



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

**Presented at FDA hearing Dec 7, 2006 by
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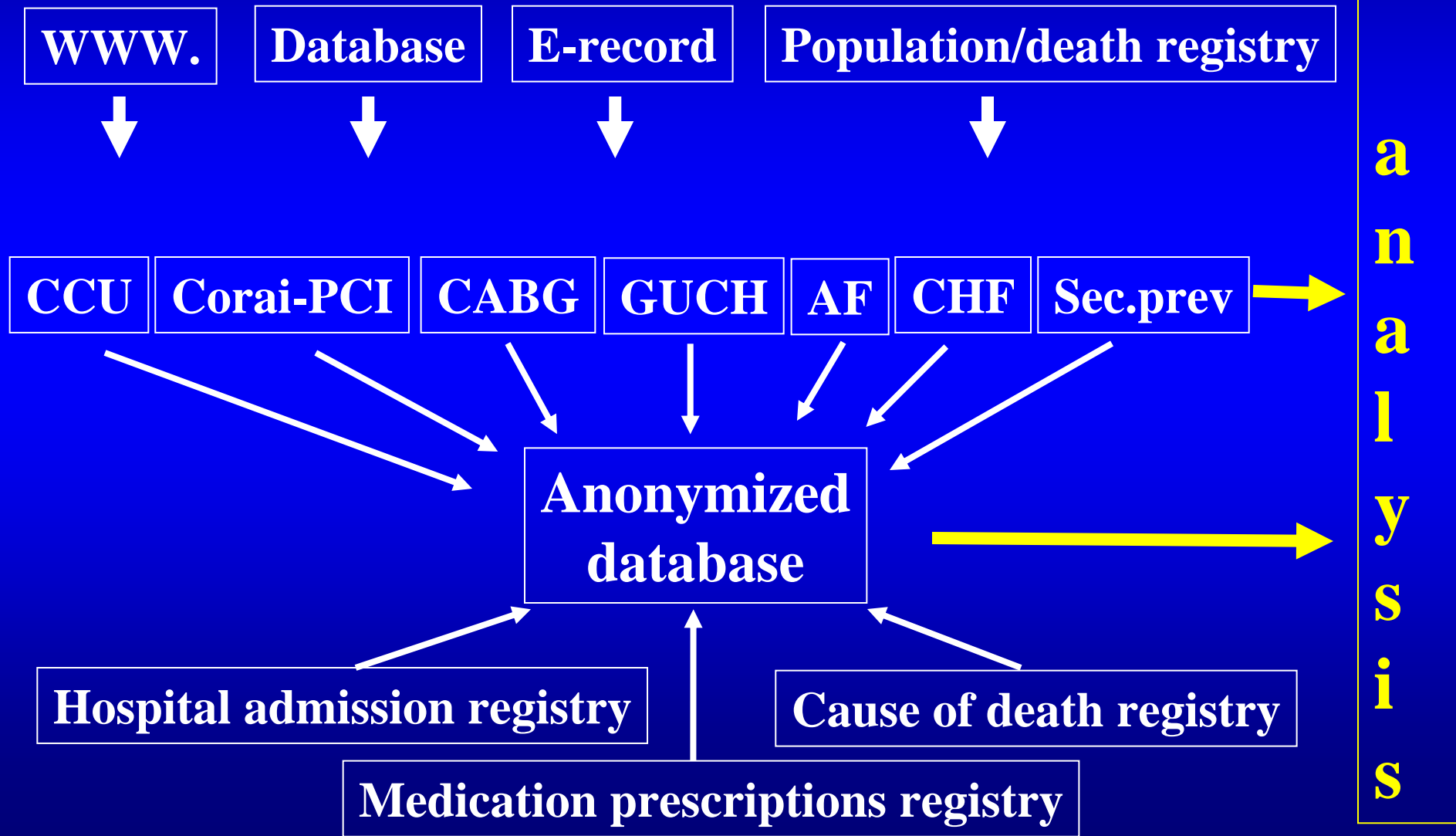
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Disclosures

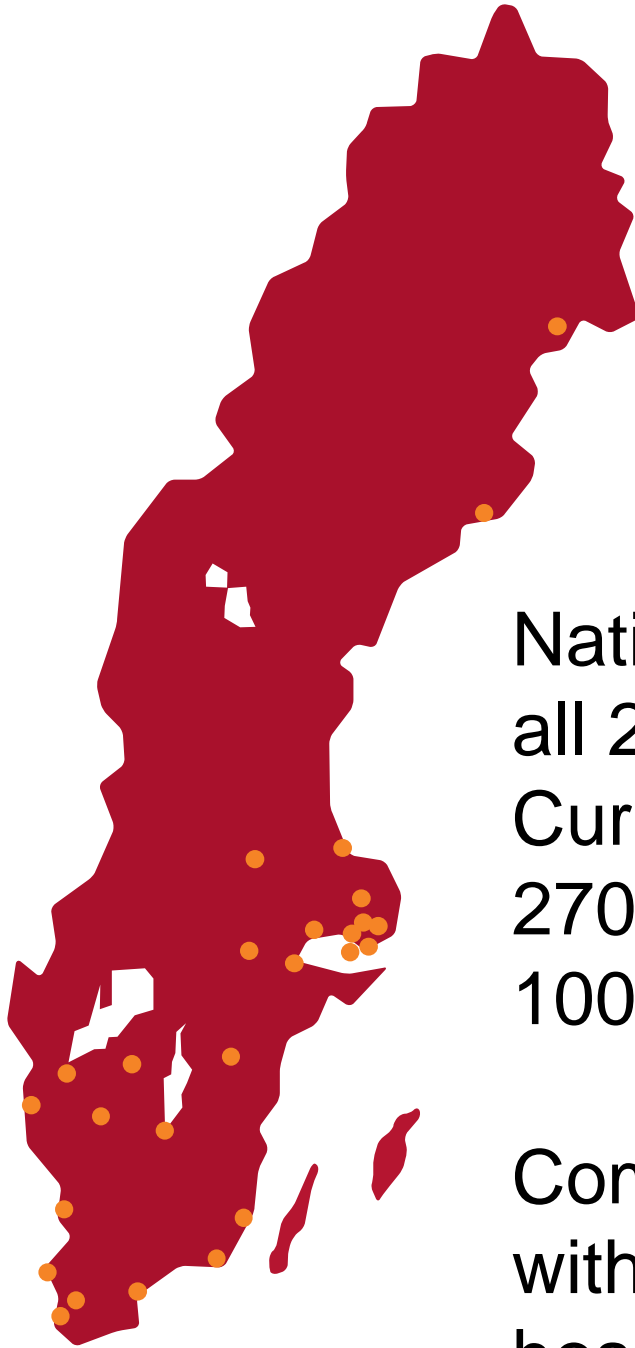
- SCAAR registry, UCR, Sweden
 - Swedish Board of Health and Welfare
 - Swedish Federation of County Councils
- Co-authors
 - No personal disclosures
- UCR
 - Research grants/contracts with Astra-Zeneca, BMS, Boehringer-Ingelheim, Boston Scientific, GSK, Lilly, Pfizer, Schering-Plough

Swedish Heart Registries



SCAAR- Swedish Coronary Angiography and Angioplasty Registry

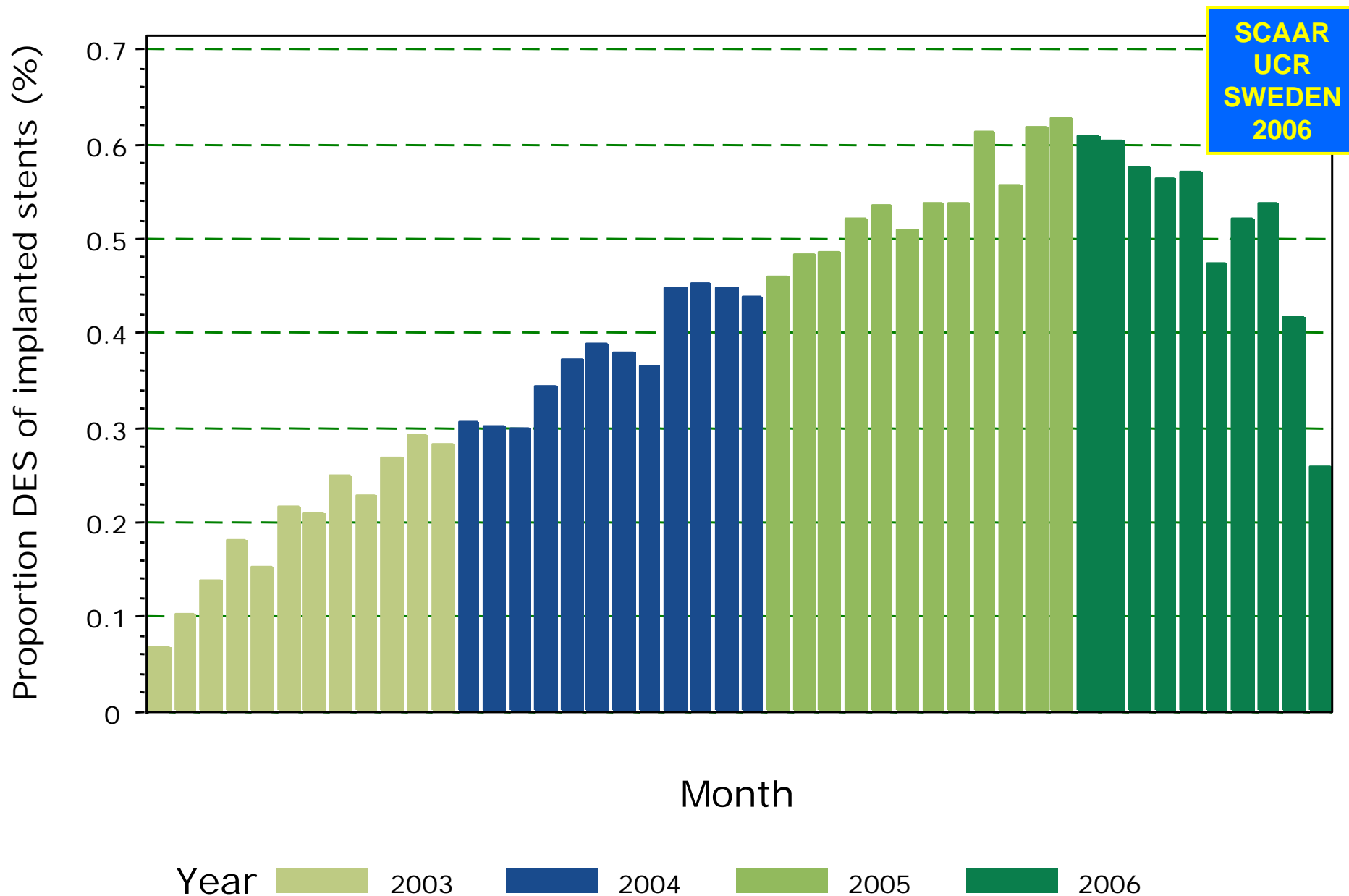
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National registry 1995-2006 covering
all 26 centres and all procedures.

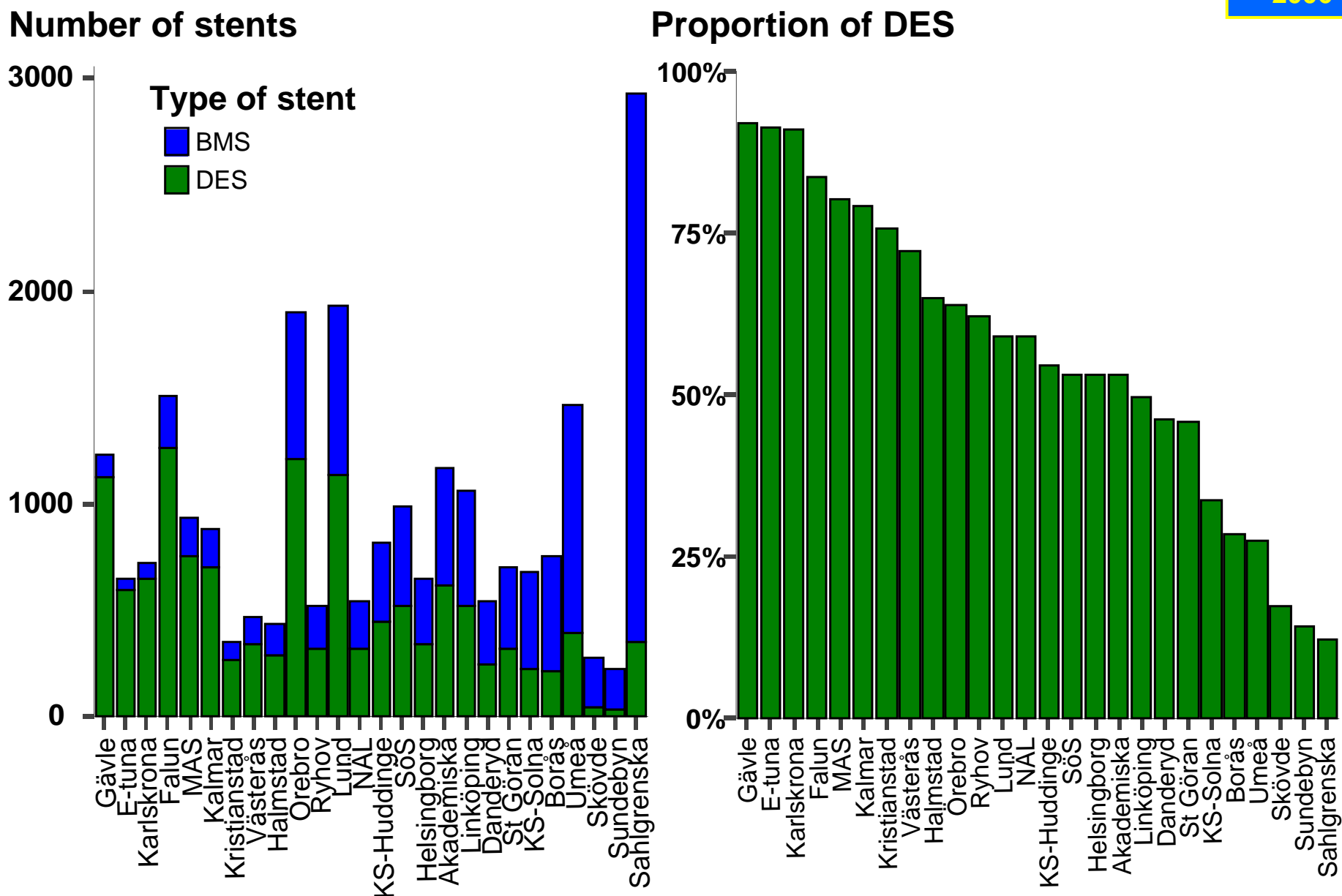
Currently in the data base
270 000 procedures, 120 000 PCI
100 000 stents (> 30 000 DES)

Complete long-term follow up by merging
with National registries of MI, CABG,
hospital care and death.



Development of the use of DES in Sweden 2003 - 2006

Used stents in Sweden 2005 by PCI center



The SCAAR database 2003-2005

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Year of PCI			
	2003-2004	2005	Total
Follow-up	> 1year	< 1 year	
Stent implanted (BMS/DES)	37 750 (26 398 / 11 352)	24 144 (10 982 / 13 162)	61 894 (37 380 / 24 514)
Stent procedures (Only BMS/ with DES)	24 215 (16 256 / 7 959)	15 217 (6 625 / 8 592)	39 432 (22 881 / 16 551)
Stented patients (Only BMS/ with DES)	19 771 (13 738 / 6 033)	11 521 (5 531 / 5 990)	31 292 (19 269 / 12 023)
End-points:			
MI, 2003-2005 (From the Swedish hospital discharge Registry)	2 463	755	3 218
Death, 2003- June 2006 (From the Swedish population Registry)	1 424	545	1 969

Statistics:

Observational study

Propensity score methods

Cox regression analyses

Background characteristics (1)

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	BMS N=13738	DES N=6033	P-value
Age	58 66 74	57 65 73	< 0.001
Gender : Women	27.5 %	29.1 %	0.0222
Indication : Stable CAD	22.5 %	30.3 %	< 0.001
Unstable CAD	51.4 %	52.5 %	
STEMI	25.4 %	16.1 %	
Diabetes	15.6 %	23.6 %	< 0.001
Hypertension	43.6 %	46.4 %	< 0.001
Smoker	21.0 %	18.8 %	< 0.001
Previous PCI	10.4 %	15.6 %	< 0.001
Previous CABG	9.8 %	11.2 %	0.003
Previous Myocardial infarction	36.7%	38.2 %	0.056
Previous heart failure	7.0 %	8.1 %	0.006
Previous stroke	5.8 %	6.2 %	0.313
Previous renal failure	0.9 %	1.3 %	0.009
COPD	4.6 %	4.3 %	0.330
Cancer (<3 years)	2.8 %	2.7 %	0.476

Background characteristics (2)

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	BMS N=13738	DES N=6033	P-value
Aspirin before	83.9 %	88.8 %	< 0.001
Clopidogrel before	51.9 %	60.1 %	< 0.001
GPIIB/IIIA	36.3 %	31.6 %	< 0.001
Angio finding :			< 0.001
No significant stenosis	0.3 %	0.3 %	
1-vessel disease	51.2 %	47.2 %	
2- vessels disease	28.3 %	29.8 %	
3- vessels disease	16.5 %	17.9 %	
Left main stenosis	3.7 %	4.8 %	
Number of stents : 1	75.2 %	60.3 %	< 0.001
2	18.8 %	27.9 %	
3 -	6.1 %	11.8 %	

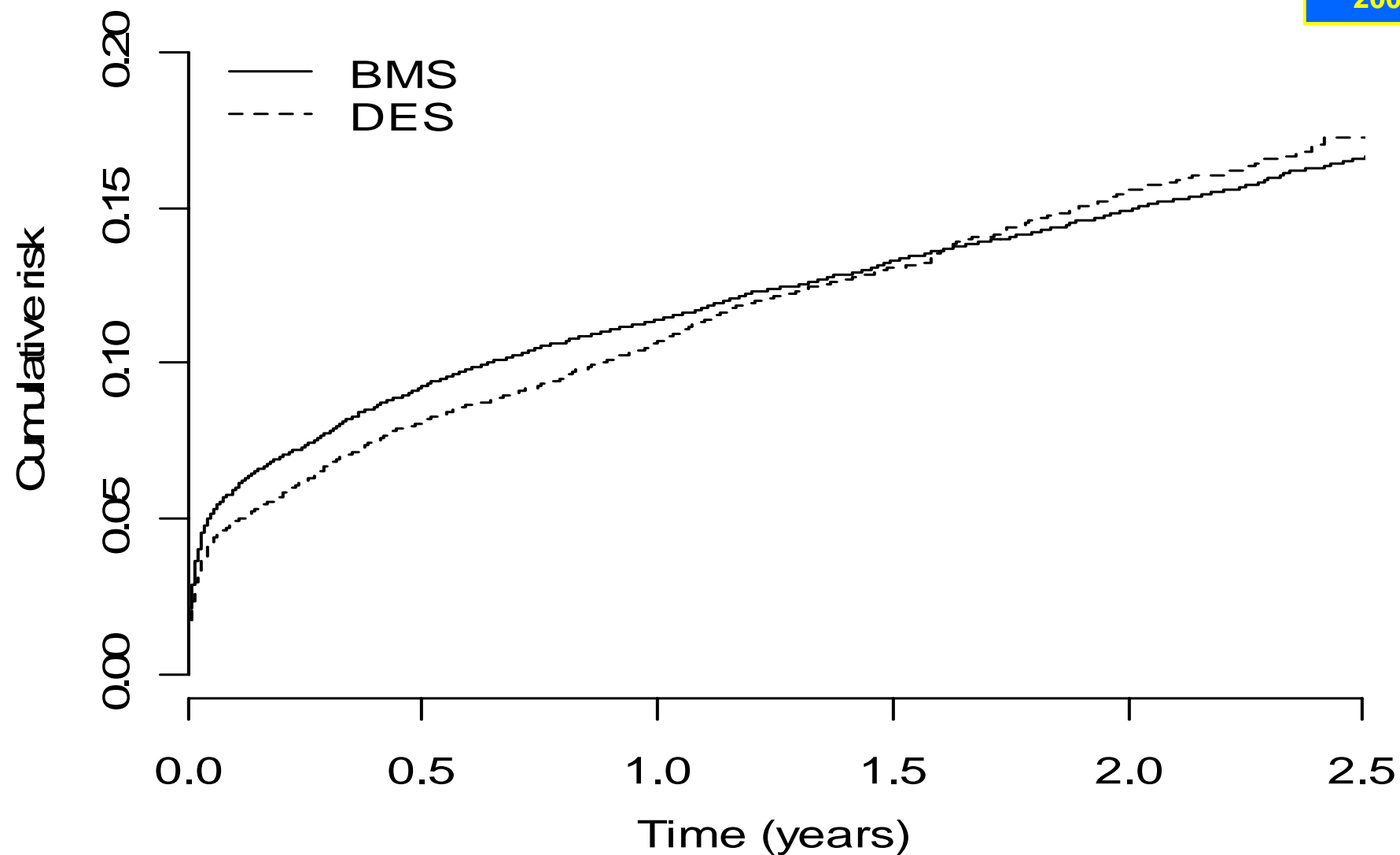
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and Angioplasty Registry**

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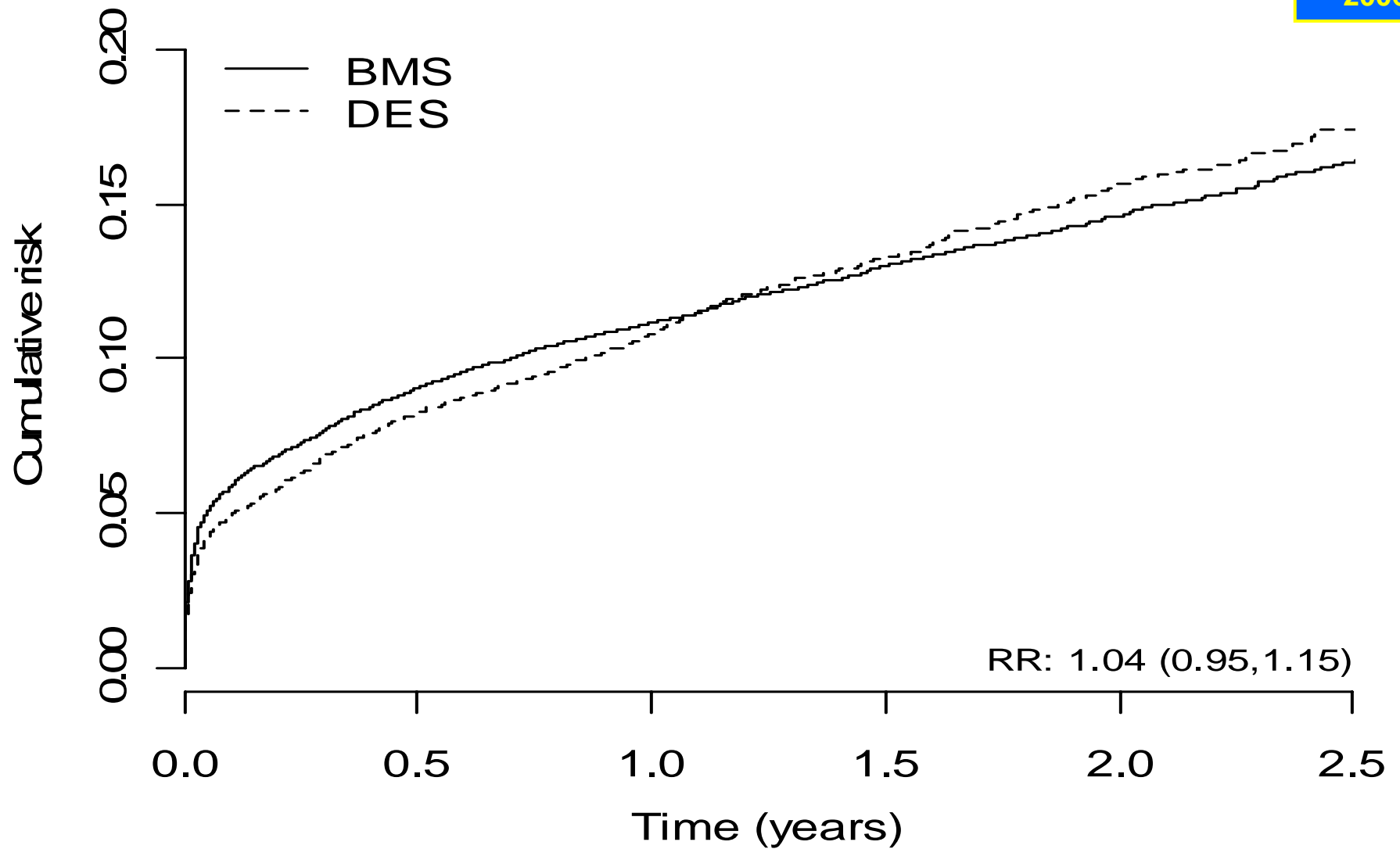
**Long-term outcome
of DES vs BMS
implanted in Sweden
2003 – 2004
RESULTS**

Death/MI (Crude)



BMS	13735	12464	12172	9277	5965	3192
DES	6033	5544	5388	3374	1676	601

Death/MI (Adjusted)



BMS12880

11703

11432

8647

5520

2951

DES 5770

5304

5158

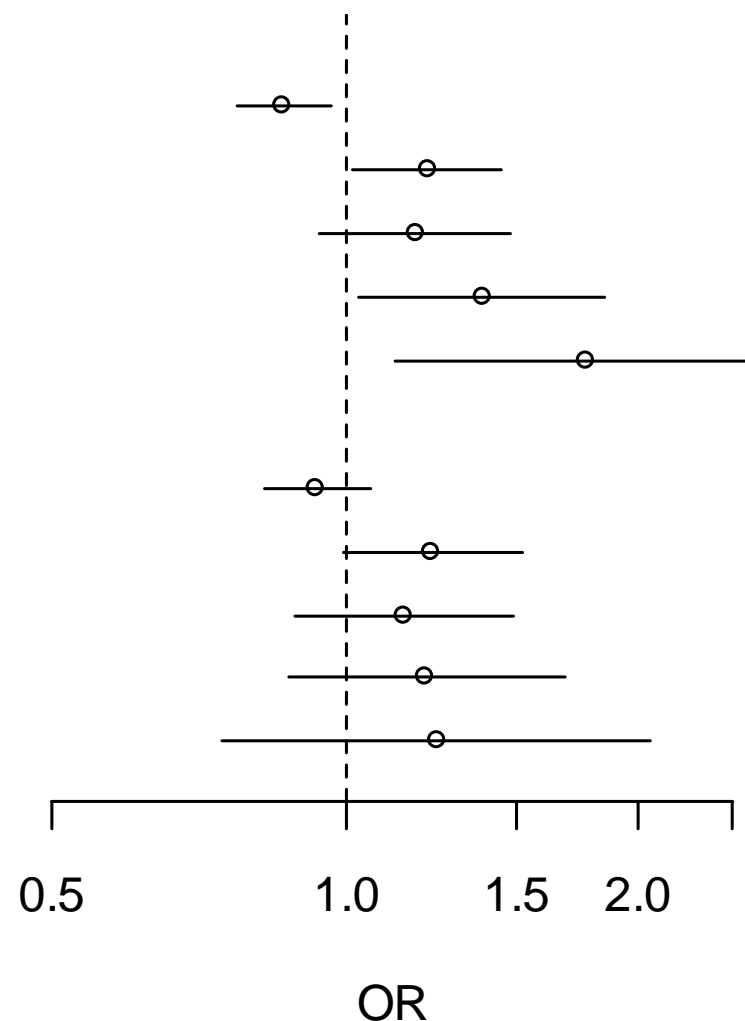
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1608

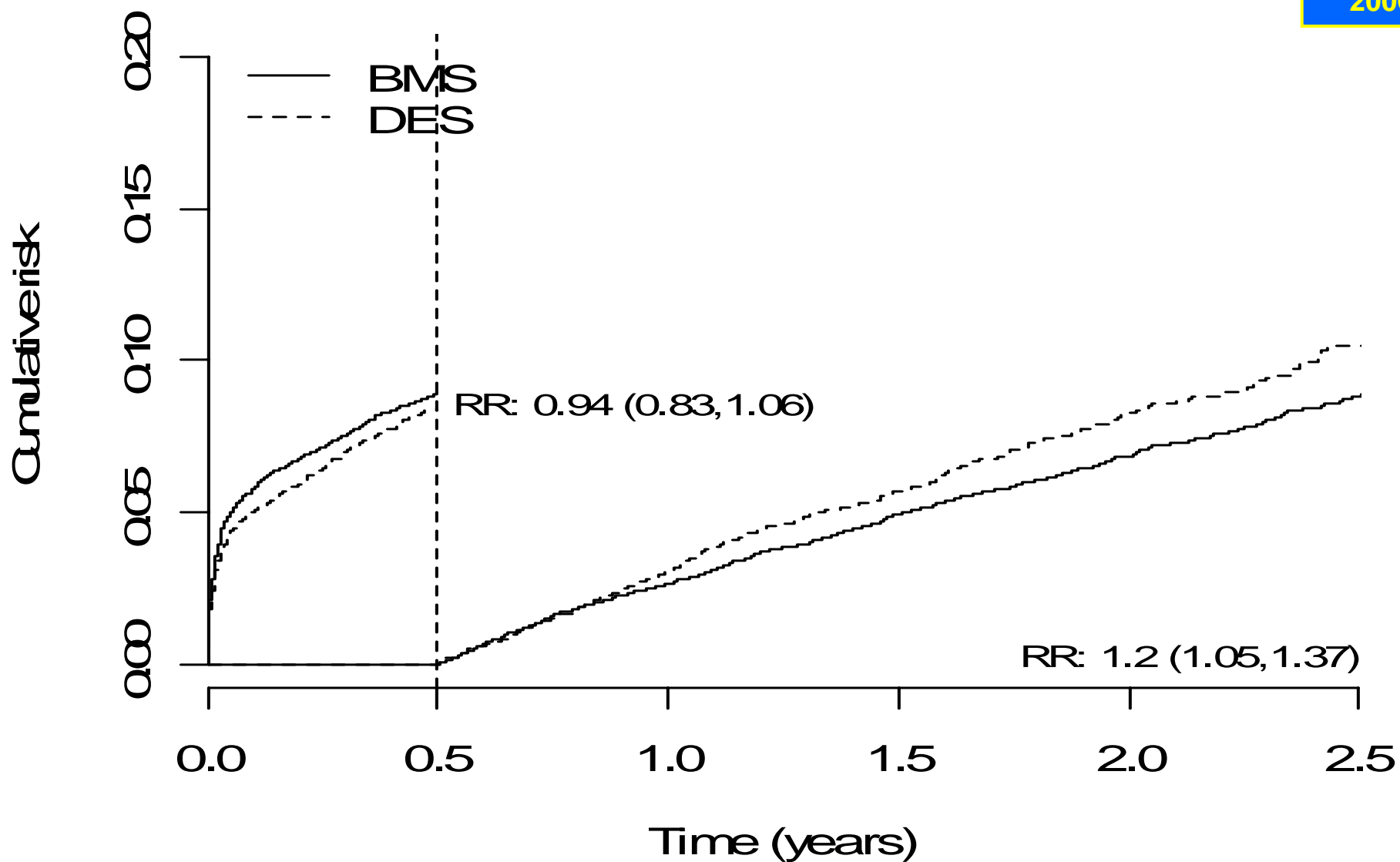
575

Death/MI within consecutive ½ year periods

	Time	DES (%)	BMS (%)	OR (C.I.)
Crude	0 - 0.5	8.1 (489/6033)	9.3 (1271/13735)	0.86 (0.78, 0.96)
	0.5 - 1	3.2 (190/5859)	2.7 (357/13296)	1.21 (1.02, 1.45)
	1 - 1.5	2.9 (109/3730)	2.5 (254/10234)	1.18 (0.94, 1.49)
	1.5 - 2	3.4 (65/1900)	2.5 (165/6611)	1.38 (1.03, 1.85)
	2 - 2.5	3.6 (25/690)	2.1 (74/3576)	1.78 (1.12, 2.82)
Adjusted	0 - 0.5	8.1 (466/5770)	9.1 (1177/12880)	0.94 (0.83, 1.06)
	0.5 - 1	3.2 (179/5604)	2.6 (328/12473)	1.23 (1, 1.52)
	1 - 1.5	3 (105/3547)	2.4 (233/9525)	1.15 (0.89, 1.49)
	1.5 - 2	3.3 (60/1823)	2.5 (154/6110)	1.21 (0.87, 1.68)
	2 - 2.5	3.6 (24/661)	2.2 (71/3301)	1.24 (0.75, 2.07)

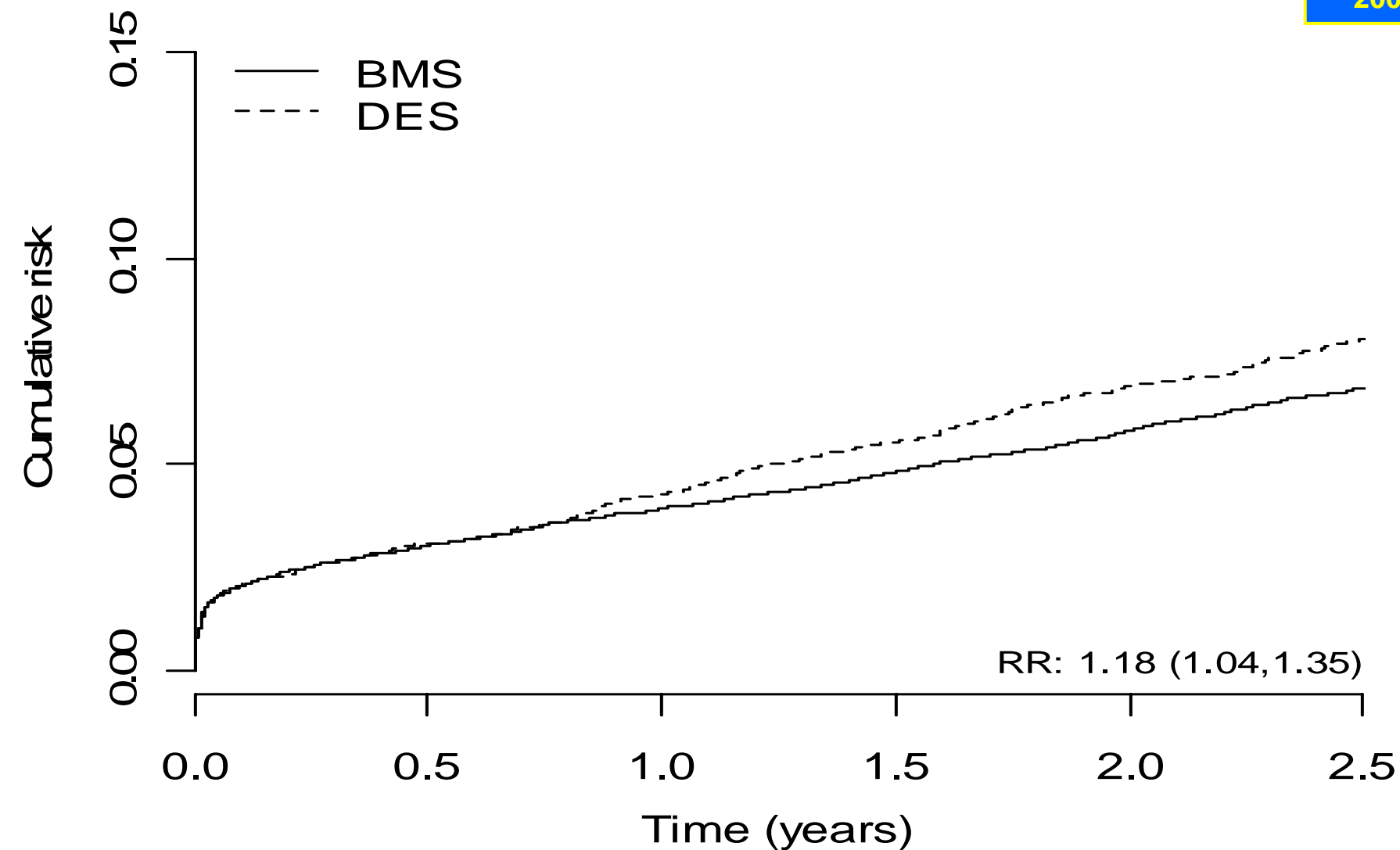


Death/MI (Adjusted)



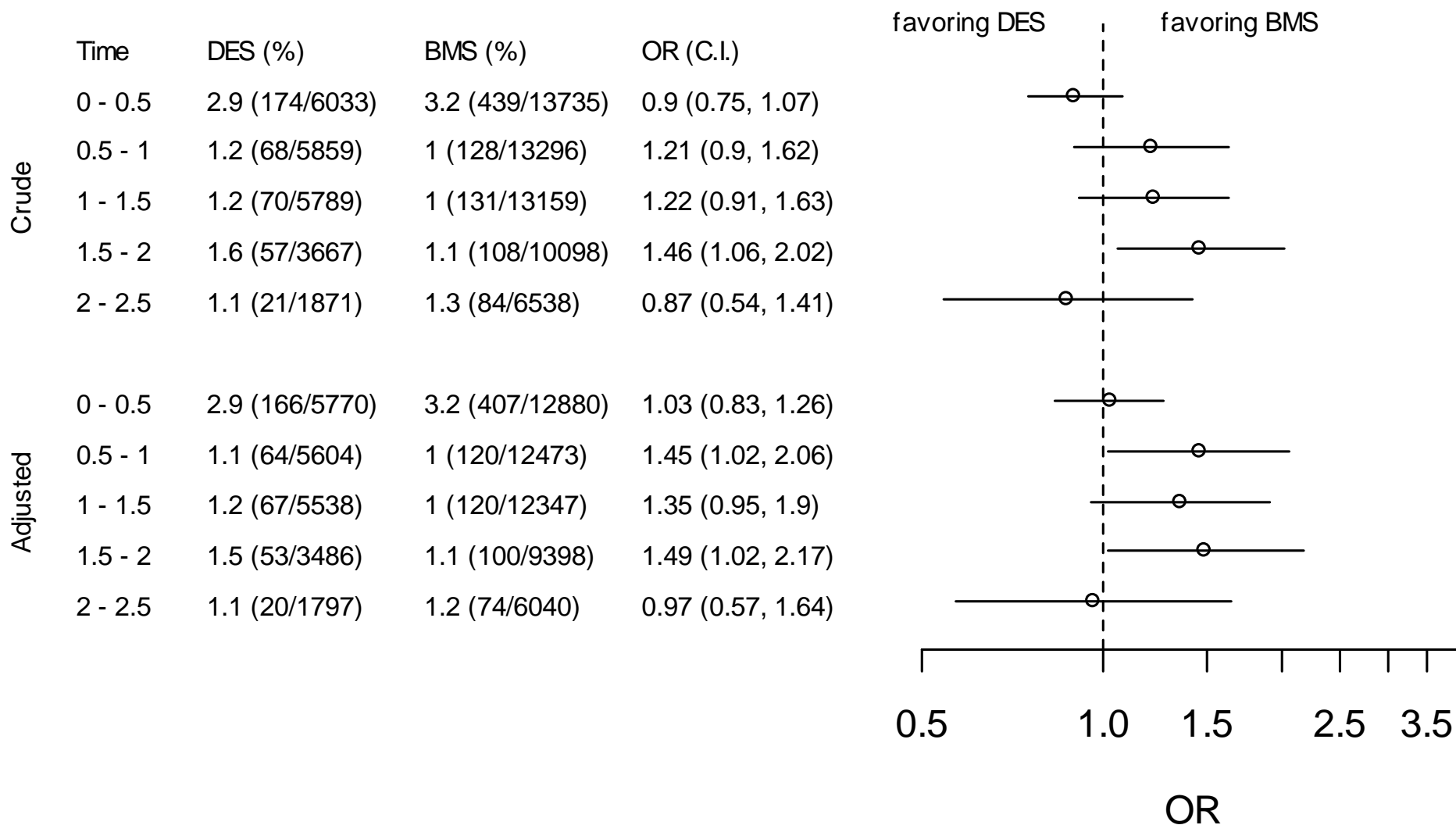
BMS	12880	12473	12146	9158	5810	3104
DES	5770	5604	5426	3378	1704	611

Death (Adjusted)

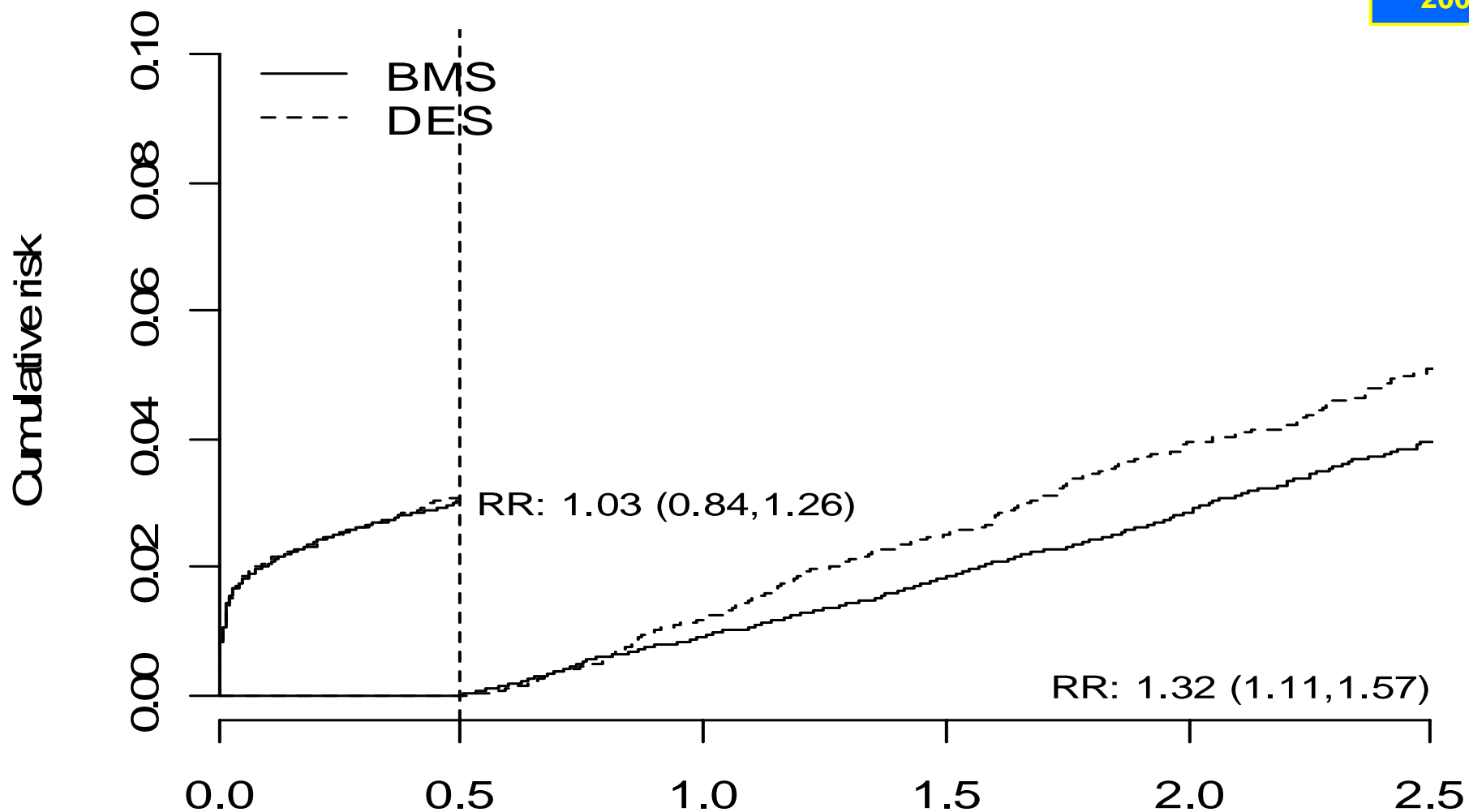


BMS	12880	12473	12354	12213	9298	5960
DES	5770	5604	5541	5468	3434	1776

Mortality within consecutive ½ year periods



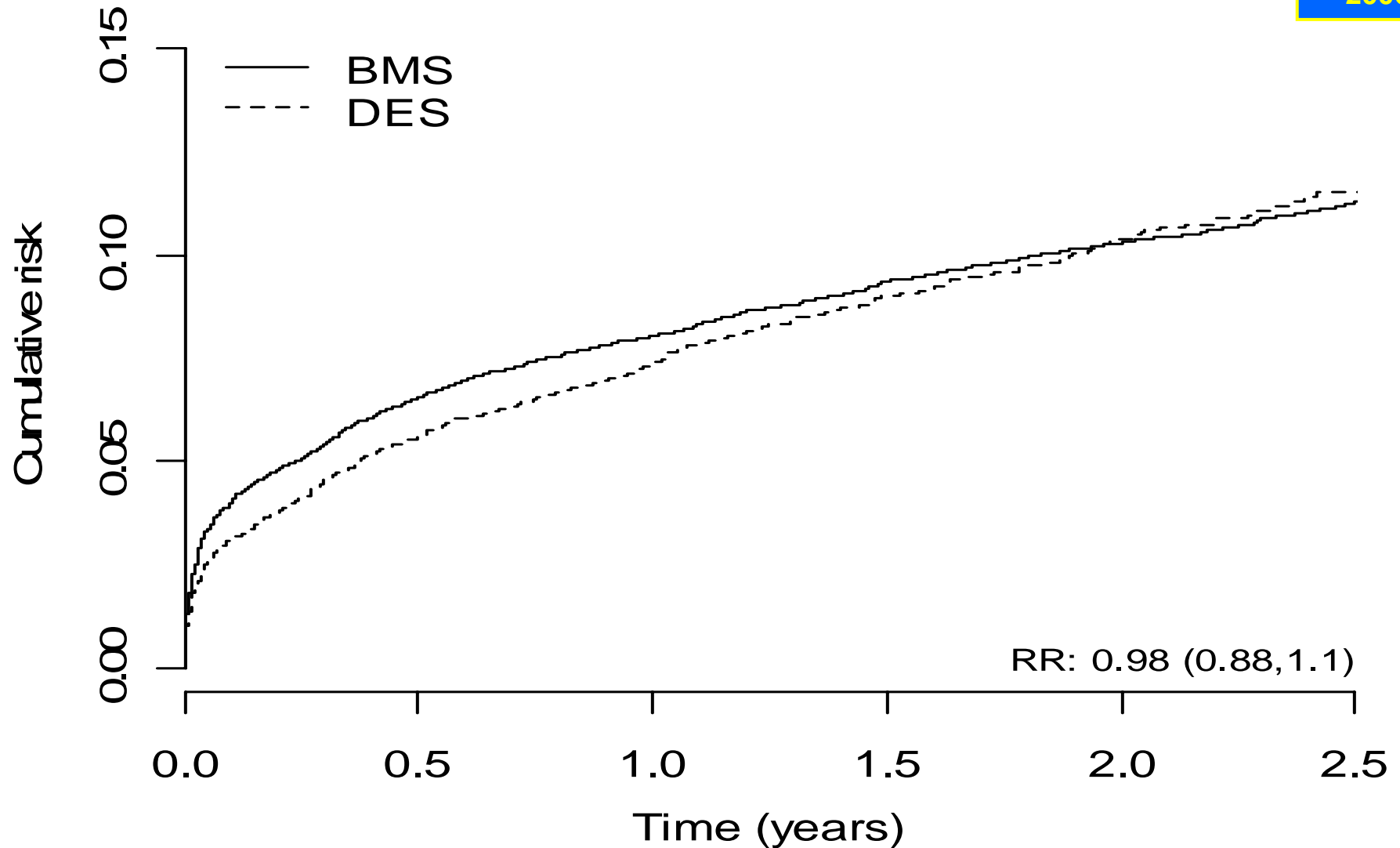
Death (Adjusted)



BMS	12880	12473	12354	12213	9298	5960
DES	5770	5604	5541	5468	3434	1776

Myocardial infarction (Adjusted)

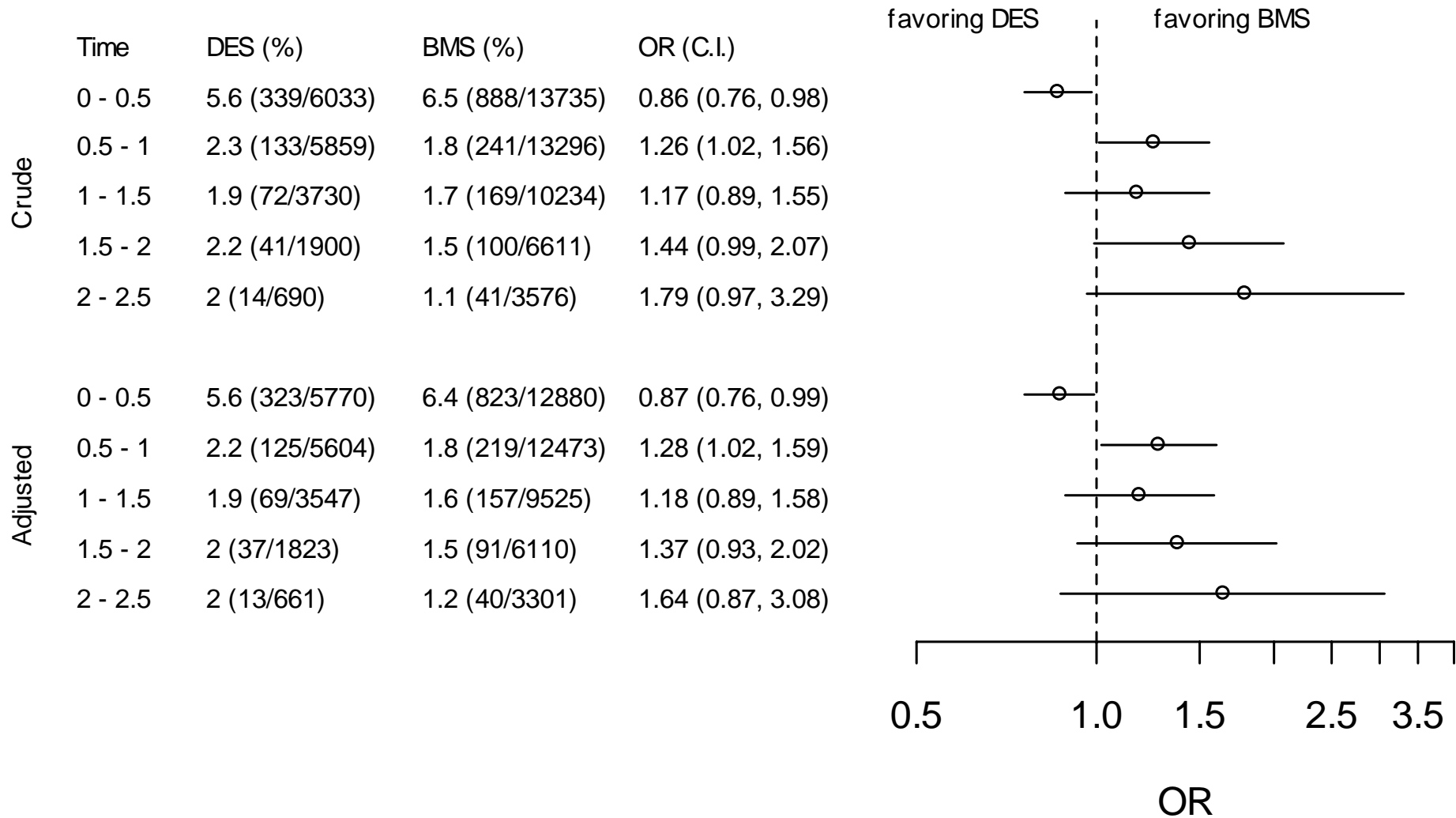
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BMS	12880	11703	11432	8647	5520	2951
DES	5770	5304	5158	3211	1608	575

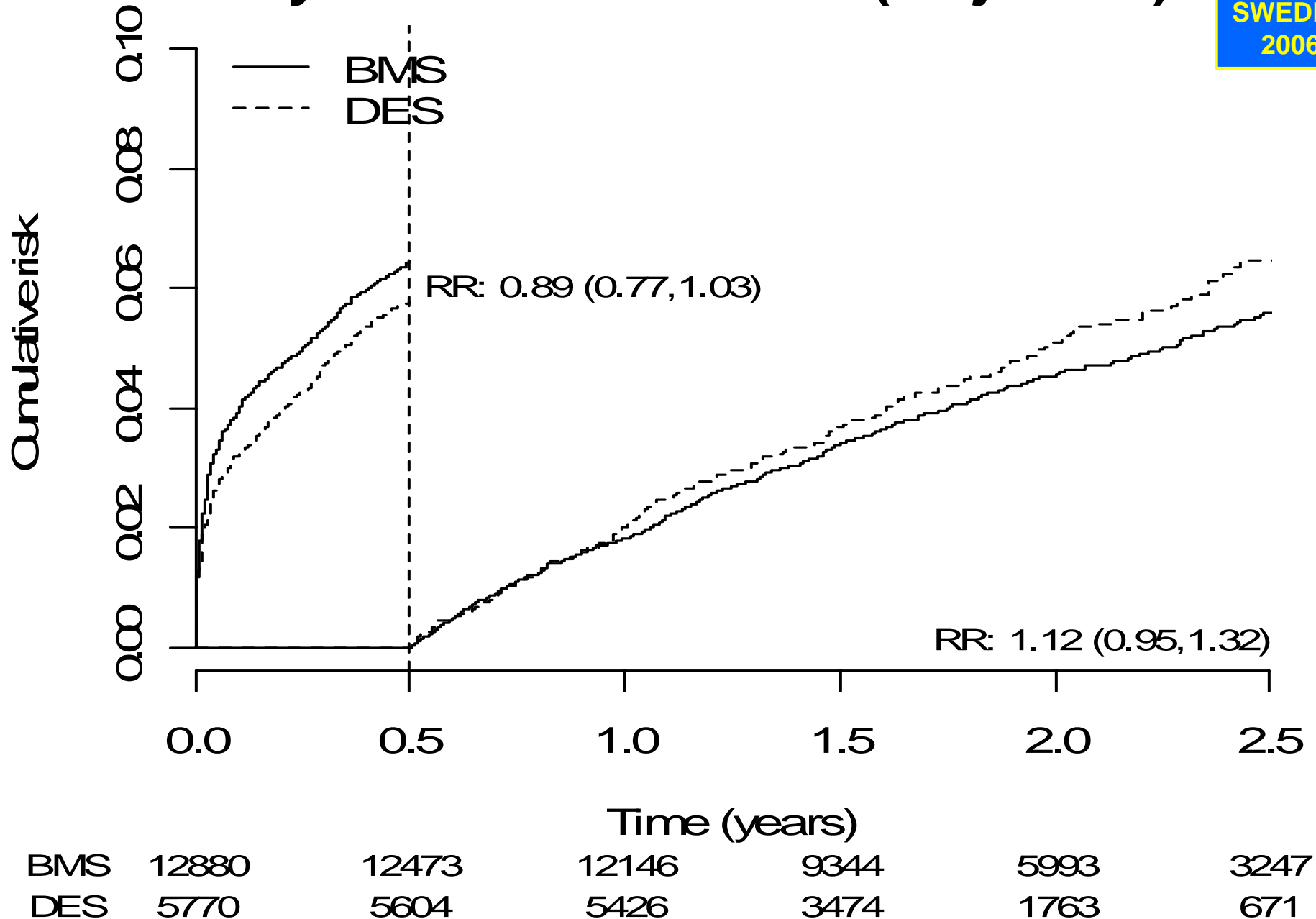
Myocardial infarction within consecutive $\frac{1}{2}$ year periods

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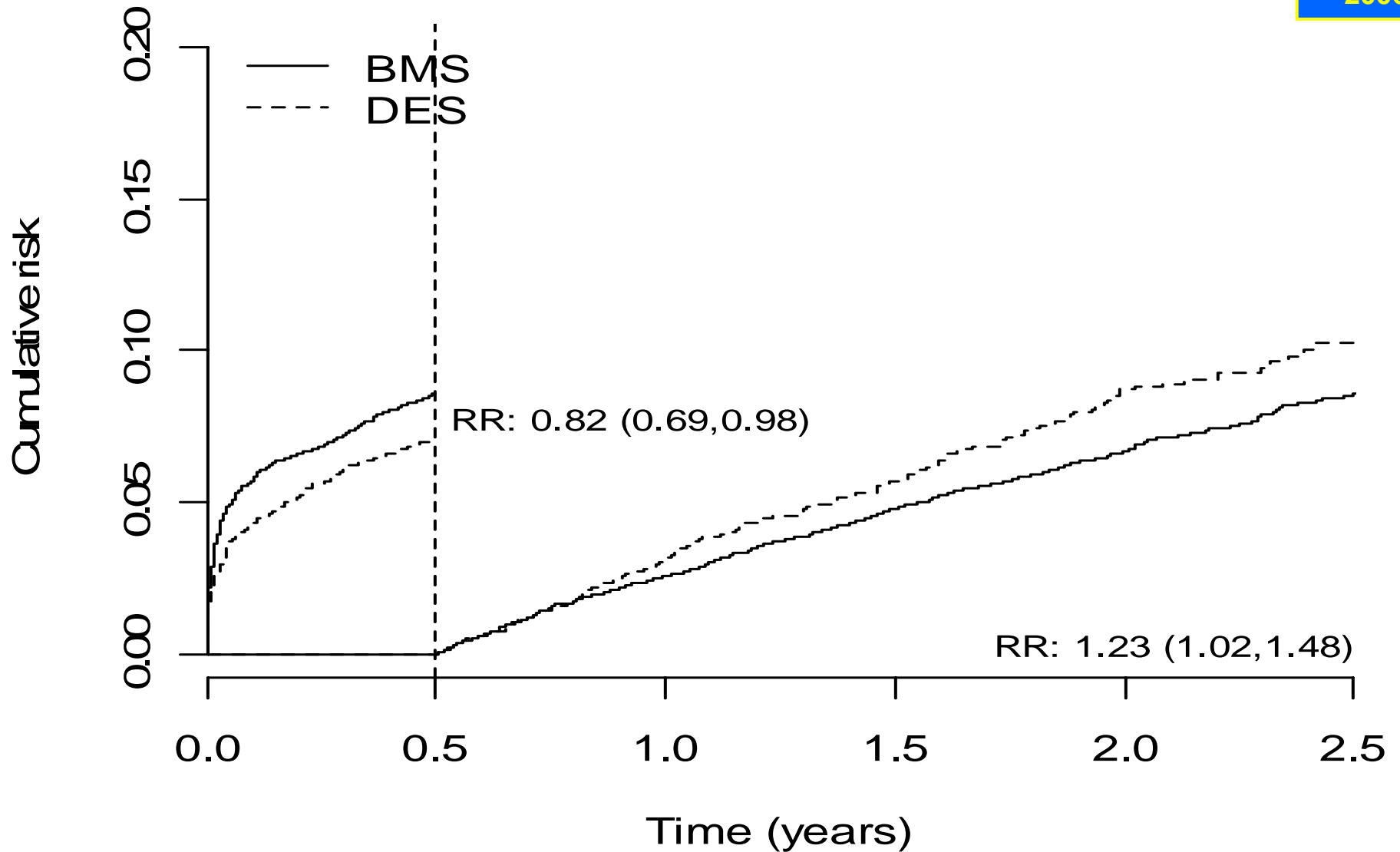
Myocardial infarction (Adjusted)

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Death/MI (Adjusted) Only one stent

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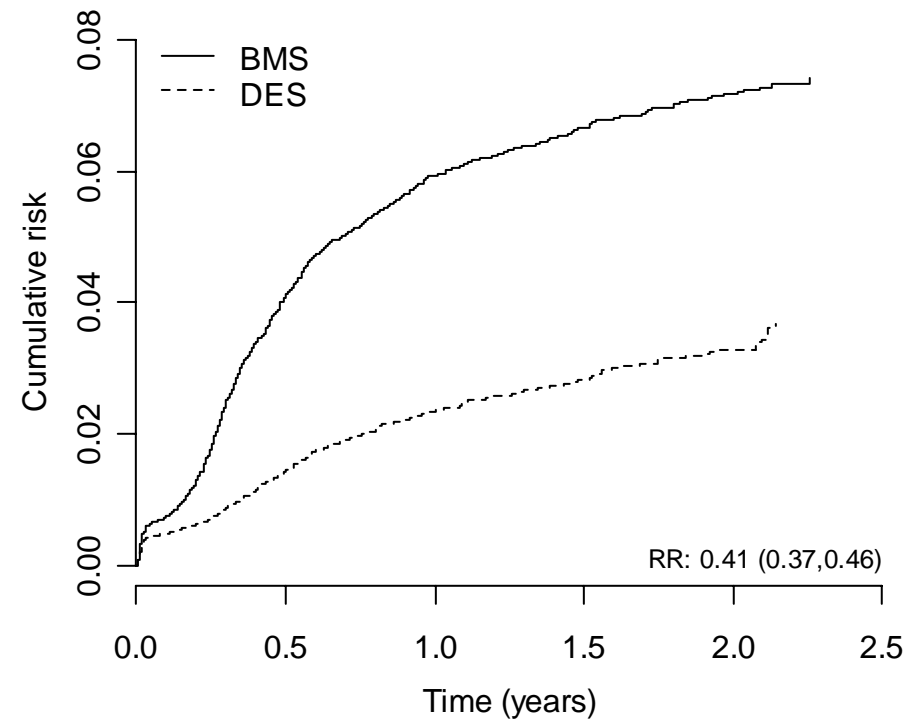
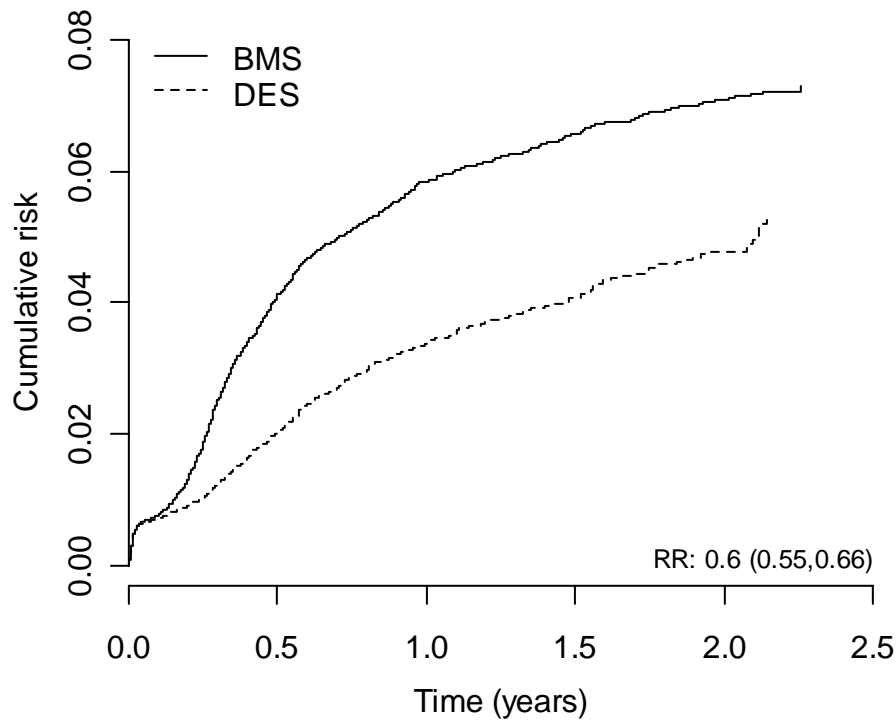


BMS	9556	8744	8541	6465	4154	2213
DES	3432	3179	3092	1897	932	347

Restenosis in individual stents 2004-2005

– crude (left) adjusted (right)

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BMS	23734	20229	15139	9478	4292	0
DES	20976	17342	10974	5669	2009	0

BMS	23734	20229	15139	9478	4292	0
DES	20976	17342	10974	5669	2009	0

Summary (1):

During 2.5 years follow-up the DES-group compared to the BMS-group, with adjustment for differences in available background characteristics, showed:

- no significant difference in the composite of death and myocardial infarction.
- increased mortality.
- no significant difference in myocardial infarction.

Summary (2):

After 6 months, the DES-group compared to the BMS-group, after adjustment for available background characteristics, showed:

- 20 % relative rise in the death/myocardial infarction, corresponding to a yearly absolute increased risk of 0.5 - 1 %
- 32 % relative increase in mortality, corresponding to a yearly absolute increased risk about 0.5 %
- unchanged increase of risk from 6 months to 3 years.

In the DES-group the rate of restenosis was halved,
- corresponding to an absolute reduction of around 3 %.

Limitations

These differences between the DES-group and the BMS group might not only be caused by differences in stent properties

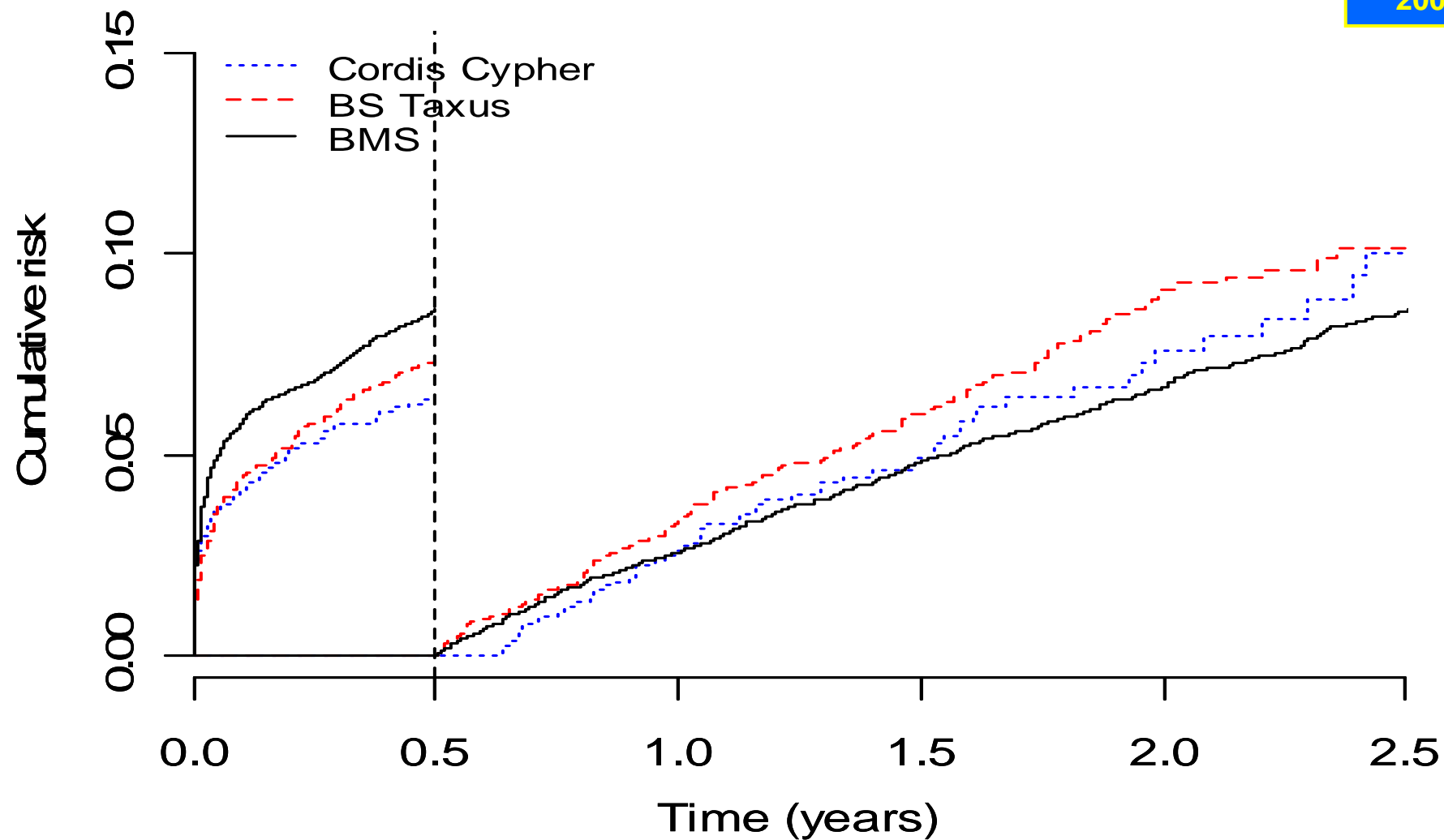
Alternative or contributing explanations:

- Non-registered differences between the patient groups?
- Differences in the need for long-term protection by dual anti-platelet treatment?



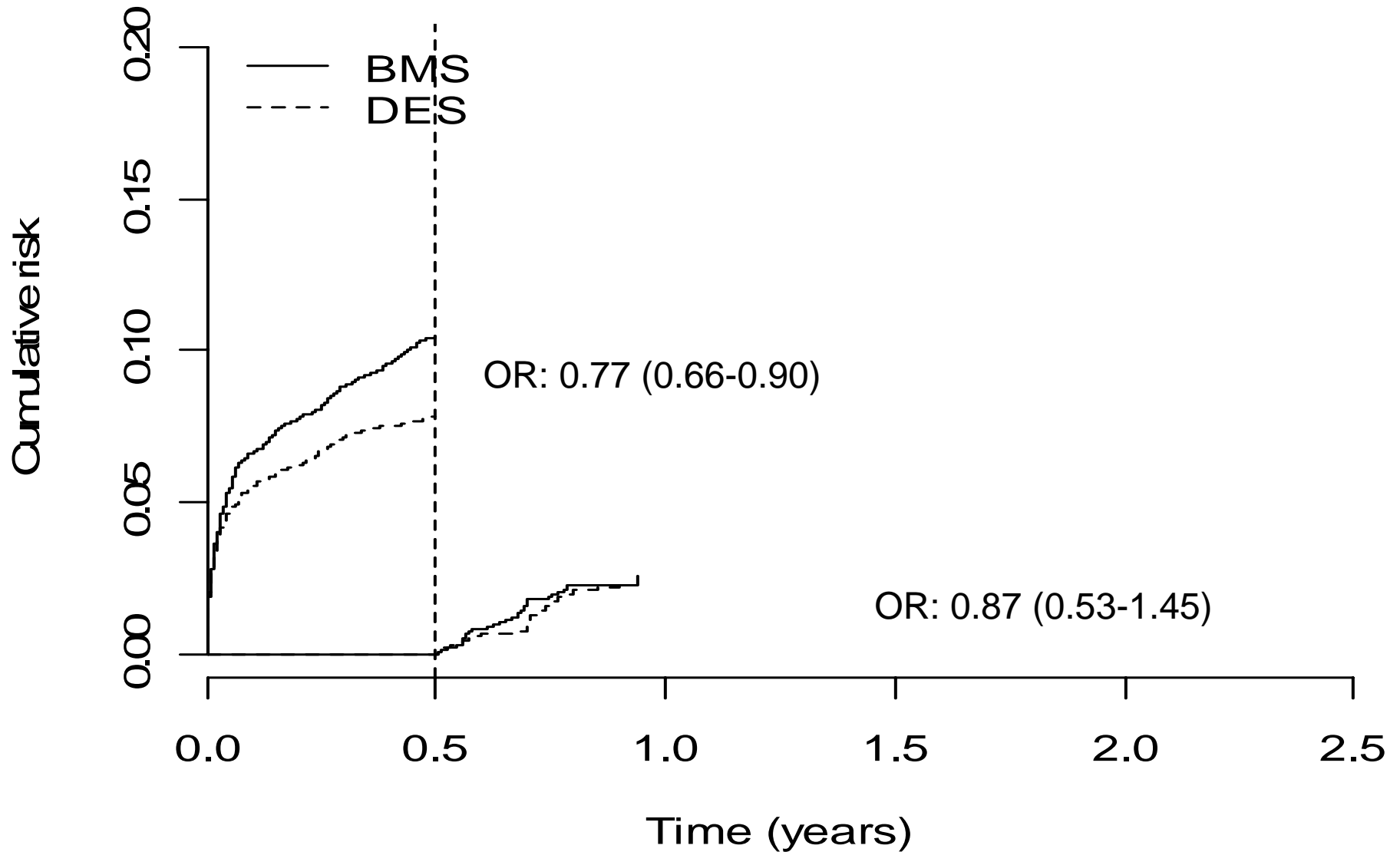
Different stents - Death/MI (crude) one stent

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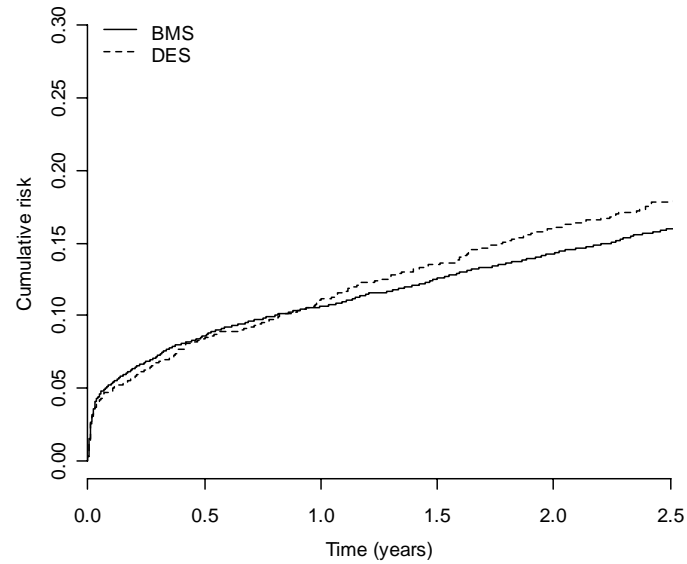
Cyph	1030	958	937	595	312	156
Taxus	2608	2406	2331	1431	682	213
BMS	10317	9434	9213	7034	4544	2417

Death/MI 2005 (Adjusted)



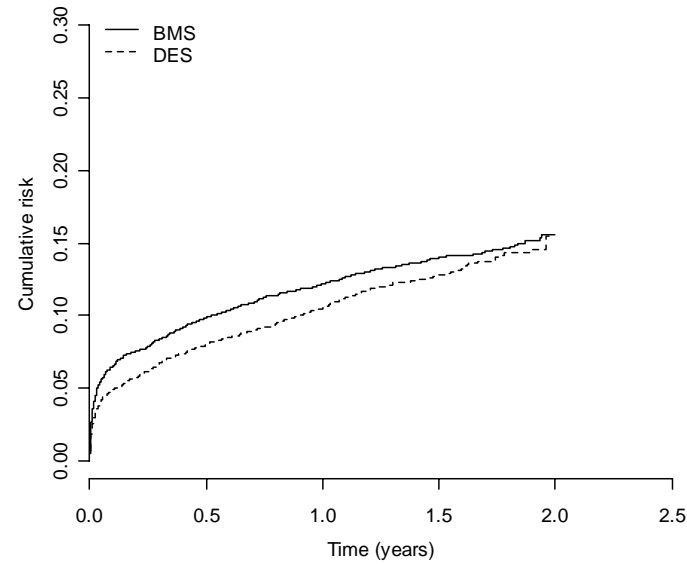
BMS	5208	2503	0	0	0	0
DES	5729	2431	0	0	0	0

2003



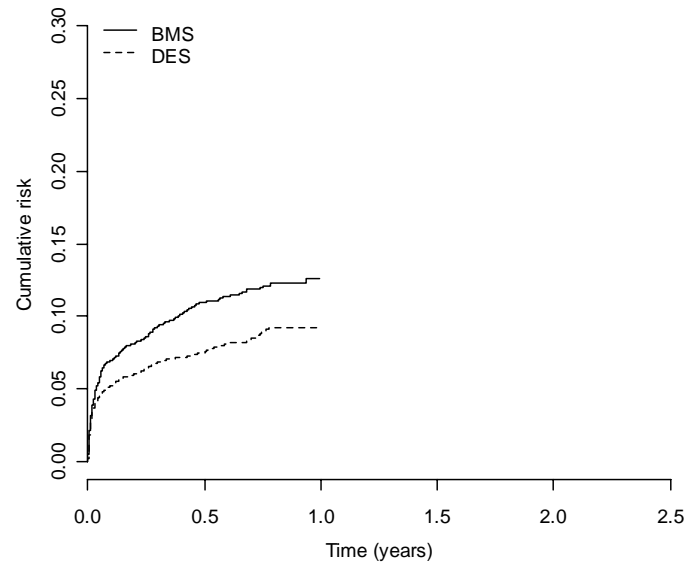
BMS	6954	6353	6215	6081	5963	3192
DES	1996	1828	1775	1726	1675	601

2004



BMS	6781	6111	5957	3196	2	0
DES	4037	3716	3613	1648	1	0

2005

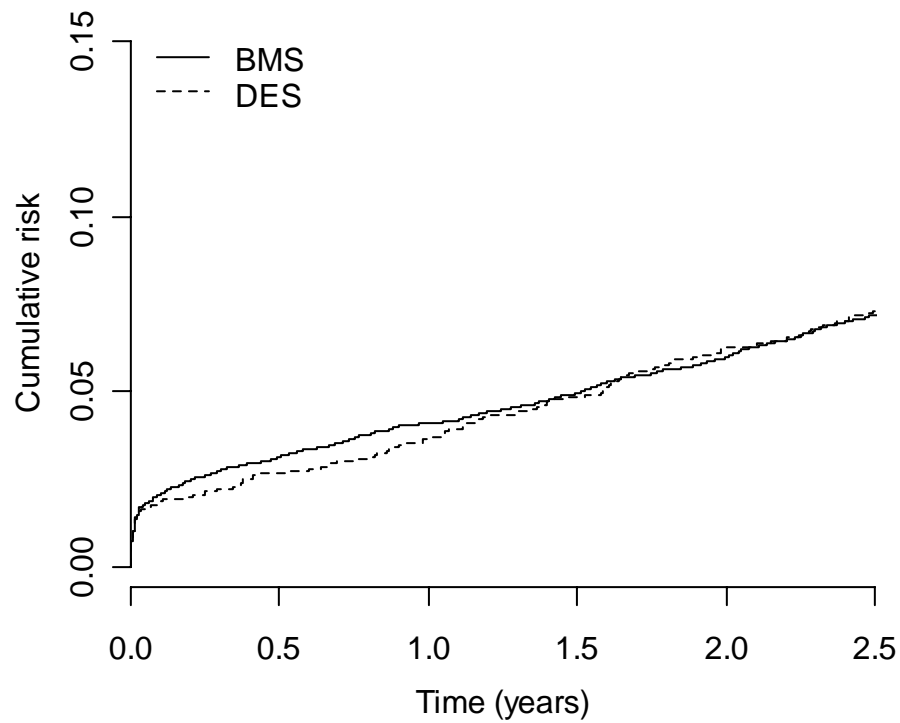


BMS	5531	2665	0	0	0	0
DES	5990	2572	0	0	0	0

Death/MI (crude) by year

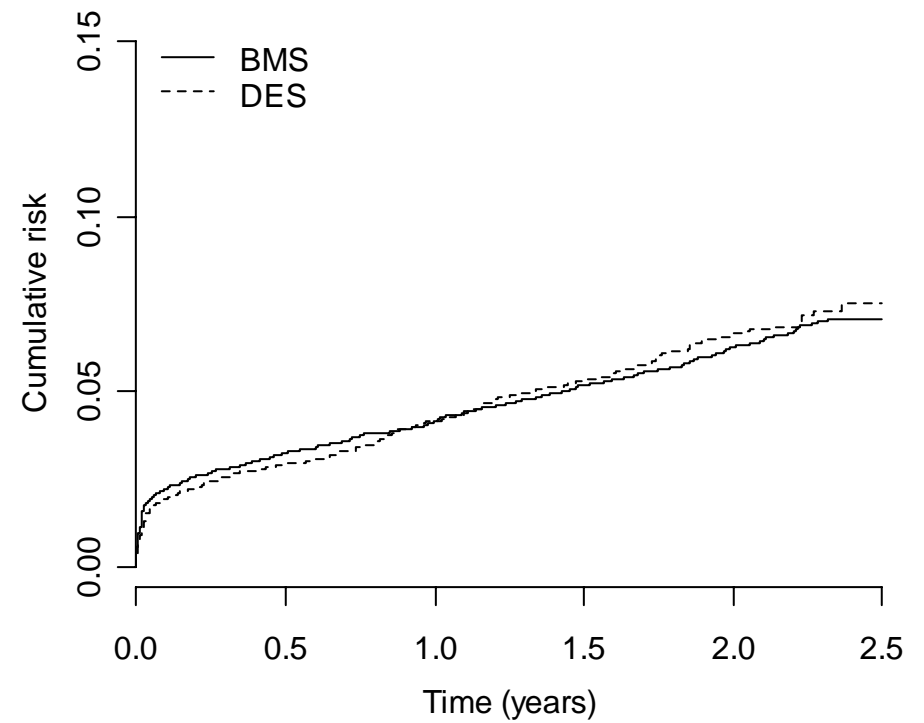
Death/MI (crude) by year

2003



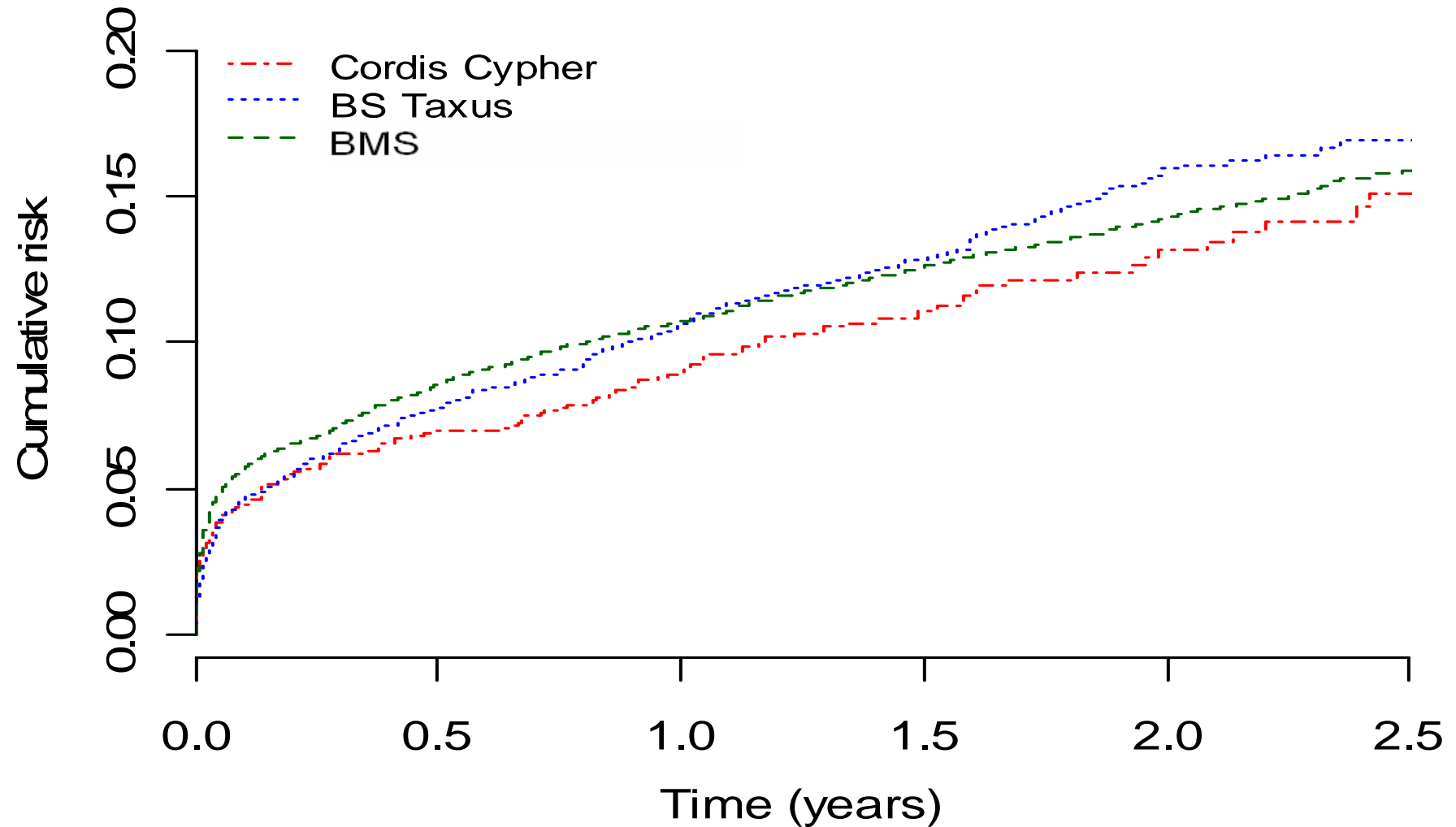
BMS	6954	6737	6669	6608	6538	6448
DES	1996	1942	1922	1899	1871	1849

2004



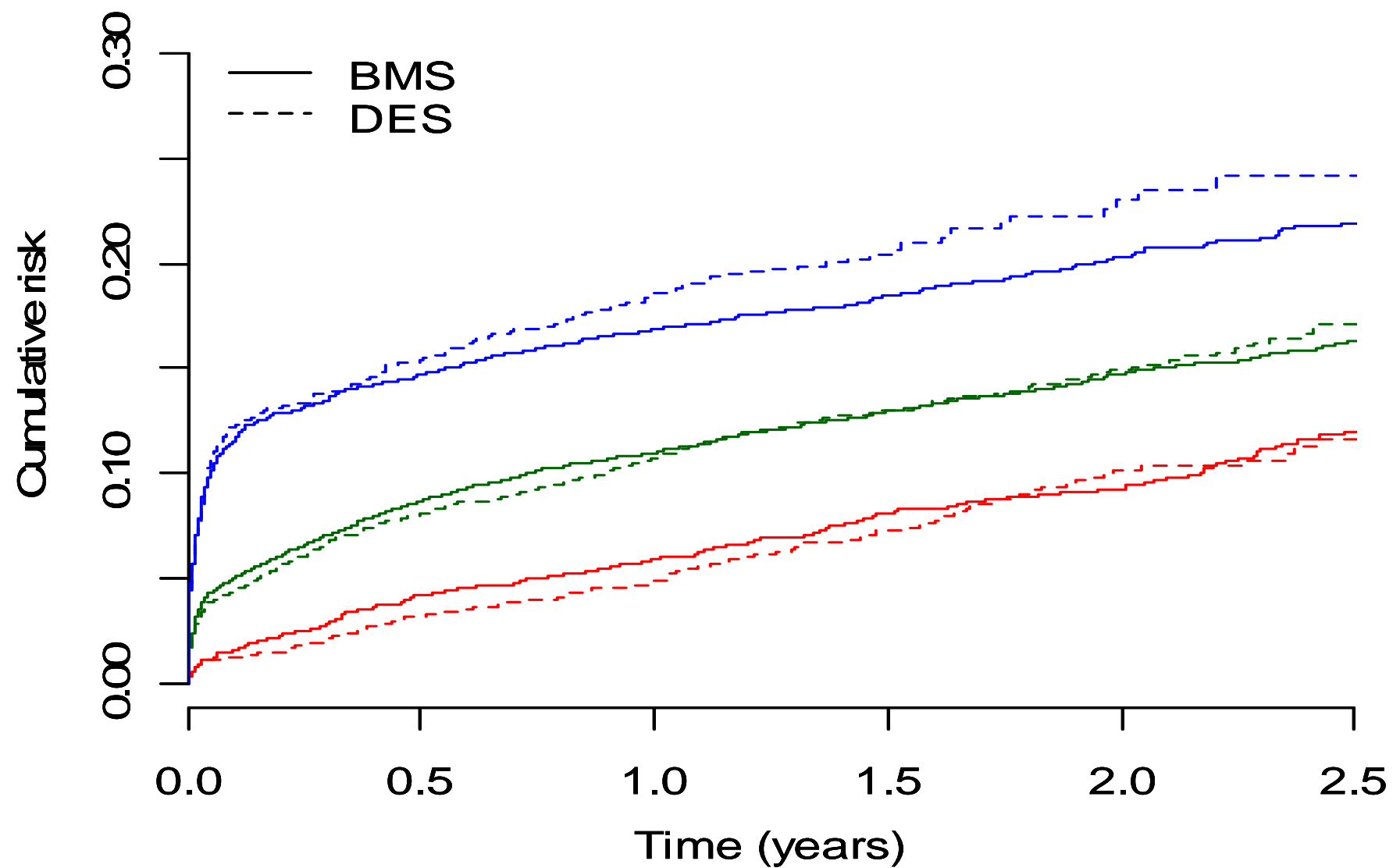
BMS	6781	6559	6500	6405	3452	0
DES	4037	3917	3870	3816	1740	0

Different stents - Death/MI (crude) one stent

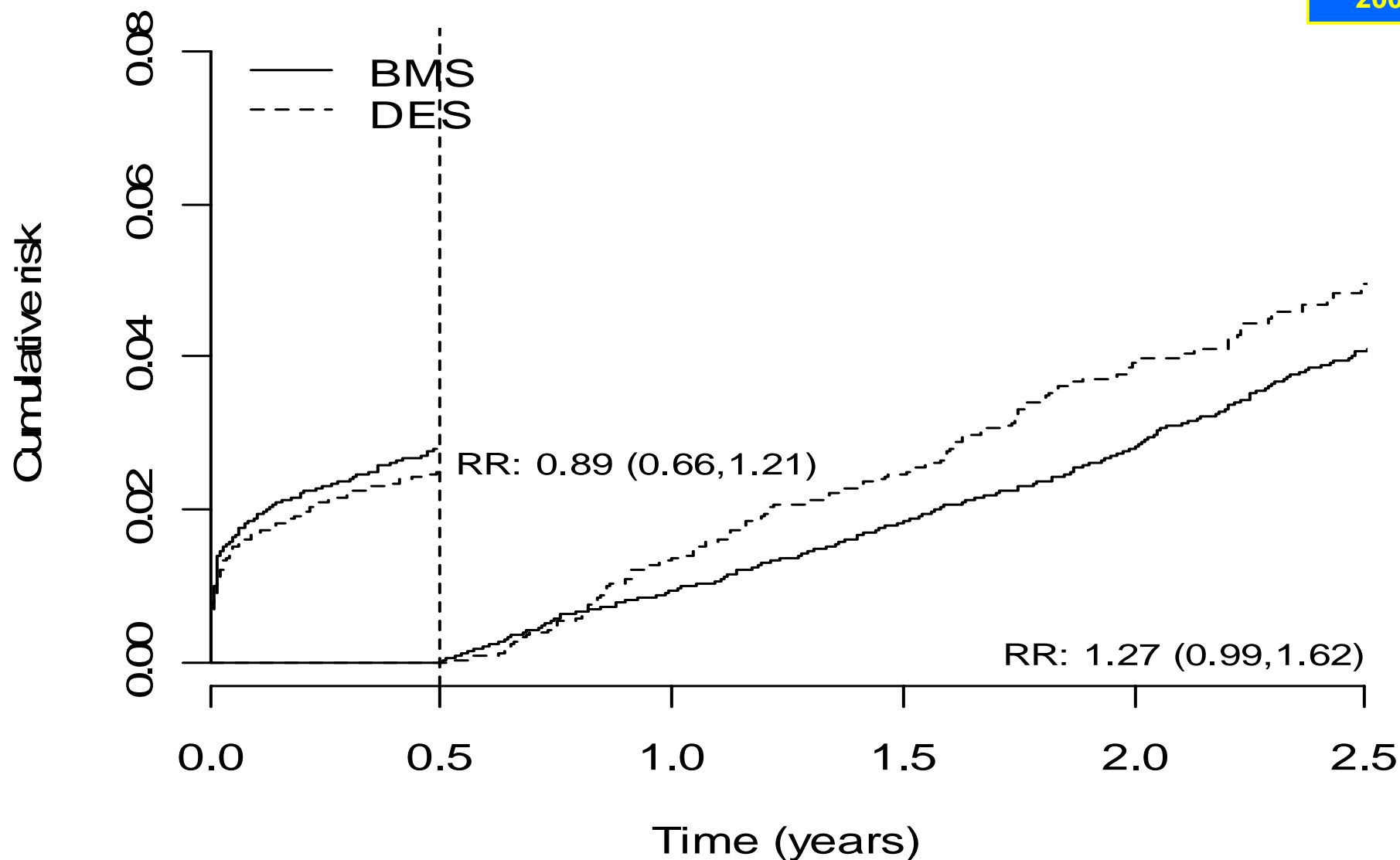


Cyph	1030	958	937	595	312	156
Taxus	2608	2406	2331	1431	682	213
End	0	0	0	0	0	0
BMS	10317	9434	9213	7034	4544	2417

Adjusted



Mortality (Adjusted) Only one stent



BMS	9556	9292	9201	9100	6928	4462
DES	3432	3341	3301	3266	2012	1025