

# Umsetzung von Studienergebnissen in die klinische Praxis

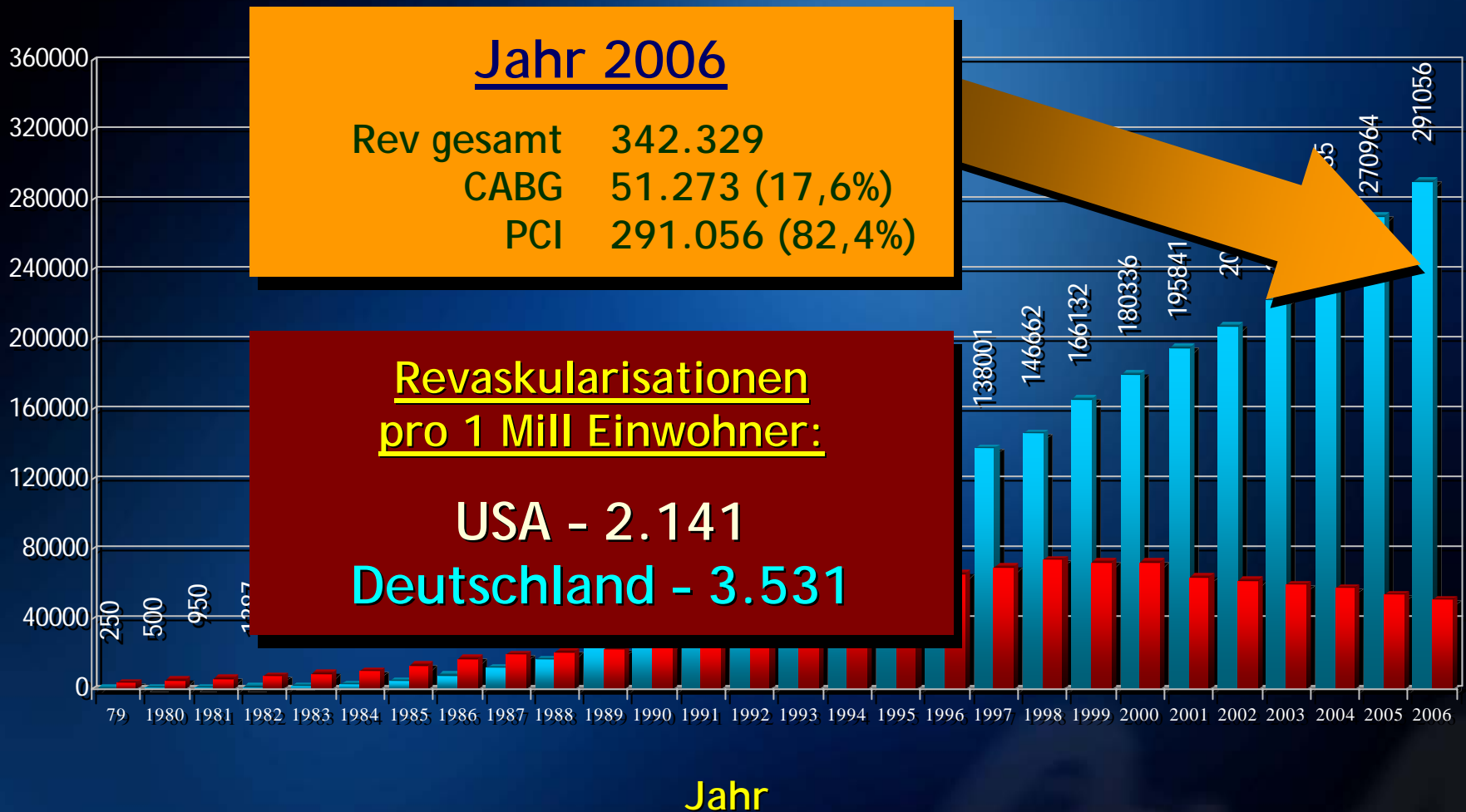
## Beispiel Kardiologie: Drug-eluting Stents

**Wolfgang Rutsch**

Leiter des Bereichs Herzkatheterlabore

Medizinische Klinik mit Schwerpunkt Kardiologie und Angiologie  
Klinik- und Zentrumsdirektor Prof. Dr. med. Gert Baumann  
Charité, Universitätsmedizin Berlin, Campus Charité Mitte

# Entwicklung von PCI und koronarchirurgischen Eingriffen in Deutschland zwischen 1979 - 2006

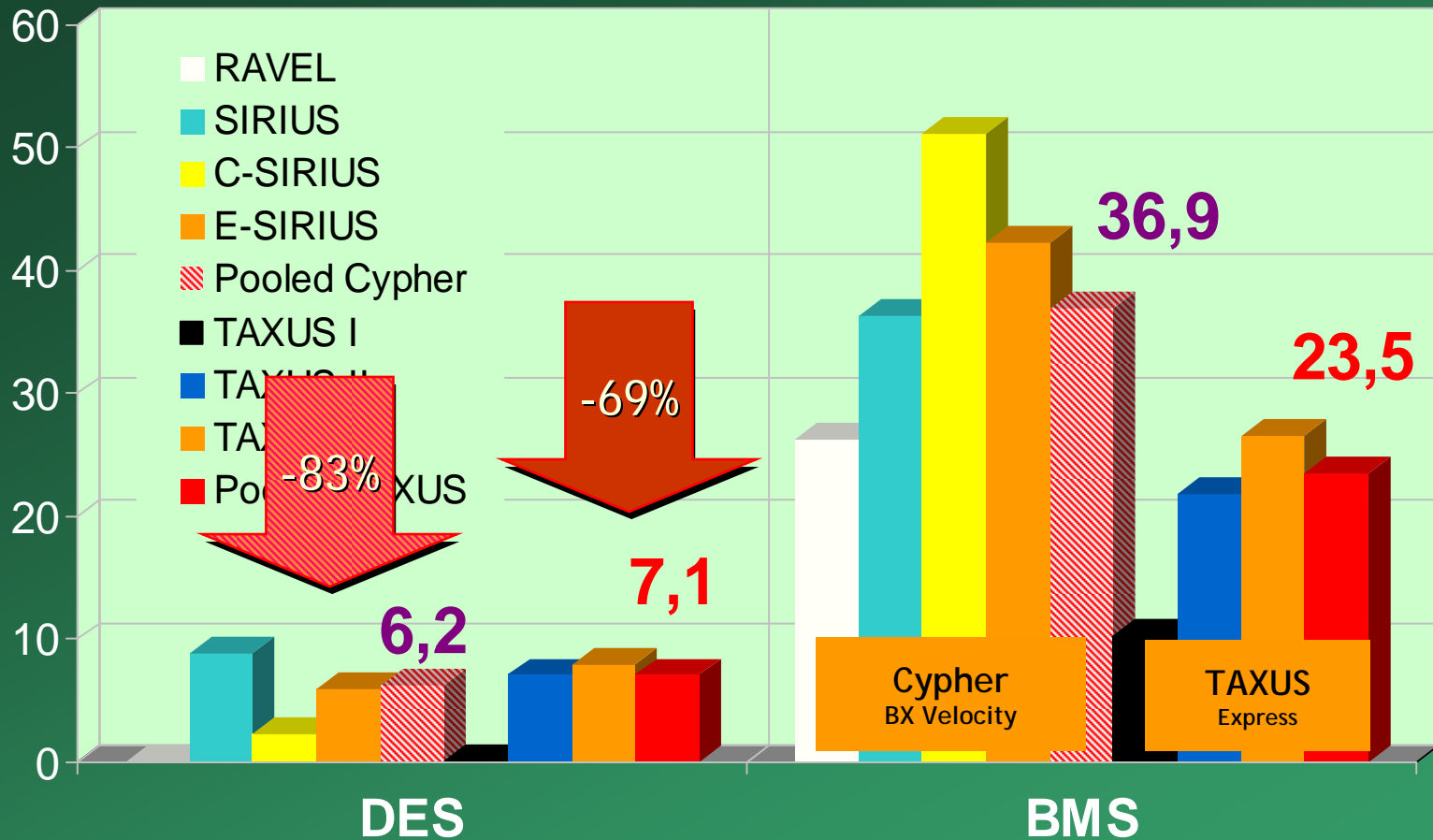


# Angiographic Restenosis in Clinical Trials

Author	Year	n	Treatment	RR, %
Raizner et al	1988	539	Prostacyclin	47
Schwartz et al	1988	625	Aspirin-dipyridamole	39
Ellis et al	1989	416	i.v. heparin	39
M-HEART	1990	1235	Corticosteroid	43
Franzen et al	1990	329	Fish oil	35
Knudtson et al	1990	494	Prostacyclin	30
CCAT	1993	136	PTCA vs. DCA	43
CAVEAT	1993	500	PTCA vs. DCA	58
BENESTENT I	1994	257	PTCA vs. stent	32
STRESS	1994	202	PTCA vs. stent	42
Weintraub et al	1994	404	Lovastatin	41
M-HEART-II	1995	752	Thromboxane antagonist	45
MARCATOR	1995	1436	Cilazapril	36
BOAT	1996	492	PTCA vs. DCA	40
BENESTENT II	1996	203	PTCA vs. stent	21
<b>TOTAL</b>				<b>38%</b>

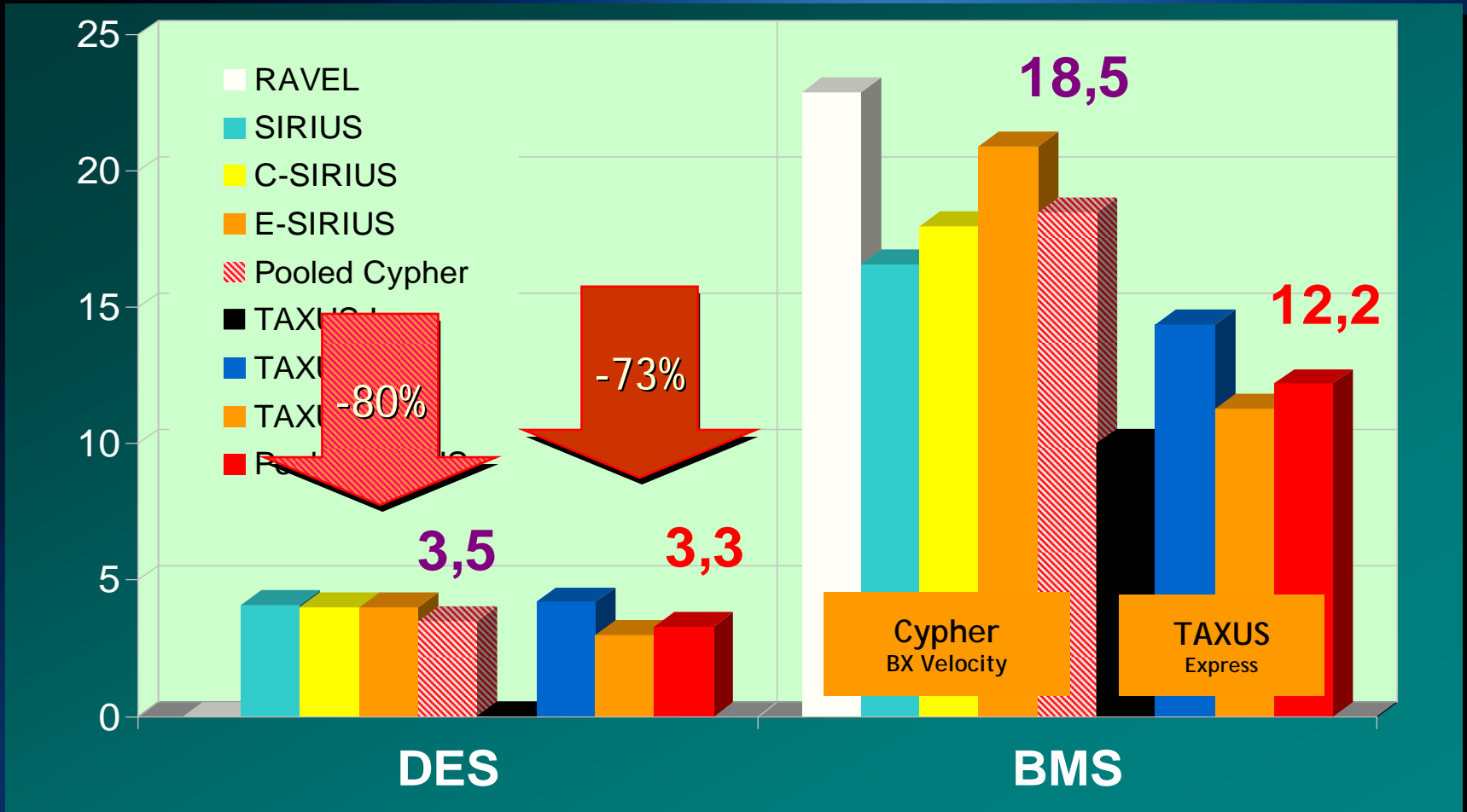
# Restenosis Rates in Randomized Trials of DES

A hierarchical Bayesian meta-analysis of randomised clinical trials of DES  
 MN Babapulle, et al. Lancet 2004, 364:583-591



# Target Lesion Revascularization Rates in Randomized Trials Investigating DES

A hierarchical Bayesian meta-analysis of randomised trials of DES MN Babapulle, et al. Lancet 2004, 364:583-591



# DES-Thrombose „Firestorm ESC Barcelona 2006“

Camenzind E, ESC 2006, Oral Presentation #992

TUESDAY


## ESC Congress News

World Congress of Cardiology 2006  
The unique meeting of the European Society of Cardiology Congress 2006 and the World Heart Federation's XVth World Congress of Cardiology

### Do drug-eluting stents increase deaths?

TWO SEPARATE, independent meta-analyses, presented in Hot Line session I, suggest drug-eluting stents (DES) may increase death, Q-wave myocardial infarction (clinical surrogates of in-stent thrombosis) and cancer deaths, bringing the long-term safety of DES firmly into the spotlight. Discussant Salim Yusuf (McMaster University, Canada) hailed the data as one of the 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."

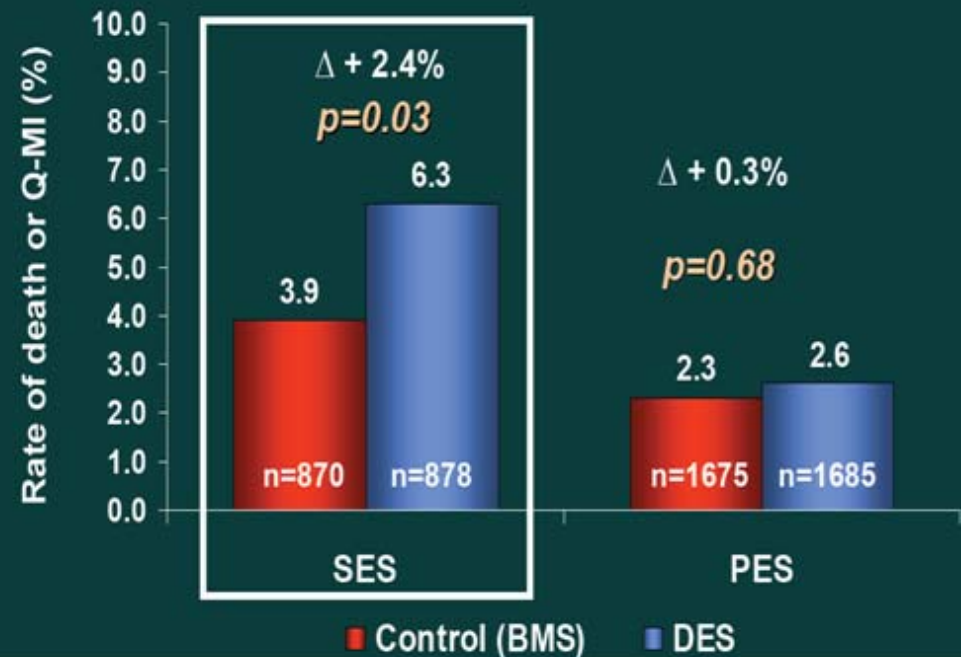


obtain this data from the manufacturer," said Nordmann. He speculated that the increase in cancer might be due to a rapid impairment of the immune system.

Yusuf widened the debate to include percutaneous coronary intervention (PCI). "The overuse of PCI is an insidious change in the culture of cardiology that needs to be reversed," 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

All randomized studies up to latest available follow-up



Analyse aller damals verfügbaren, publizierten, randomisierten Studien, Analyse auf Studienebene!

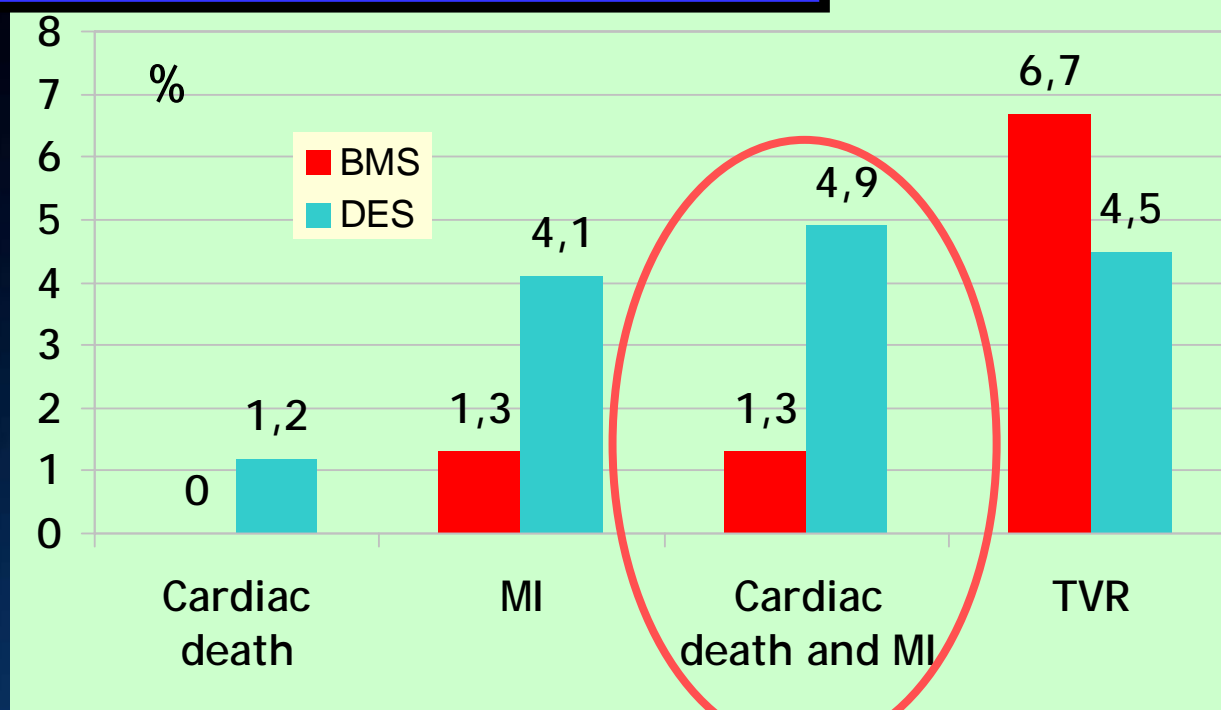
## Late Clinical Events After Clopidogrel Discontinuation May Limit the Benefit of Drug-Eluting Stents

An Observational Study of Drug-Eluting Versus Bare-Metal Stents

Matthias Pfisterer, MD, FACC,\* Hans Peter Brunner-La Rocca, MD,\* Peter T. Buser, MD, FACC,\* Peter Rickenbacher, MD,§ Patrick Hunziker, MD,† Christian Mueller, MD,‡ Raban Jeger, MD,\* Franziska Bader, RN,\* Stefan Osswald, MD, FACC,\* Christoph Kaiser, MD,\* for the BASKET-LATE Investigators

Basel, Switzerland

# BASKET-LATE

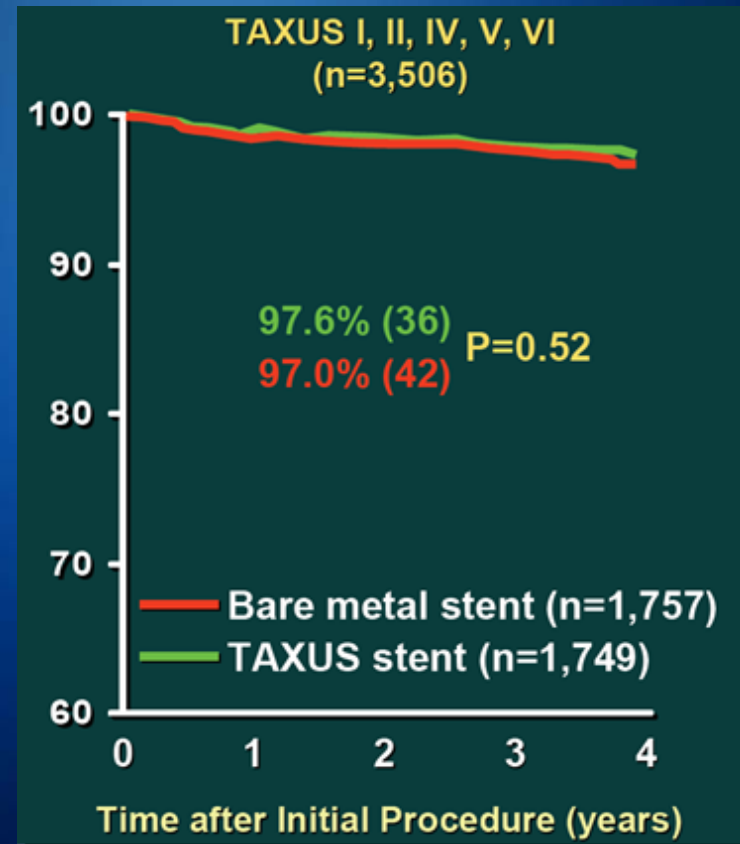
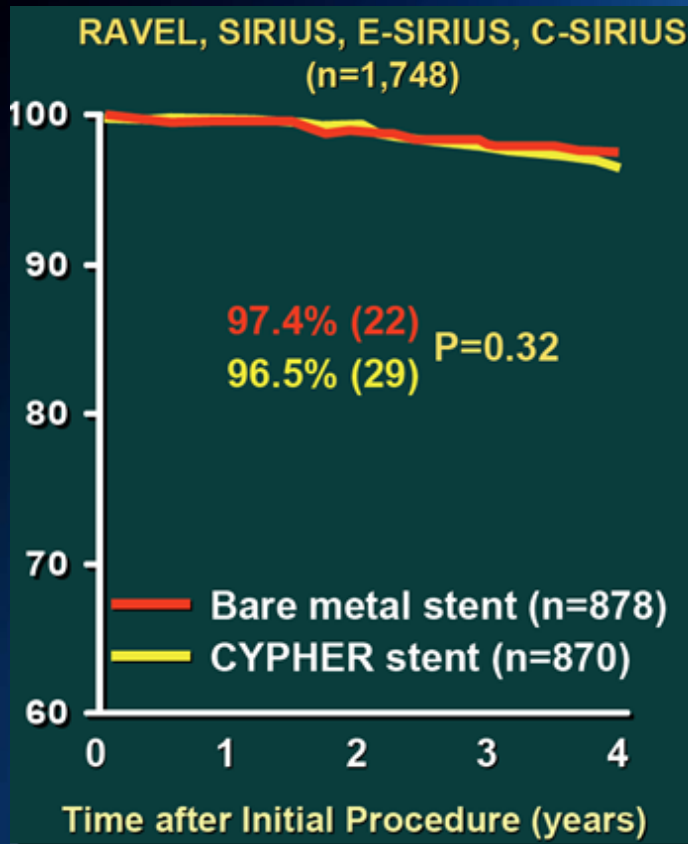


**Late major cardiac events (months 7 to 18).** Cardiac death or nonfatal myocardial infarction (MI), was significantly greater in drug-eluting stent (blue) versus bare-metal stent (red) groups, which contrasts with a trend toward a lower restenosis-related target vessel revascularization (TVR) rate after drug-eluting stents.

# 9 Prospective, Double-Blind, Randomized Trials

## Freedom From Cardiac Death

Independent CRF patient-level meta-analysis

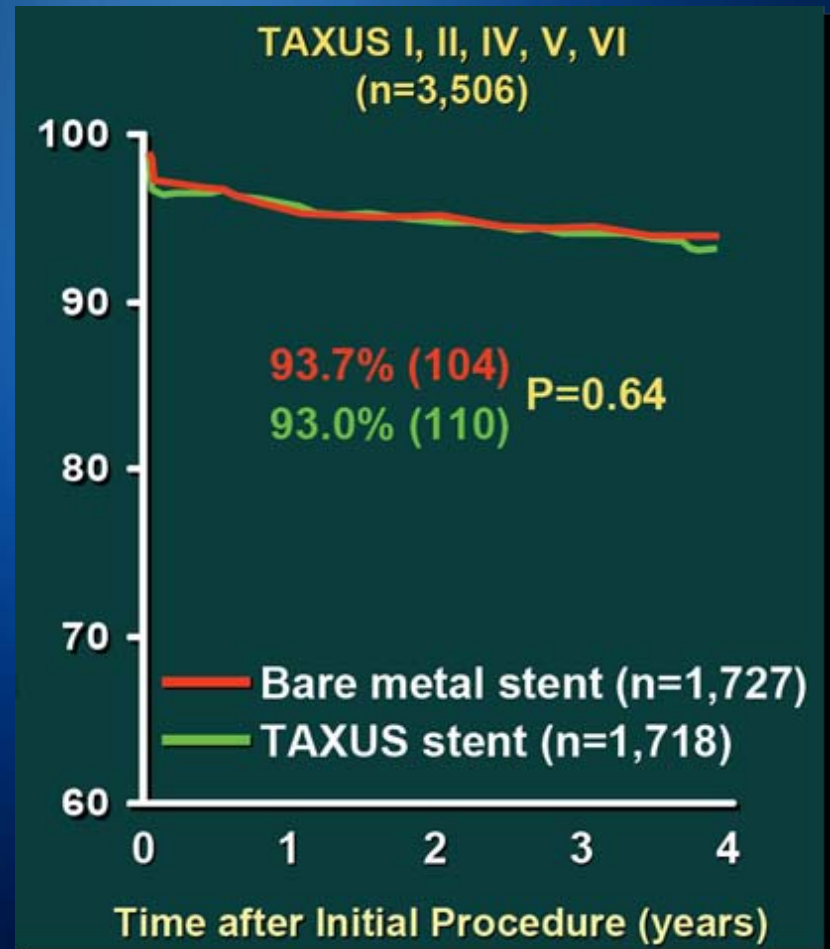
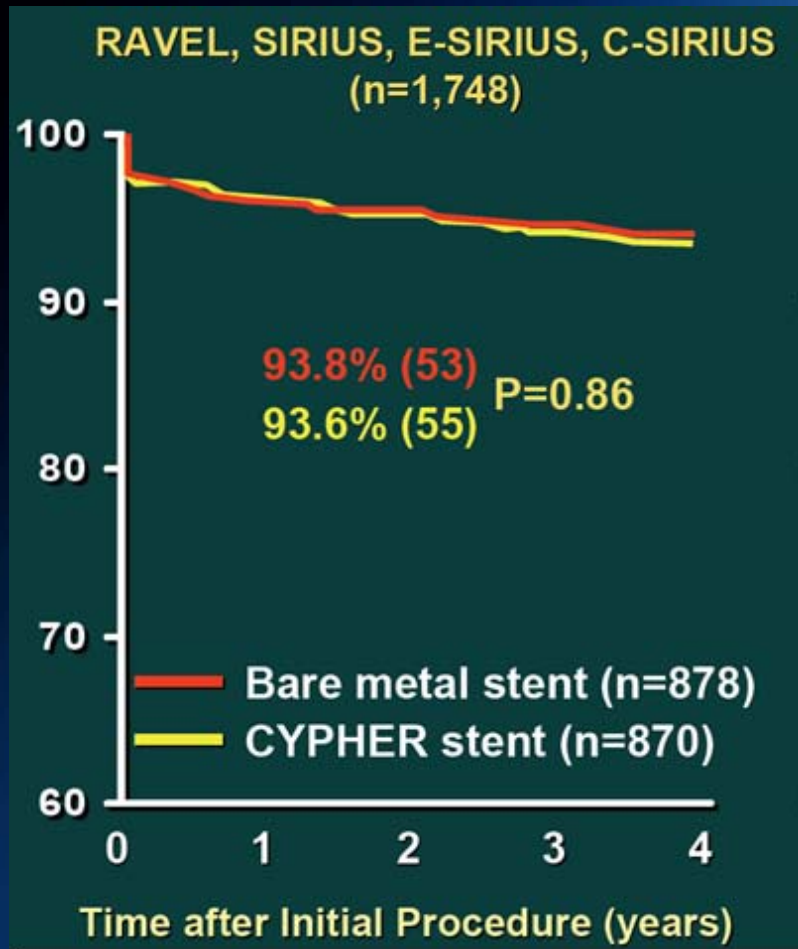




# 9 Prospective, Double-Blind, Randomized Trials

## Freedom From Myocardial Infarction

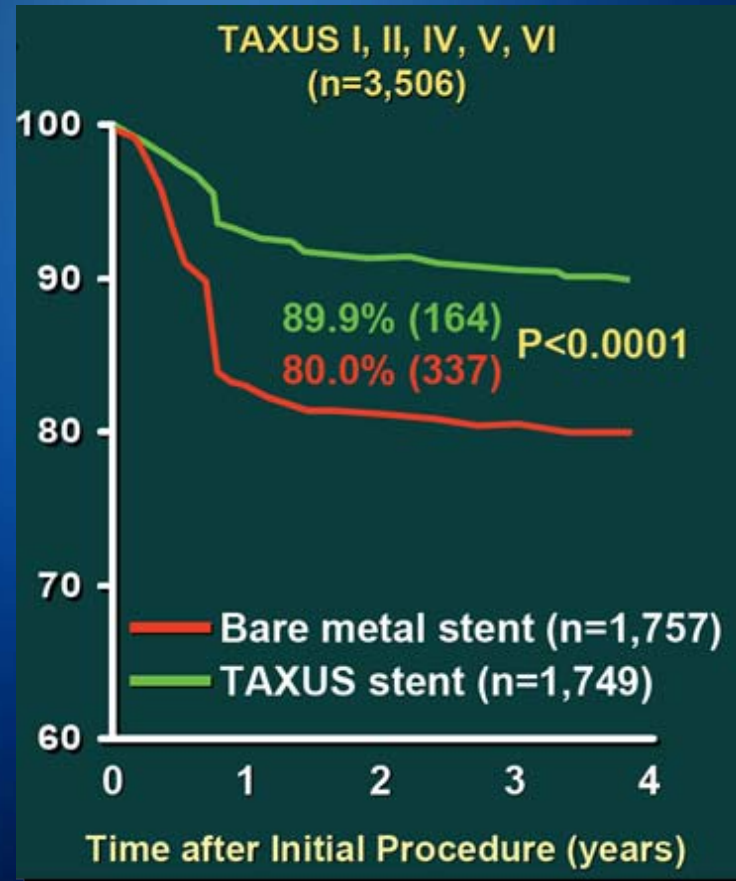
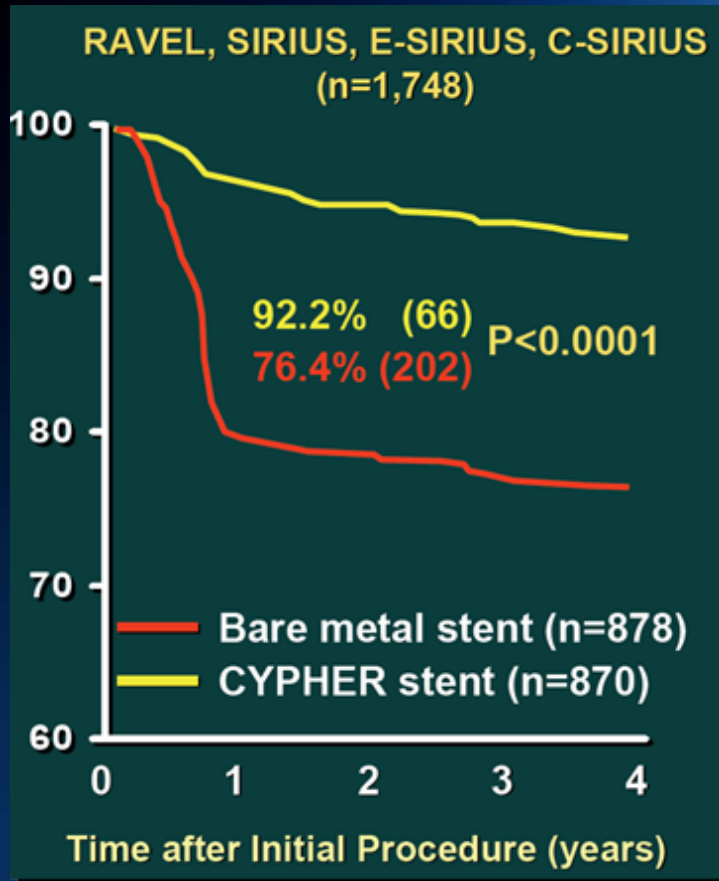
Independent CRF patient-level meta-analysis



# 9 Prospective, Double-Blind, Randomized Trials

## Freedom From Ischemic TLR

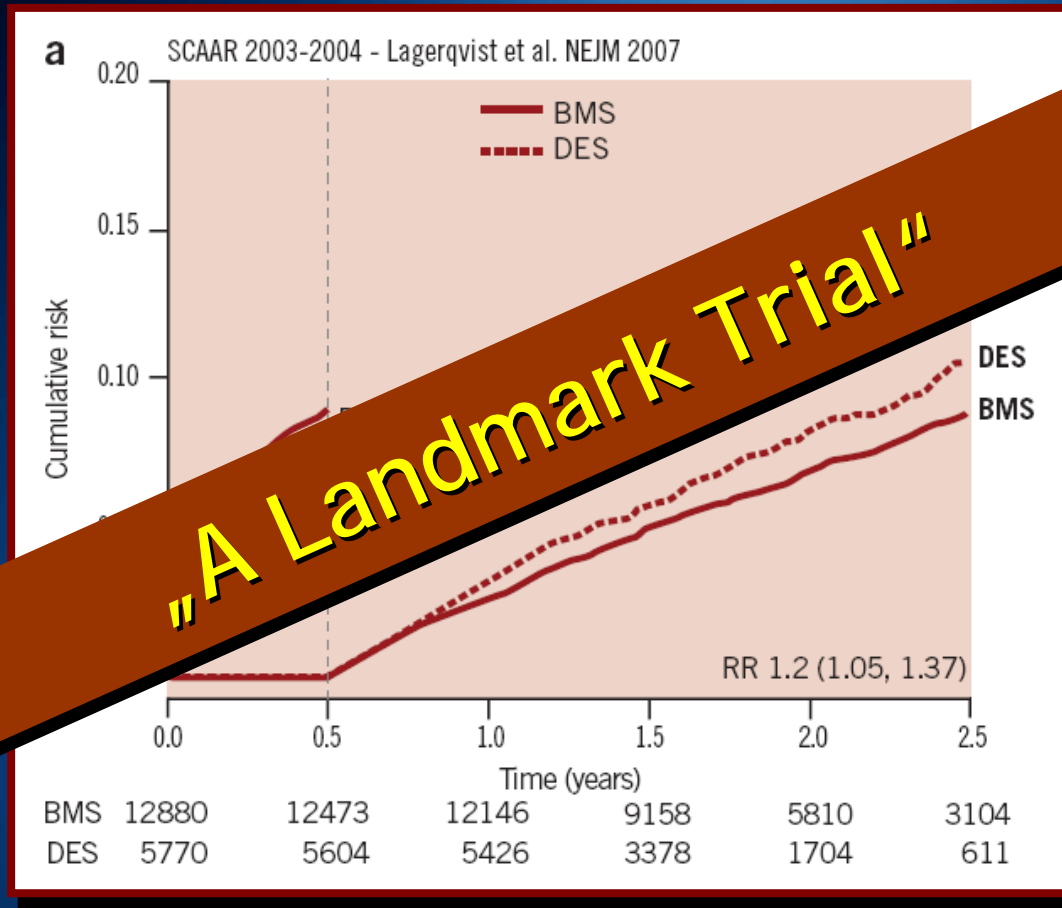
Independent CRF patient-level meta-analysis



# SCAAR - Swedish Coronary Angiography and Angioplasty Registry

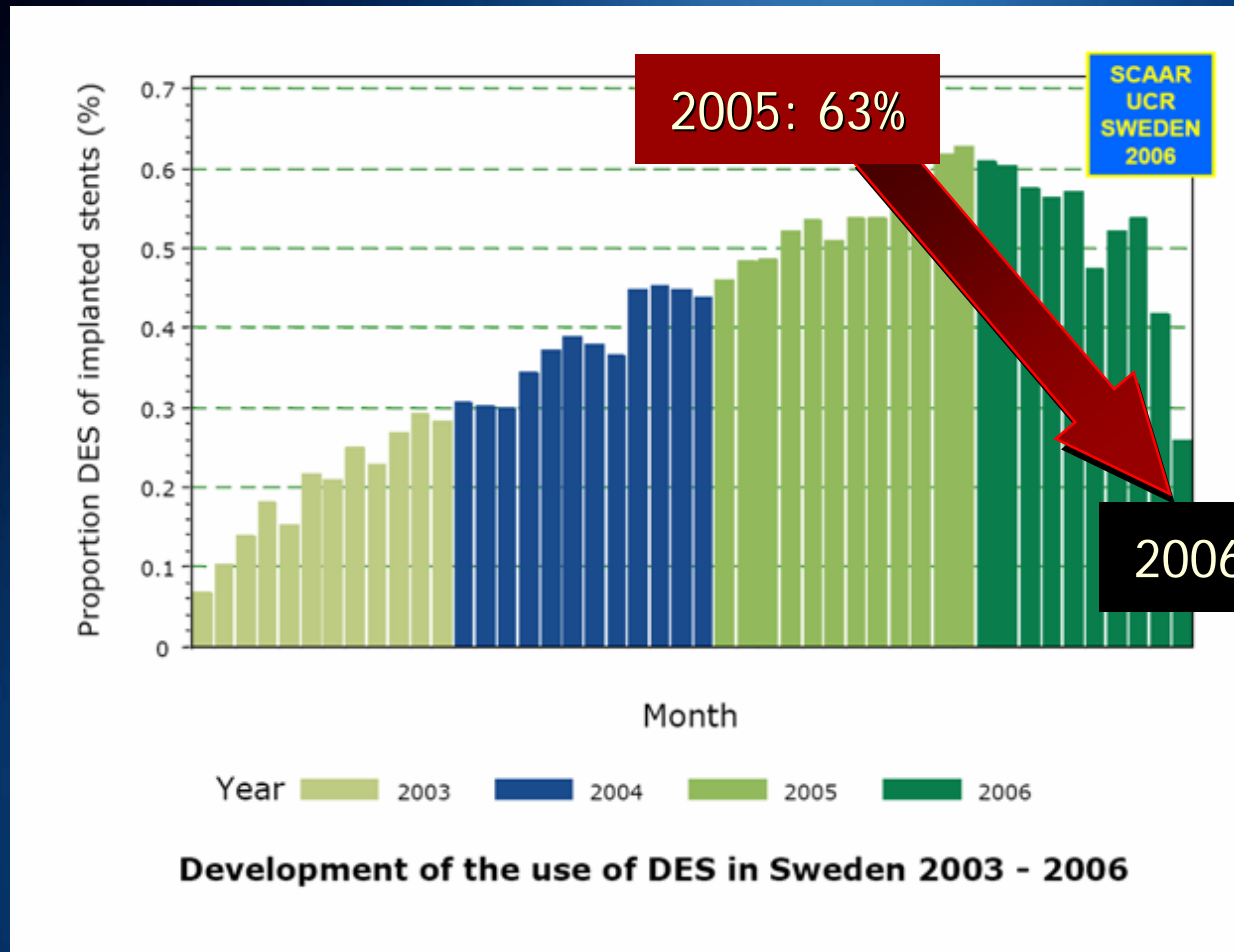
Lagerqvist B, et al, for the SCAAR Study Group, NEJM 2007

6-month cumulative incidence of *death and myocardial infarction* of the 2003-2004 cohort of the SCAAR registry.



# SCAAR - Swedish Coronary Angiography and Angioplasty Registry

Lagerqvist B, et al, for the SCAAR Study Group, NEJM 2007

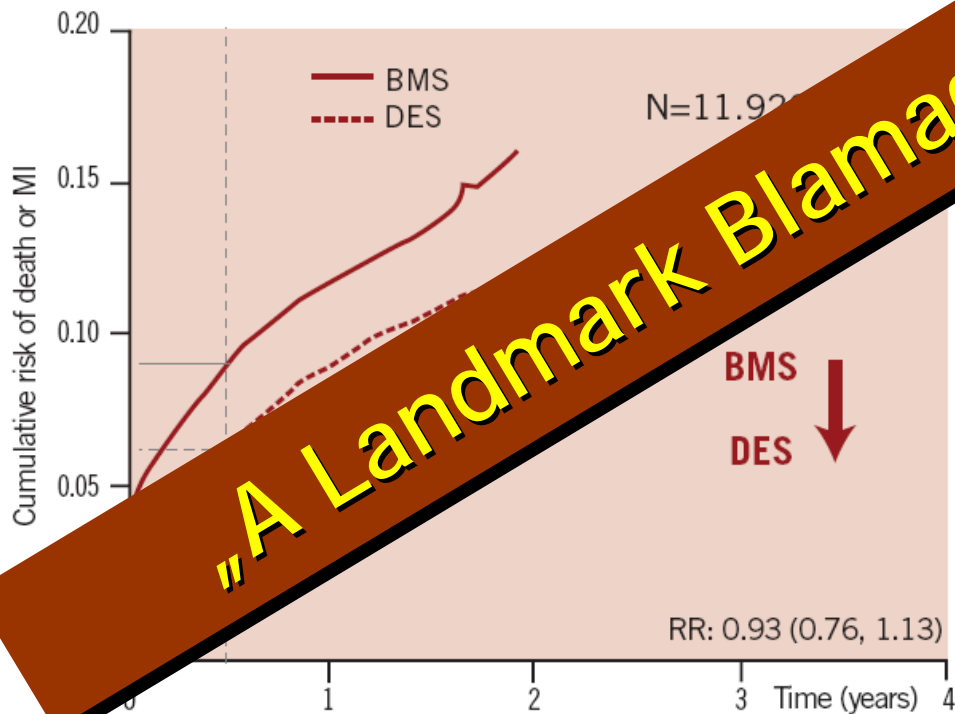


# The SCAAR registry or the Swedish yo-yo

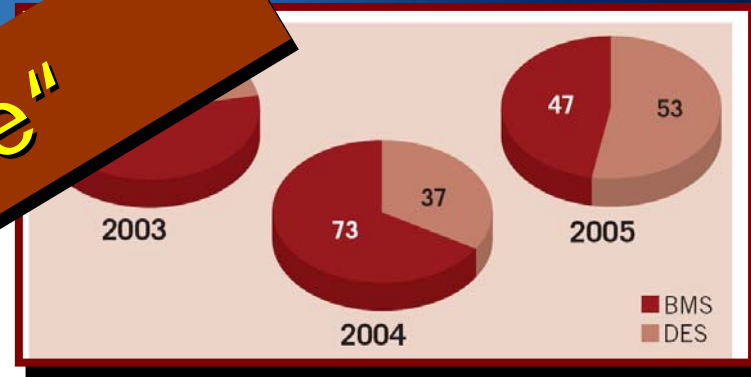
Patrick W. Serruys\*, MD PhD; Joost Daemen, MD

Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands, EuroIntervention Nov 2007

6-month cumulative incidence of *death and myocardial infarction* of the 2005 cohort of the SCAAR registry.



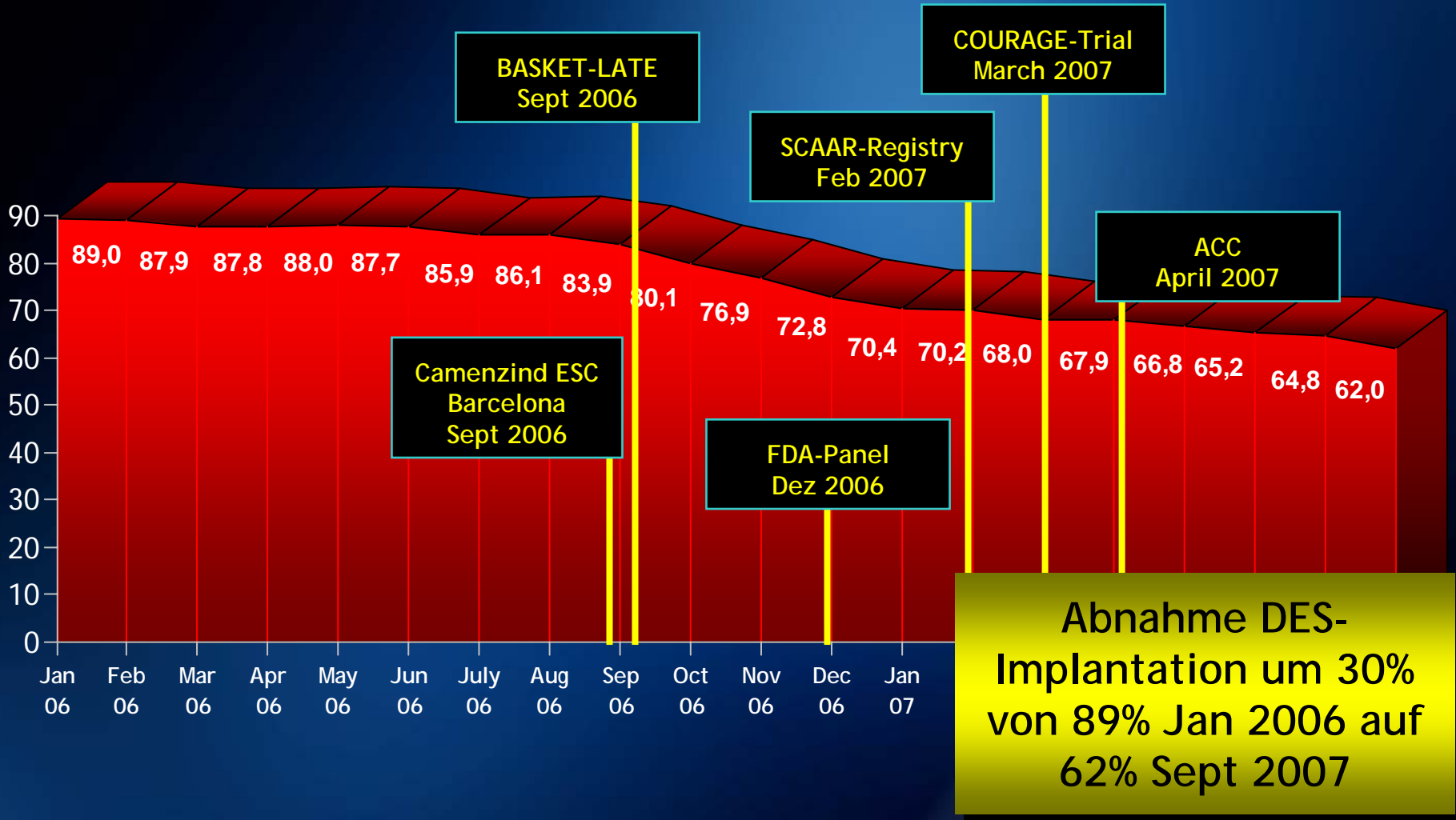
BMS	5584	5061	4949	2611	0	0	0	0	0
DES	6336	5963	5809	2573	0	0	0	0	0



Percentage of DES and BMS use per year in Sweden (SCAAR registry)

# DES Penetration in the US

Source: Millenium Research Group



# Academic Research Consortium (ARC)

## Definitions of Stent Thrombosis

### Timing

- Acute stent thrombosis: 0-24 h after stent implantation
- Subacute stent thrombosis: 24 h-30 d after stent implantation
- Late ST: 30 d-1 y after stent implantation
- Very late ST\*: 1 y after stent implantation

### Three categories of evidence in defining stent thrombosis

- Definite stent thrombosis
- Probable stent thrombosis
- Possible ST

# Academic Research Consortium Definitions of ST in a Pooled Meta- Analysis of the Randomized RAVEL, SIRIUS, E-SIRIUS, and C-SIRIUS Trials



**Are drug-eluting stents associated with a higher rate of late thrombosis than bare metal stents?**

## Late Stent Thrombosis

*A Nuisance in Both Bare Metal and Drug-Eluting Stents*

*Patrick W. Serruys, MD, PhD; Joost Daemen, MD*

