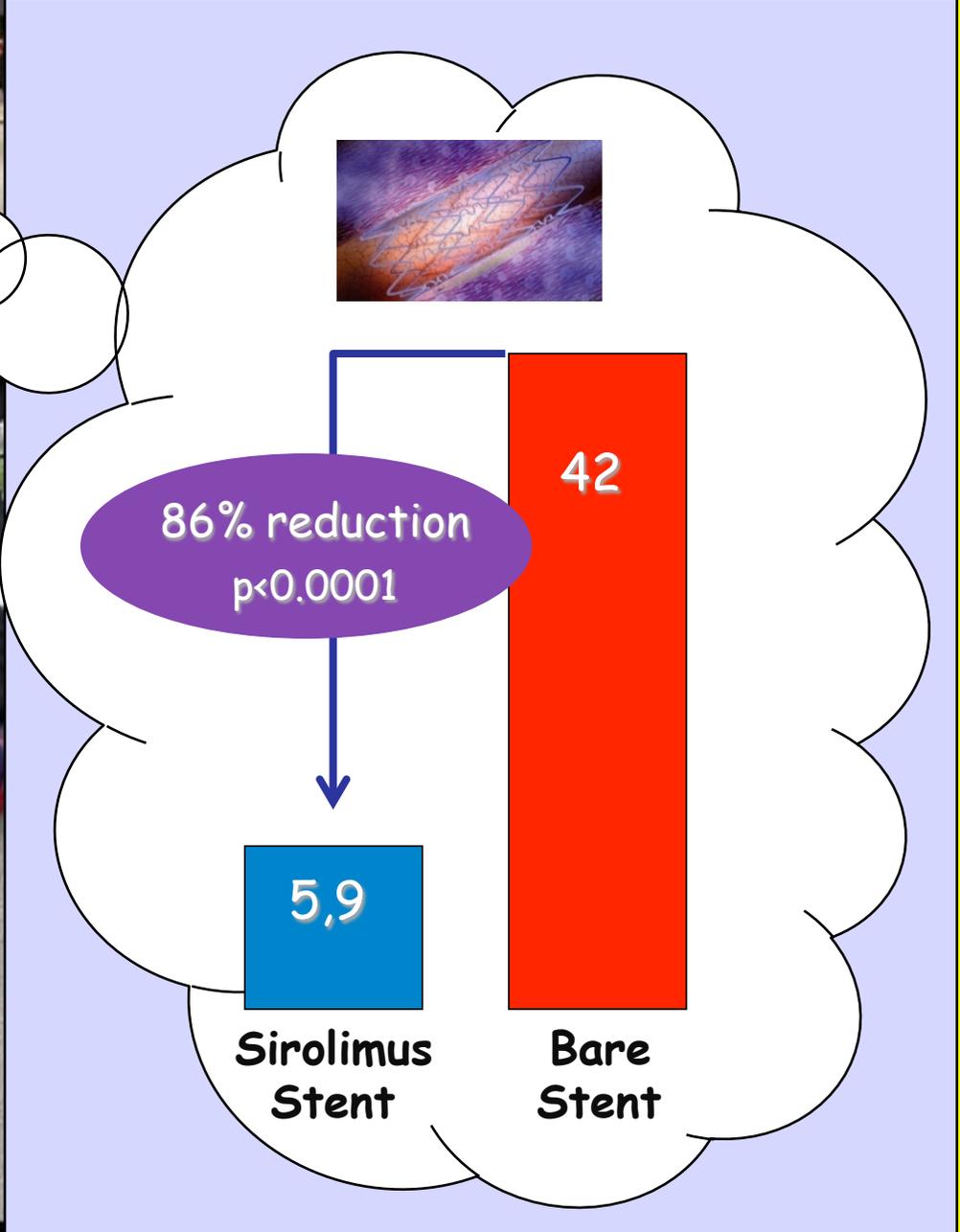
BMS	4003	42/4000	4/3048	3/1928	1/1806
PES	4327	46/4321	20/3711	5/1853	1/762
SES	4643	52/4642	9/3804	3/2257	2/1070

# Utilisation stent "ACTIF" (FRANCE)



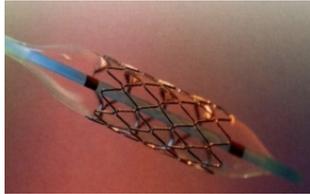
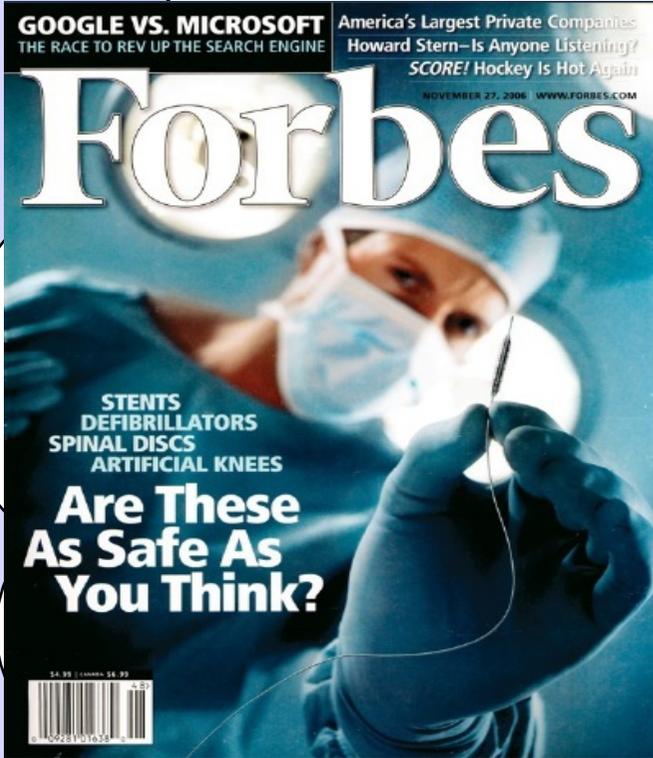


**ACTIF ?**





Sirolimus 16 Months after Deployment



**ACTIF ?**

**PASSIF ?**

**H.A.S**



