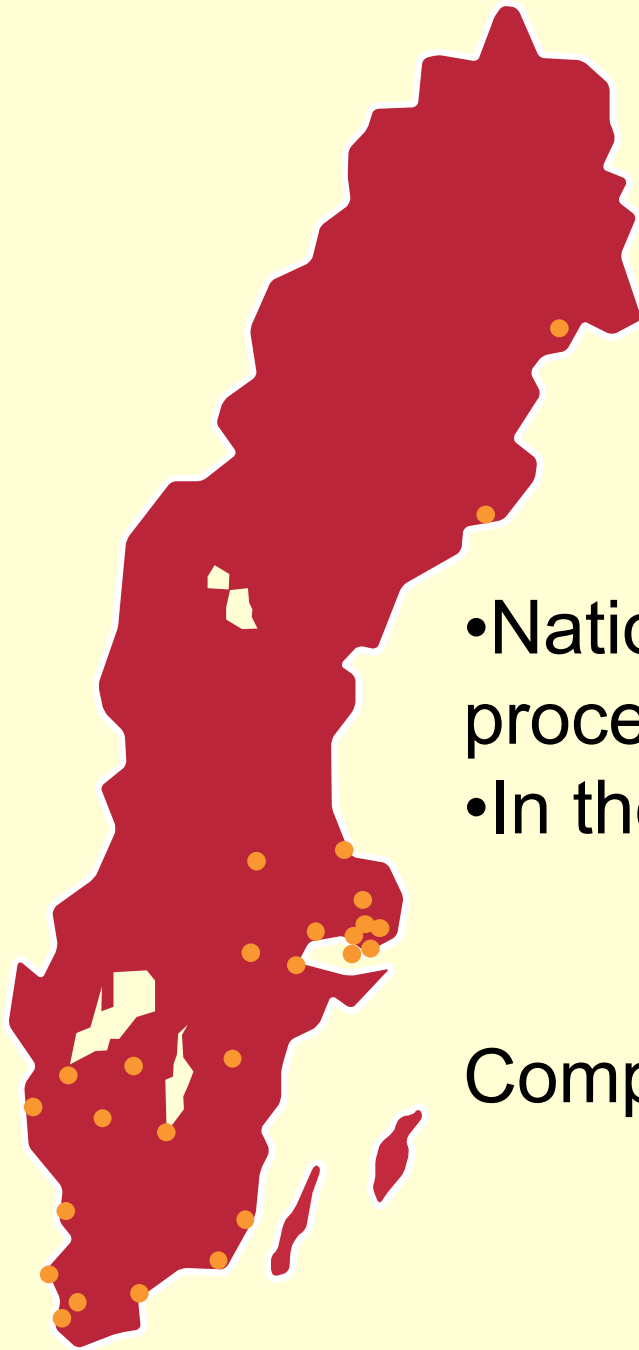


Long term outcome with  
drug eluting stents vs.  
bare metal stents in Sweden  
– one additional year of follow-up

Stefan James, Jörg Carlsson, Johan Lindbäck, Tage  
Nilsson, Ulf Stenestrand, Lars Wallentin and Bo Lagerqvist  
for the SCAAR study group

**None of the authors have any conflicts of interest in relation to the  
presentation**

## SCAAR- Swedish Coronary Angiography and Angioplasty Registry [www.ucr.uu.se](http://www.ucr.uu.se)



- National registry 1989-2007 with all procedures in Sweden.
- In the data base:
  - 294 000 procedures, 123 000 PCI
  - 118 000 stents ( > 37 000 DES)
- Complete long-term follow up by merging with National registries of MI, CABG, hospital care and death.

# Inclusion

SCAAR  
UCR  
SWEDEN  
2007

	2003 - 2004	2003-2005
<b>Follow -up</b>	<b>1-3 years</b>	<b>1-4 year</b>
<b>Stents implanted</b> (BMS/DES)	<b>37 750</b> (26 398 / 11 352)	<b>61 896</b> (37 377 / 24 519)
<b>Stent procedures</b> (Only BMS/ with DES)	<b>24 215</b> (16 256 / 7 959)	<b>39 432</b> (22 878 / 16 554)
<b>Stented patients</b> (Only BMS/ with DES)	<b>19 771</b> (13 738 / 6 033)	<b>35 266</b> (21 480 / 13 786)
<b>End -points:</b>		
<b>MI, 2003 -2006</b> (From the Swedish hospital discharge Registry and the Riks-HIA registry)	<b>2 463</b>	<b>4 160</b>
<b>Death, 2003 - 2006</b> (From the Swedish population Registry)	<b>1 424</b>	<b>2 957</b>

# Characteristics

SCAAR  
UCR  
SWEDEN  
2007

	N	Total cohort, %	
		BMS N=21 477	DES N=13 785
Age#	35259	66 y	65 y
Female gender	35262	27	29
Diabetes	35262	16	23
Hypertension	35262	44	47
Previous PCI	34726	10	14
Previous CABG	34567	9	11
Previous MI	33678	28	29
Previous heart failure	35262	6.9	7.9
Previous renal failure	35262	1.0	1.3
Previous dialysis	35262	0.4	0.6
COPD	35262	4.7	4.5
Dementia	35262	0.1	0.1
Cancer < 3 year	35262	2.6	2.6
Aspirin before	35206	86	91
Clopidogrel before	35133	56	67
GP2B/3A during	35075	39	30

		Total cohort, %		
		N	BMS	DES
Number of stents	1	35 247	67	54
	2		23	29
	3-		9	17
Severity	1-vessel disease	34 388	48	44
	2-vessel disease		30	32
	3-vessel disease		18	19
	Left main 0-3 vd		4	5
Indication	Stable CAD	34 868	21	29
	Unstable CAD		50	53
	STEMI		28	17

**DES penetration in health care regions :**

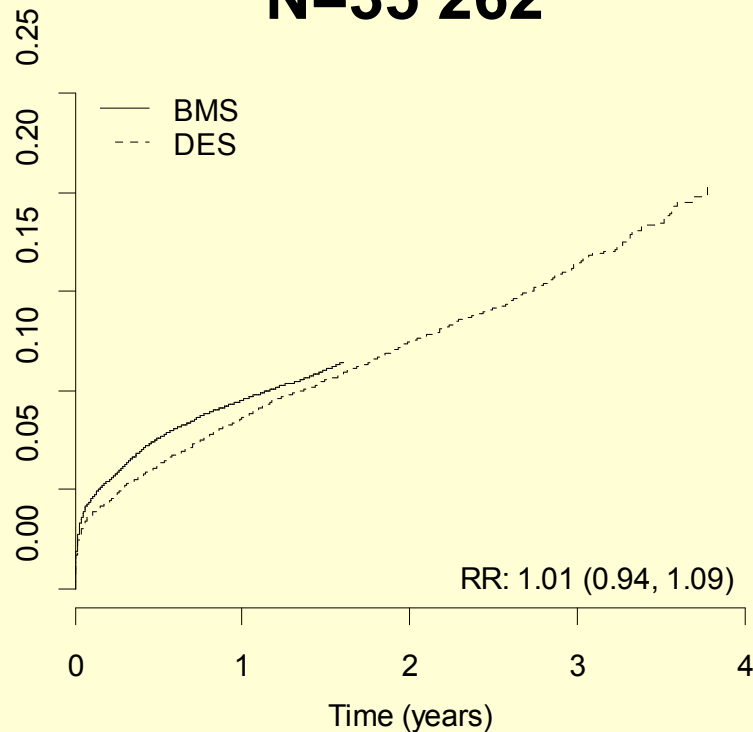
North	35 262	12
Stockholm		35
Southeast		46
South		50
Middle		52
West		1

	N	One stent cohort, %	
		BMS N=12 556	DES N=6 381
Stent diameter — mm (25-75 perc)	21 775	3.0 (3.0- 3.5)	3.0 (2.5-3.0)
Stent length — mm (25-75 perc)	21 814	16 (12-19)	18 (13-23)
Restenotic lesion — no. (%)	21 763	1.0	4.7
Treated vessel — no. (%)	21 870		
Right coronary artery		34	18
Left main coronary artery		0.9	2.3
Left anterior descending artery		38	57
Left circumflex artery		23	20
CABG graft		3.7	3.4

# Adjusted Death /MI

## Total cohort

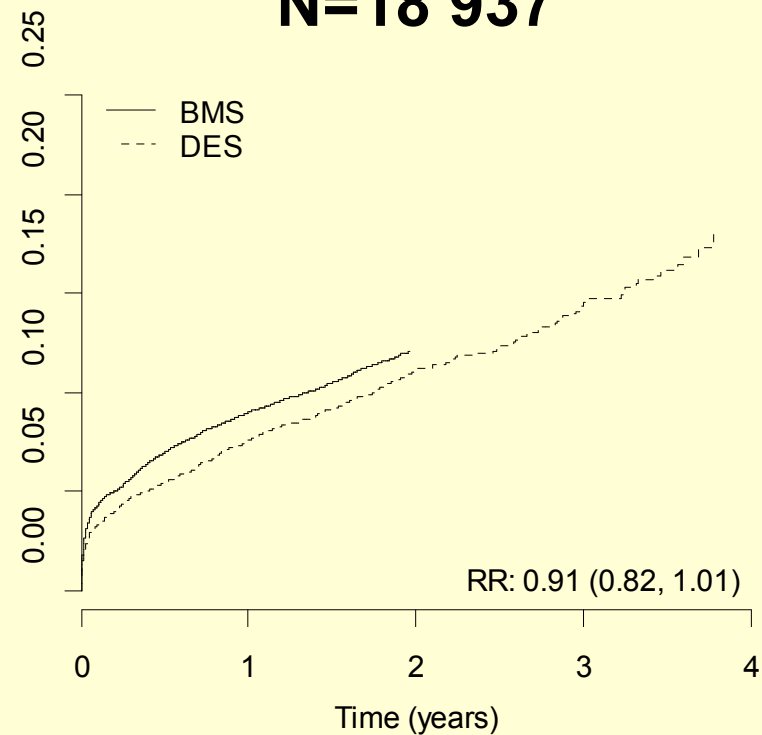
**N=35 262**



BMS	18769	17326	16957	14414	11596	8755	5523	2934	7
DES	12015	11286	11003	7648	4956	3062	1498	535	0

## One stent cohort

**N=18 937**

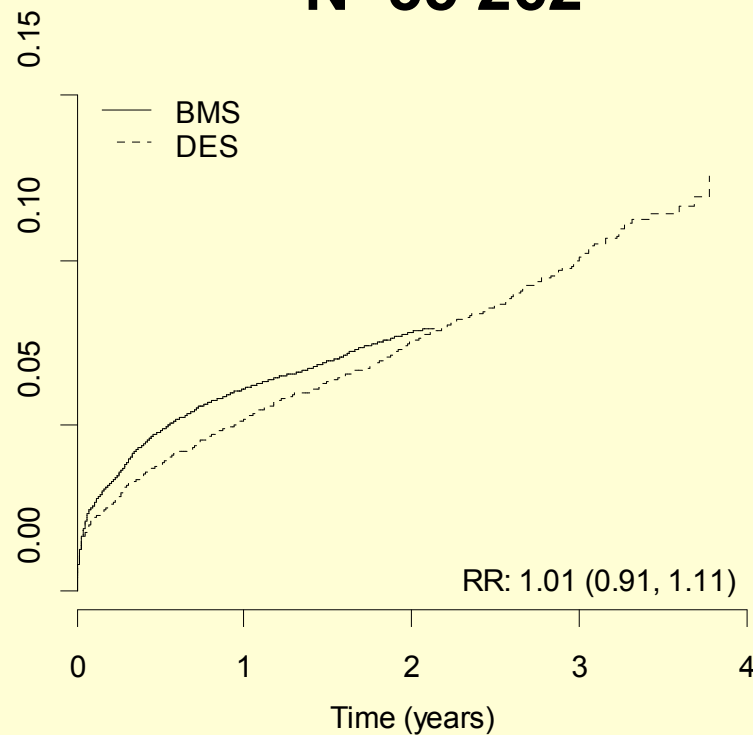


BMS	12556	11701	11453	9731	7799	5878	3739	1977	7
DES	6381	6017	5875	4103	2644	1631	798	295	0

# Adjusted MI

## Total cohort

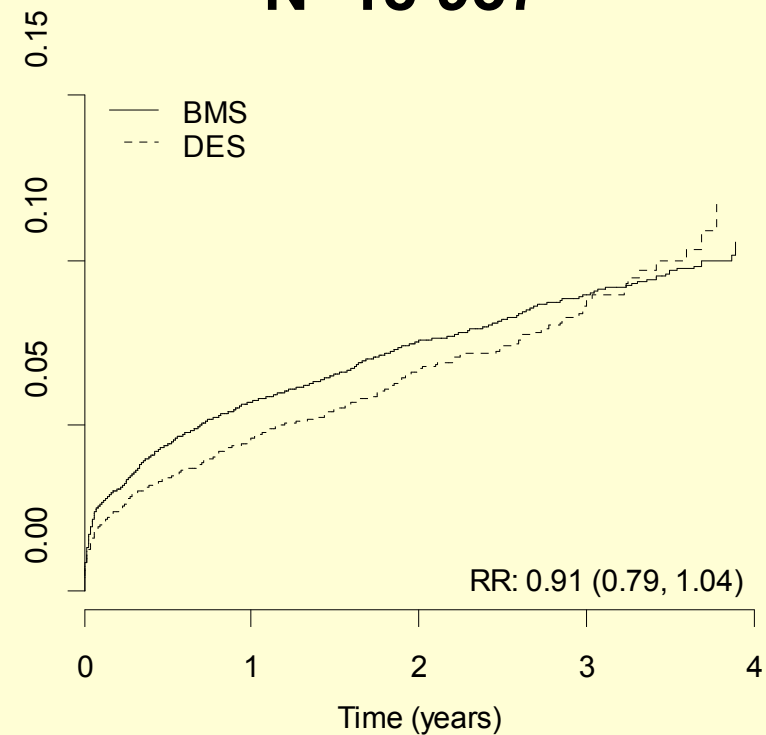
**N=35 262**



BMS	18769	17326	16957	14414	11596	8755	5523	2934	7
DES	12015	11286	11003	7648	4956	3062	1498	535	0

## One stent cohort

**N=18 937**

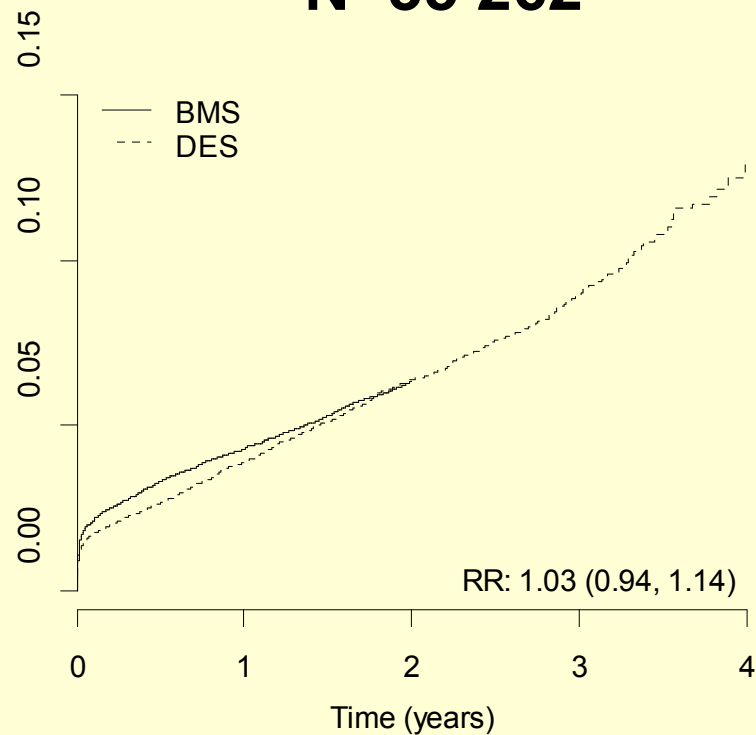


BMS	12556	11701	11453	9731	7799	5878	3739	1977	7
DES	6381	6017	5875	4103	2644	1631	798	295	0

# Adjusted Death

## Total cohort

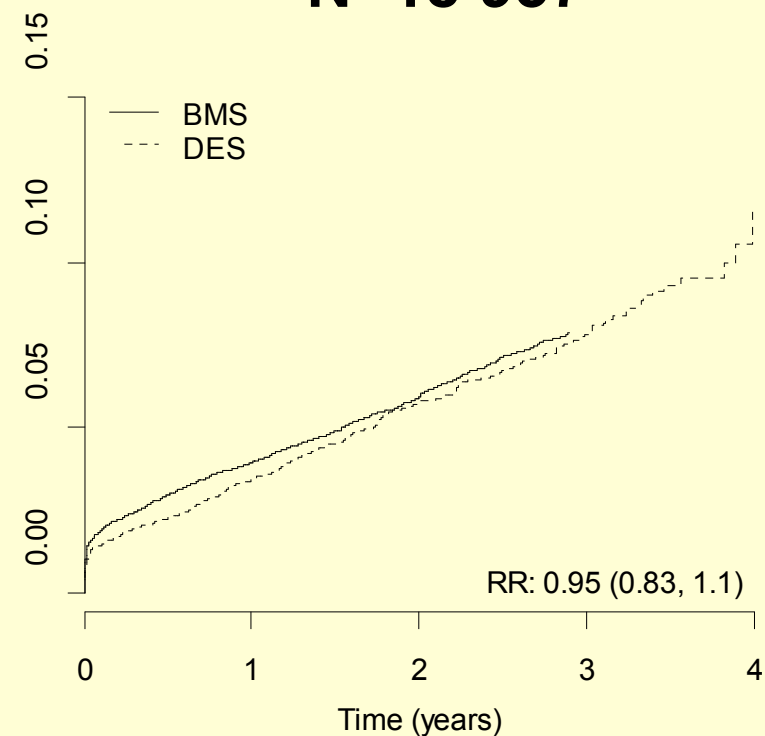
**N=35 262**



BMS	18769	18136	17948	16109	13401	10326	7158	3970	1179
DES	12015	11705	11559	9020	6181	3844	2153	847	115

## One stent cohort

**N=18 937**

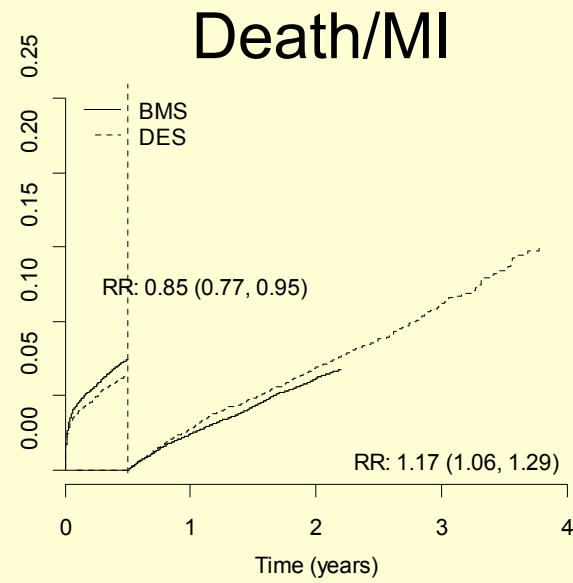


BMS	12556	12185	12061	10837	9001	6920	4824	2697	783
DES	6381	6237	6161	4844	3280	2038	1140	462	58

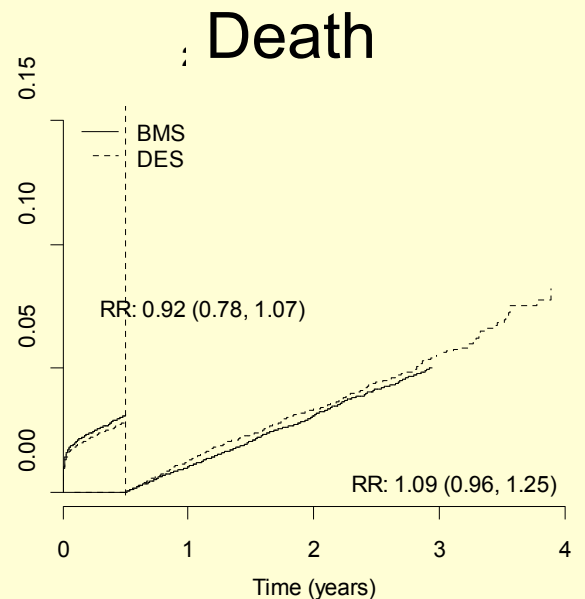
# Landmark analyses-

## Total cohort

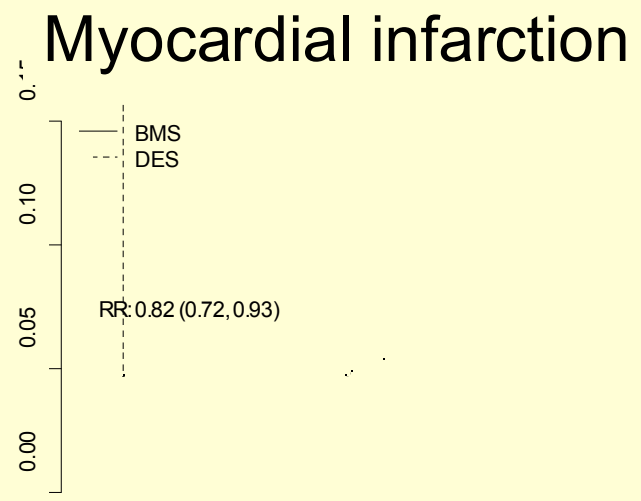
Prespecified landmarks at 6 months



BMS	18769	17326	16957	14414	11596	8755	5523	2934	7
DES	12015	11286	11003	7648	4956	3062	1498	535	0

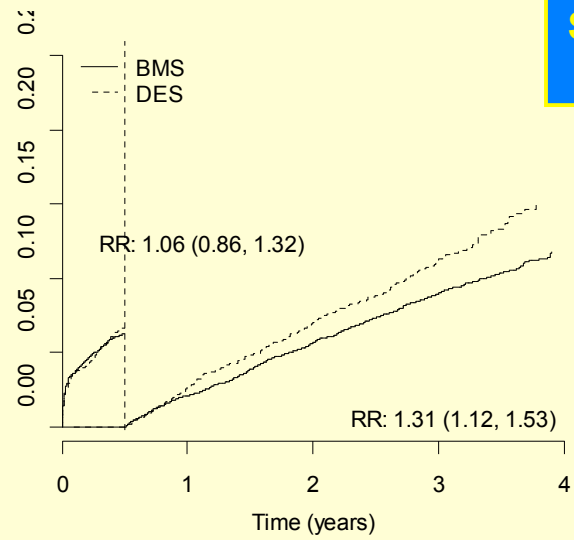


BMS	18769	18136	17948	16109	13401	10326	7158	3970	1179
DES	12015	11705	11559	9020	6181	3844	2153	847	115



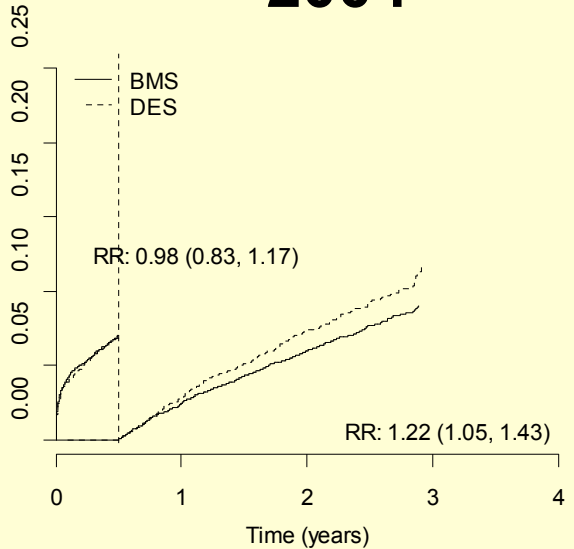
# Death/MI- total cohort Year by year

2003



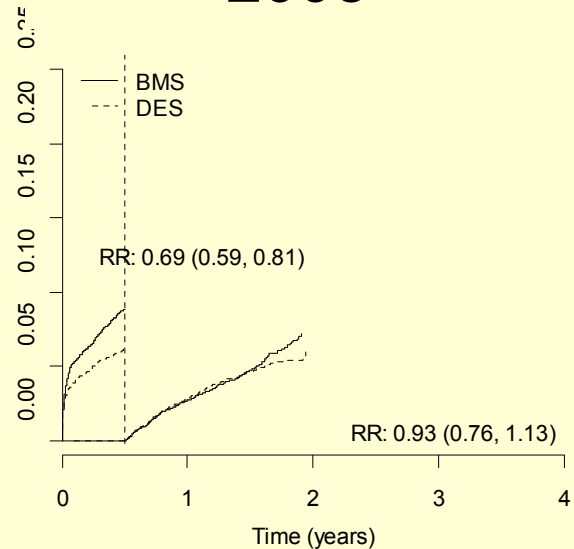
BMS	6448	6037	5918	5820	5713	5612	5520	2934	7
DES	1799	1685	1644	1607	1568	1539	1496	535	0

2004



BMS	6737	6228	6090	5983	5883	3143	3	0	0
DES	3880	3638	3550	3468	3388	1523	2	0	0

2005



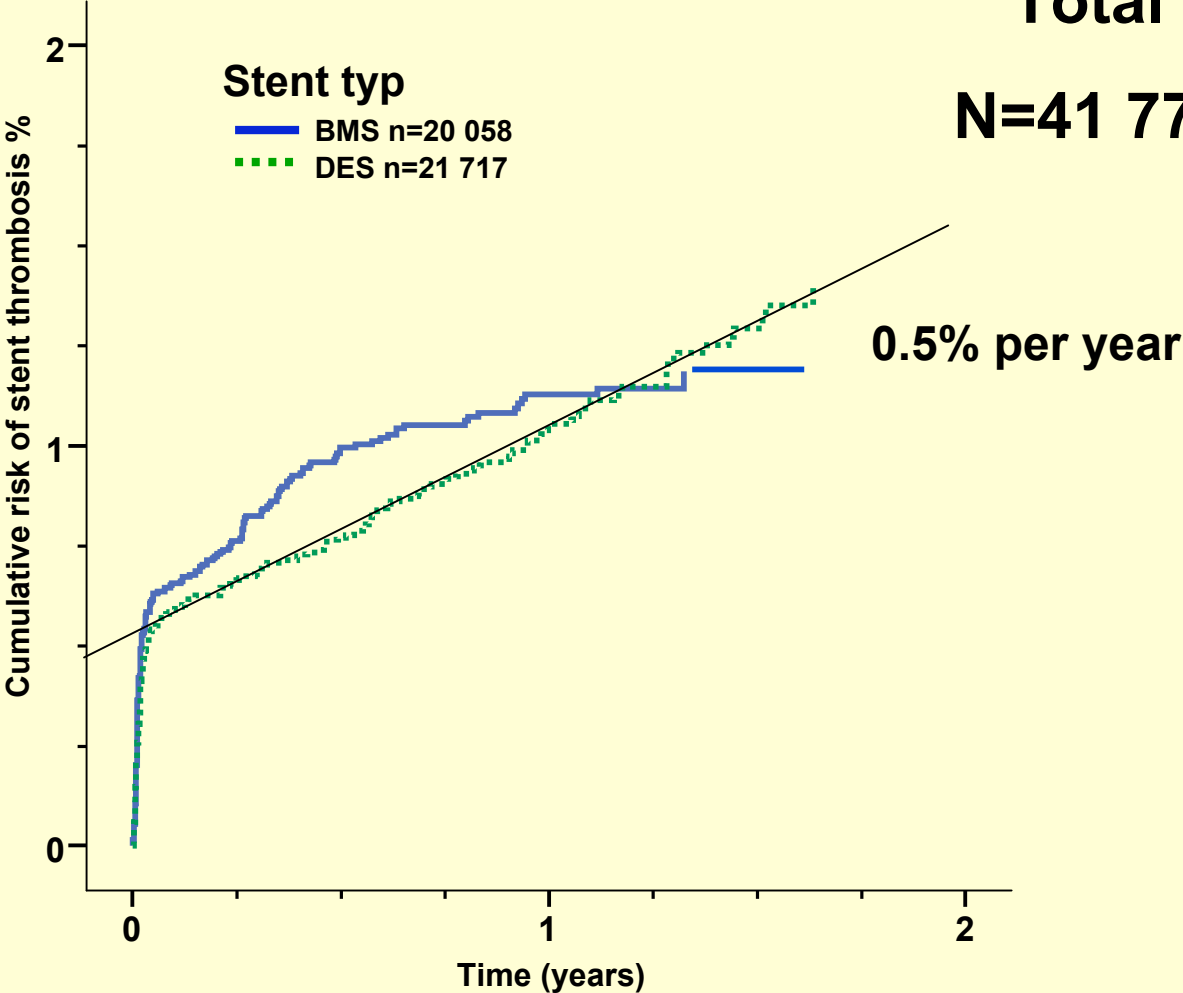
BMS	5584	5061	4949	2611	0	0	0	0	0
DES	6336	5963	5809	2573	0	0	0	0	0

# Stent thrombosis

Unadjusted

Total cohort

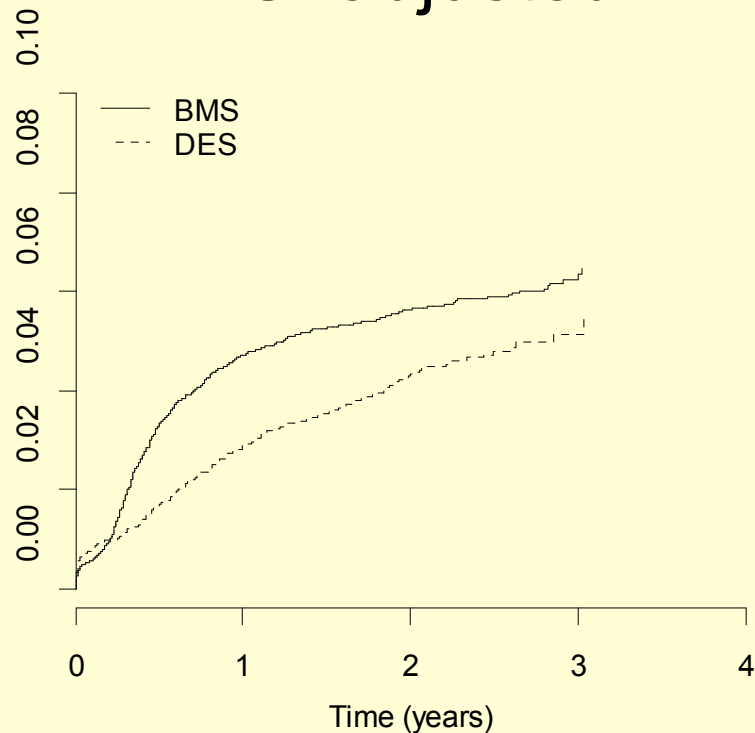
N=41 775 stents



# Restenosis one stent cohort

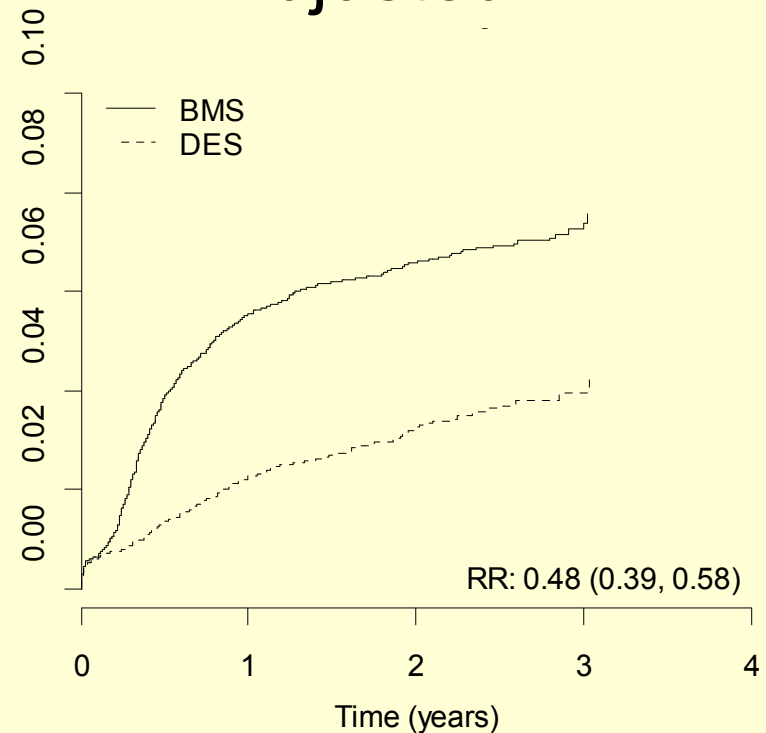
SCAAR  
UCR  
SWEDEN  
2007

## Unadjusted



BMS	9217	8615	8399	7147	5205	3057	887	0	0
DES	6229	5967	5822	4429	2738	1334	317	0	0

## Adjusted



BMS	8235	7708	7505	6326	4602	2668	753	0	0
DES	5438	5223	5097	3809	2294	1110	257	0	0

# Limitations

Possible unknown confounders:

- Non-registered differences between the patient groups.
- Non-registered differences over time
- Non registered differences in duration of dual anti-platelet therapy.

# Strengths

- Complete unselected population
- Complete follow-up on hard endpoints
- No angiographically driven revascularization
- Based on a large number (>7000) of hard end-point events

# Conclusions

SCAAR  
UCR  
SWEDEN  
2006

During 4 years follow-up the DES-group compared to the BMS-group, with adjustment for differences in available background characteristics, showed:

- no overall significant difference in mortality or myocardial infarction
- a significantly lower event rate during the initial 6 months
- a significantly higher event rate after 6 months which is compensated by the lower early event rate
- An relative reduction of restenosis by almost 50% corresponding to an absolute reduction of 3.5%

## Possible explanations for the more favourable outcome in the 2005 DES cohort

- Increased awareness of risk of late stent thrombosis associated with DES:
  - Longer duration of dual antiplatelet therapy ?
  - Improved stenting technique with higher balloon pressure and more accurately sized stents ?
  - Improved selection of patients for DES ?
- Lower risk of late stent thrombosis with later generations of DES ?

# Implications

SCAAR  
UCR  
SWEDEN  
2007

The slightly increased risk of late events with DES seems counterbalanced by an early gain.

The reduction in clinically relevant restenosis is less in real world than in randomized angiography trials.

Selection of stent types needs to be based on consideration of benefits and risks in relation to individual patient characteristics.

Prospective large scale randomized trials of DES vs BMS and different durations of dual antiplatelet treatment are urgently warranted.