Long-Term Outcomes with SES vs. BMS

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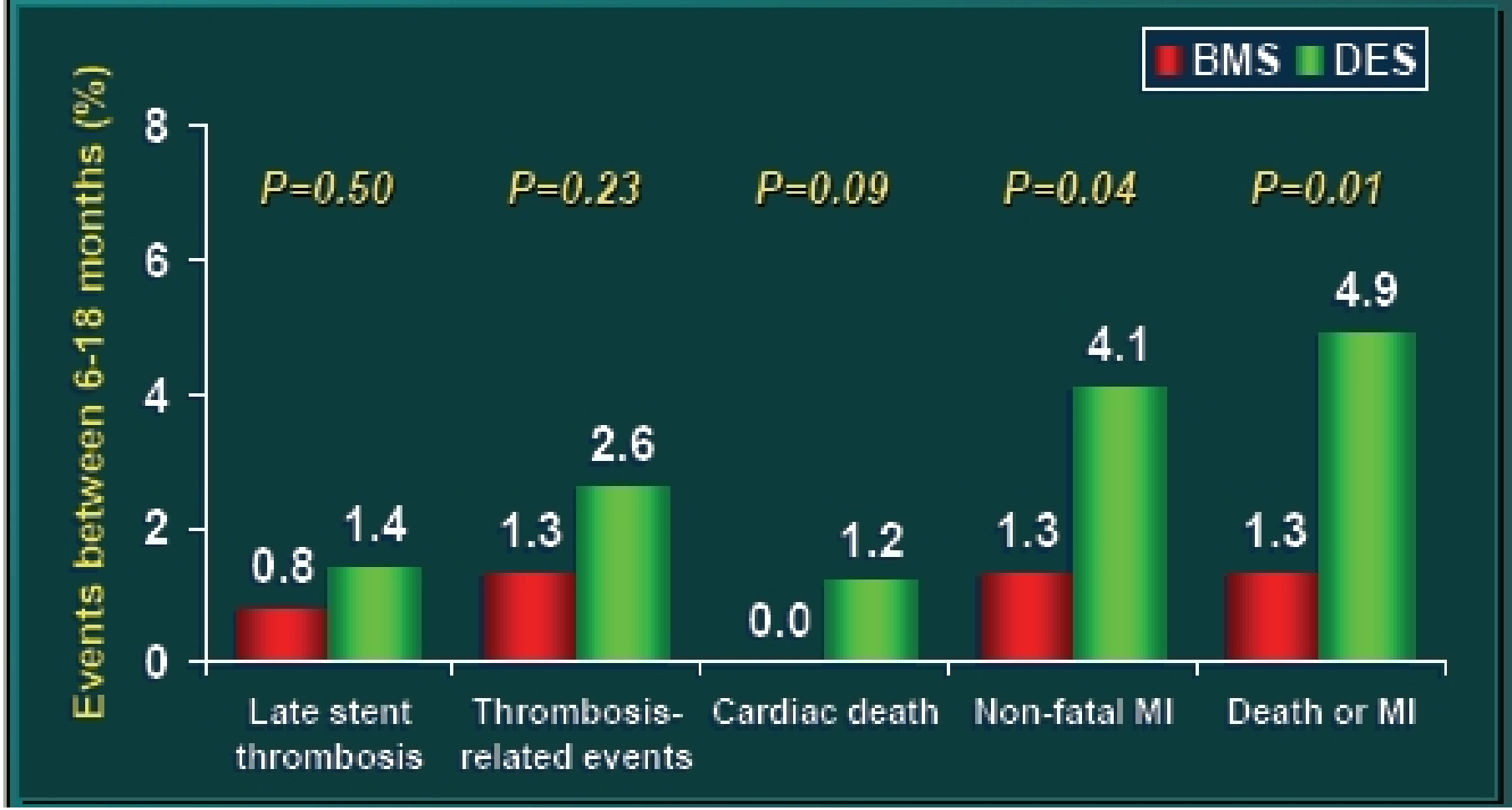
Background

- Recent reports have showed an increased risk of late stent thrombosis with the use of DES

- Long-term population-based cohort data from the Swedish SCAAR Registry reported initially increased mortality risk with the use of DES

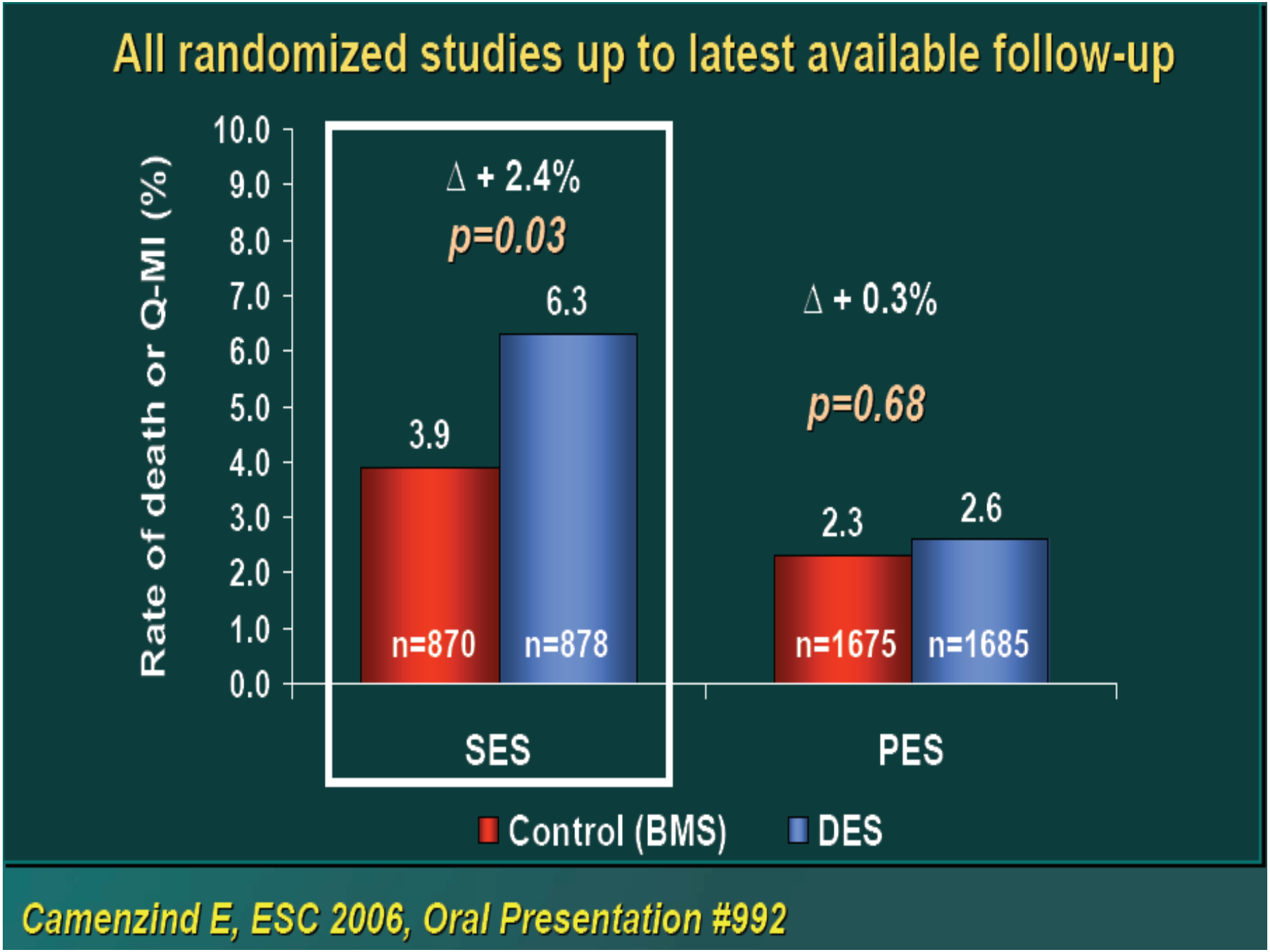
BASKET LATE Trial: 6-18 Mo MACE

N=743 (pts with early events excluded)



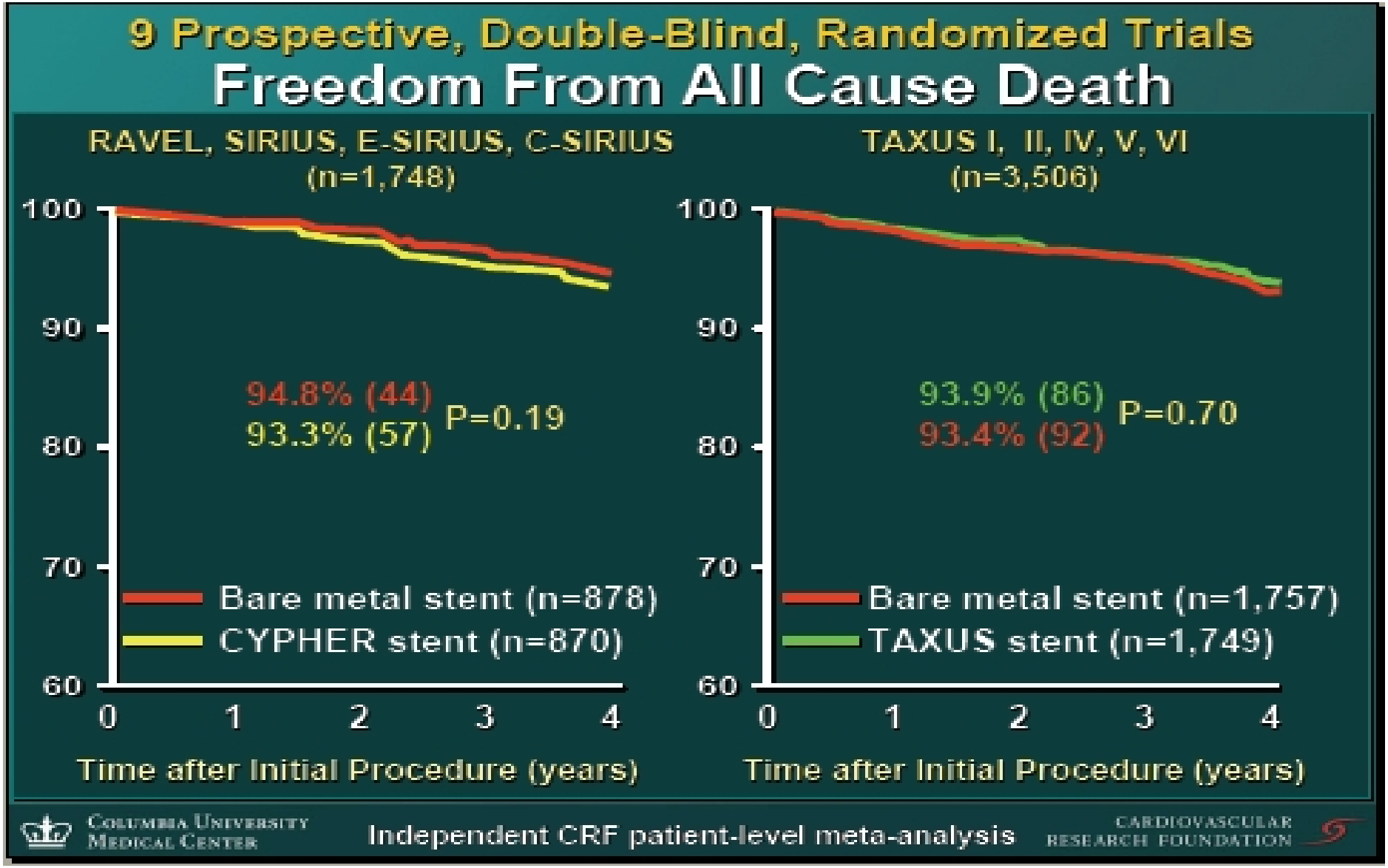
Pfisterer M. ACC 2006

All randomized studies up to latest available follow-up



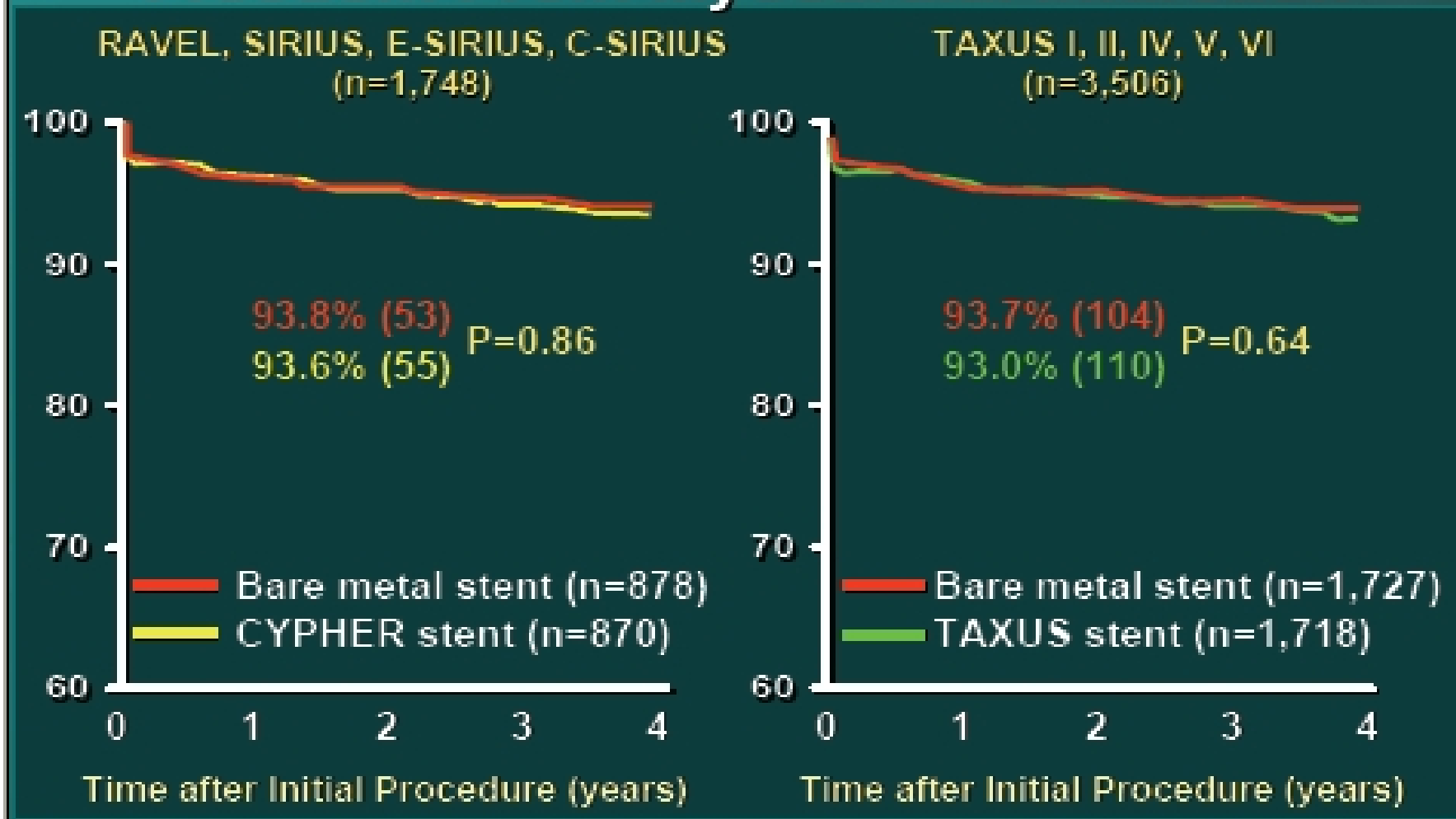
Camenzind E, ESC 2006, Oral Presentation #992

Patient-level Meta-analysis



9 Prospective, Double-Blind, Randomized Trials

Freedom From Myocardial Infarction



Columbia University Medical Center

Independent CRF patient-level meta-analysis

Cardiovascular Research Foundation

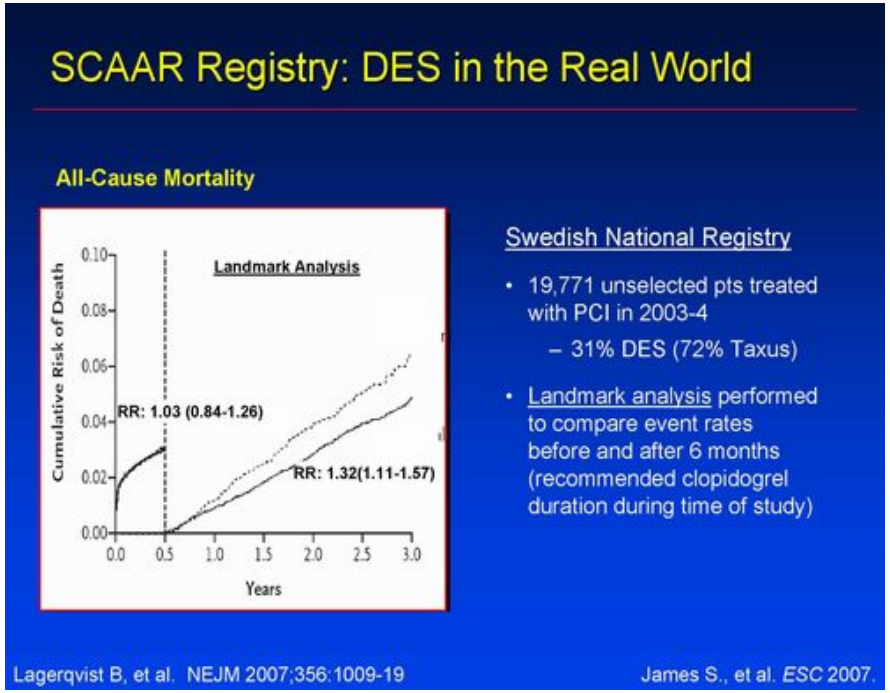
CYPHER RCT Stent Thrombosis
4 yr Follow-up: *Expanded Definition*

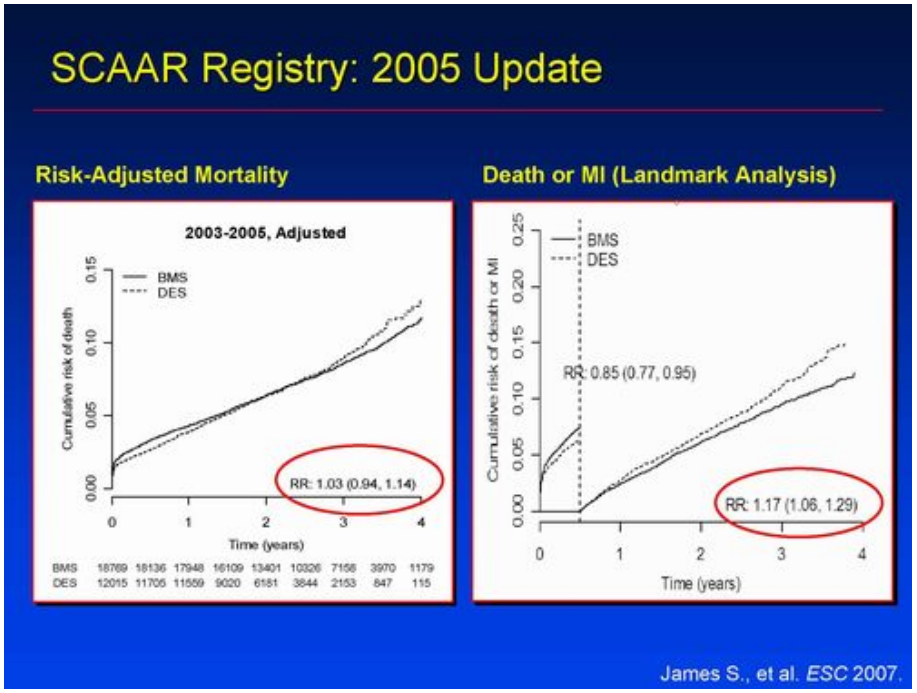
definite + probable + possible

Thrombosis	CYPHER N=878 Patients	BMS N=870 Patients	P Value*
All Thrombosis	3.2% (27)	3.2% (27)	0.9951

Data from 4 pooled RCT: SIRIUS, E and C SIRIUS and RAVEL

SCAAR Registry
2007 ESC





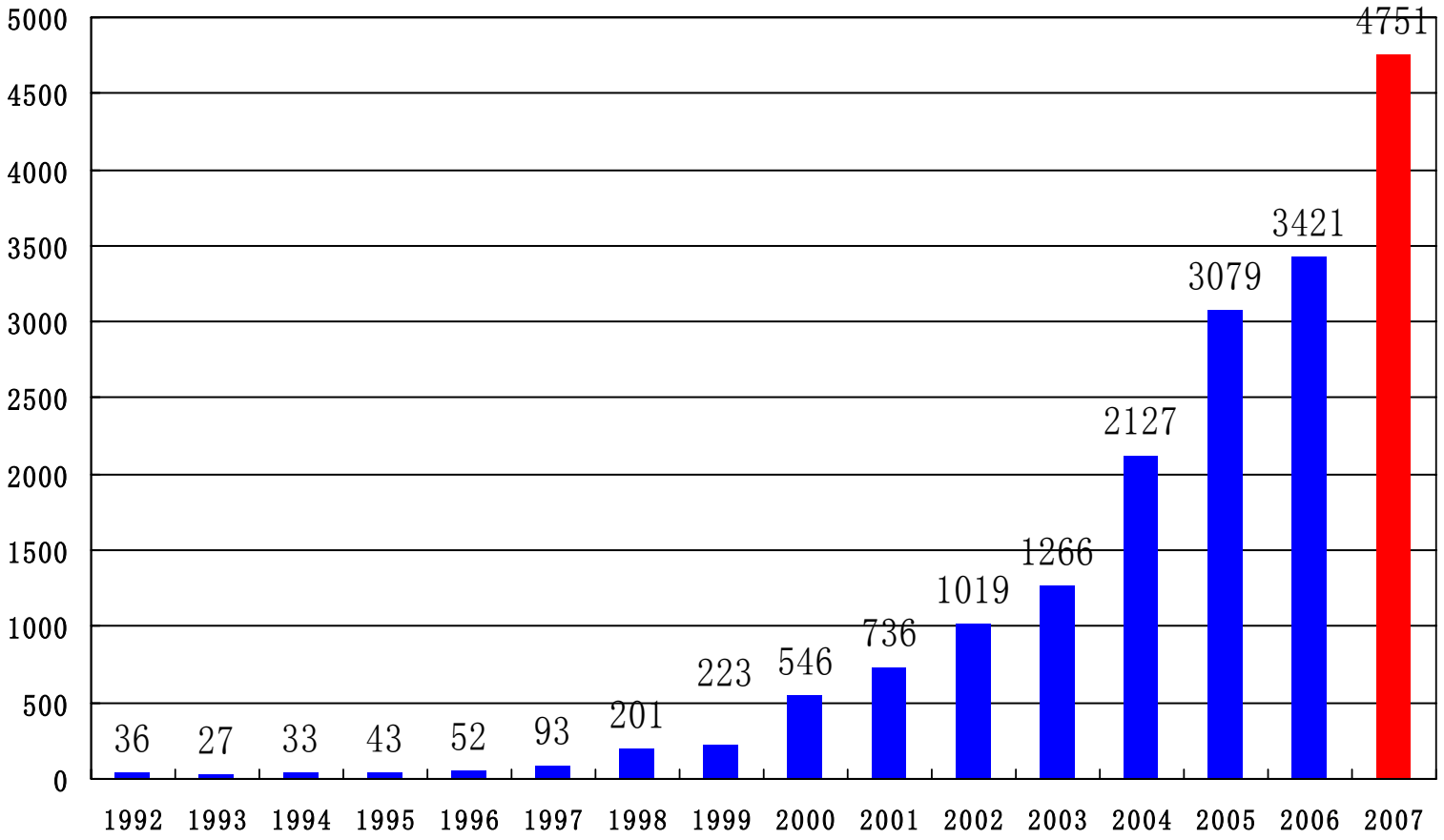
2003-2004,19771 patients.

At 3 years, mortality was significantly higher with DES

2003-2005, 35266 patients

No difference in mortality

PCI in Beijing Anzhen Hoapital



Methods(1)

- Retrospective single center, historical control study
  - 1420 consecutive patients with coronary heart disease were treated
  - 436 patients in BMS group (Jan 2001- Mar 2003)
  - 984 patients in SES group (Jan 2004- Jan 2005)
  - The long-term clinical outcomes covering a period of up to 2 years were compared between two groups

Methods(2)

- 1202 of 1420 patients were clinically followed up for 2 years
- 405 (92.9%, 405/436) patients were followed up in BMS group
- 897 (91.2%, 897/984) patients were followed up in SES group
- The follow-up by outpatient , telephone and some patients by angiography

Methods(3)

- Dual antiplatlet therapy
  - BMS group: Asprin 100mg/d + ticlopidine 75mg/d
    1 month
  - SES group : Asprin 100mg/d + Clopidogrel 75mg/d
    9-12 months

Purpose

- To evaluate the SES Safety
  - Death
  - Stent thrombosis
  - Myocardial infarction

Definition

Stent thrombosis (defined according to the Academic Research Consortium)

Definite: Angiographic confirmation
Probable: Any unexplained death within the first 30 days after intracoronary stenting
Possible: Any unexplained death occurring from 30 days after intracoronary stenting until the end of the follow-up period

Statistical Method

- Chi-Square comparison of categorical variables and outcomes
- Kaplan-Meier plots of cumulative survival to 2 years with log rank test for differences
- $P<0.05$ considered significant
- SPSS version 13.0

Results

Characteristics of All Patients

Variable	BMS	SES	P value
Age (mean yrs)	58.6±10.6	59.9±10.8	0.035
Male sex (%)	76.2	51.1	0.000
Hypertension (%)	53.1	50.4	0.330
Diabetes (%)	17.8	21.0	0.309
Hyperlipemia (%)	9.5	10.2	0.149
Smoking (%)	40.2	36.0	0.111
SAP (%)	8.9	10.2	0.441
ACS (%)	91.9	89.8	0.441
STEMI (%)	38.6	16.7	0.000

Findings on angiography

Variable	BMS	SES	P value
1-vessel disease (%)	53.1	52.9	0.964
2-vessel disease (%)	25.5	28.2	0.241
3-vessel disease (%)	16.4	18.9	0.241
Bifcation disease (%)	7.5	13.0	0.001
CTO (%)	5.1	7.0	0.164

2yr Follow-up:clinical outcomes

Variable	BMS	DES
	n(%)	n(%)
All cause death	7(1.7)	6(0.7)
Cardiac	4	3
No cardiac	3	3
Nonfatal MI	4(1.0)	5(0.6)
Death / Nonfatal MI	11(2.7)	11(1.2)
Stent thrombosis	4(1.0)	7(0.8)
LST	2(0.5)	5(0.6)

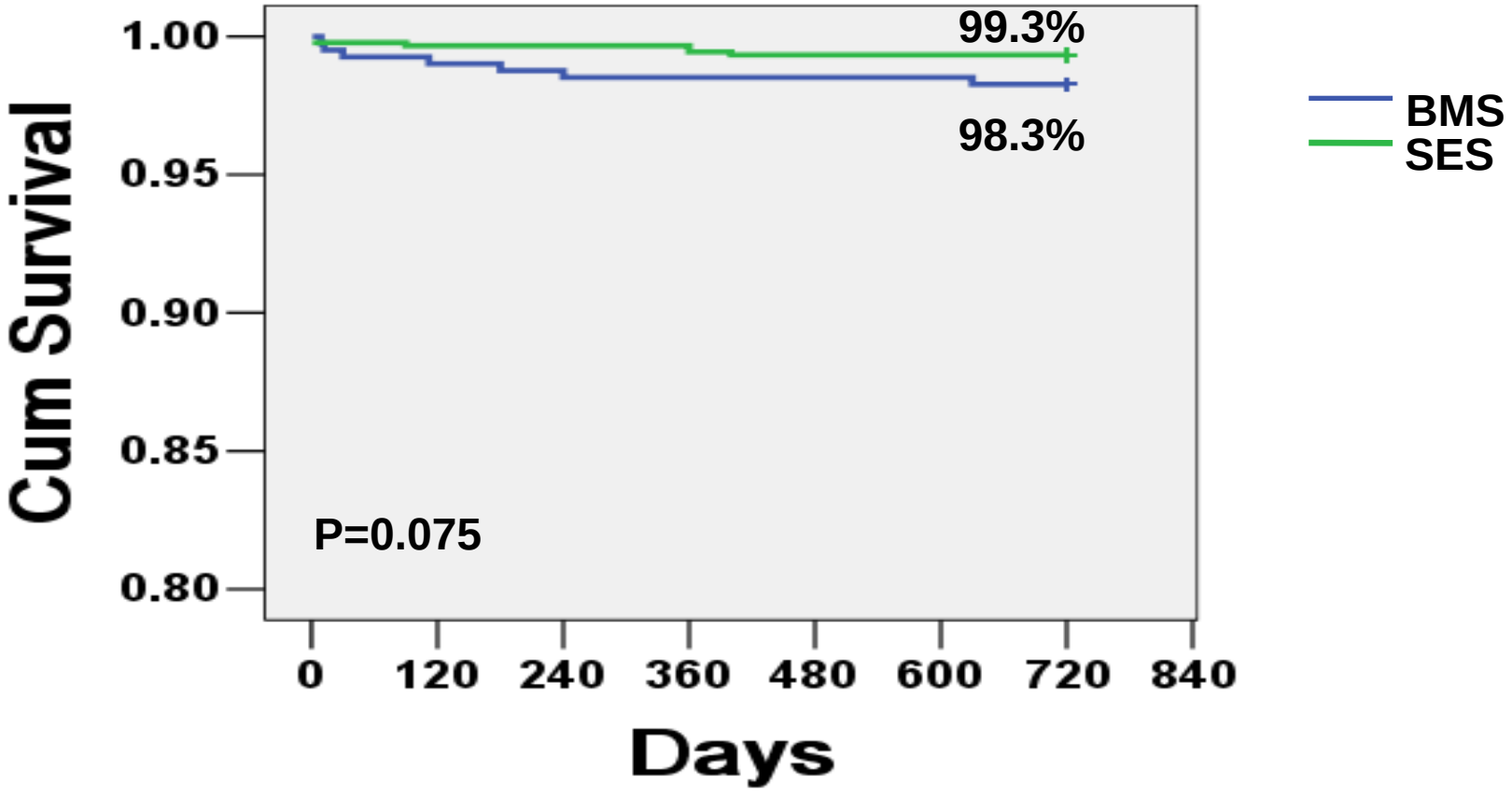


Figure 1. Kaplan–Meier Survival Curves for Patients Who Received SES and Those Who Received BMS.
The survival rates at 720 days are shown. P values were calculated with the use of the log-rank test (unadjusted).

Variable	BMS	DES
All cause death n(%)	7(1.7)	6(0.7)
Cardiac	4	3
No cardiac	3	3
Nonfatal MI n(%)	4(1.0)	5(0.6)
Death / Nonfatal MI n（%）	11(2.7)	11(1.2)
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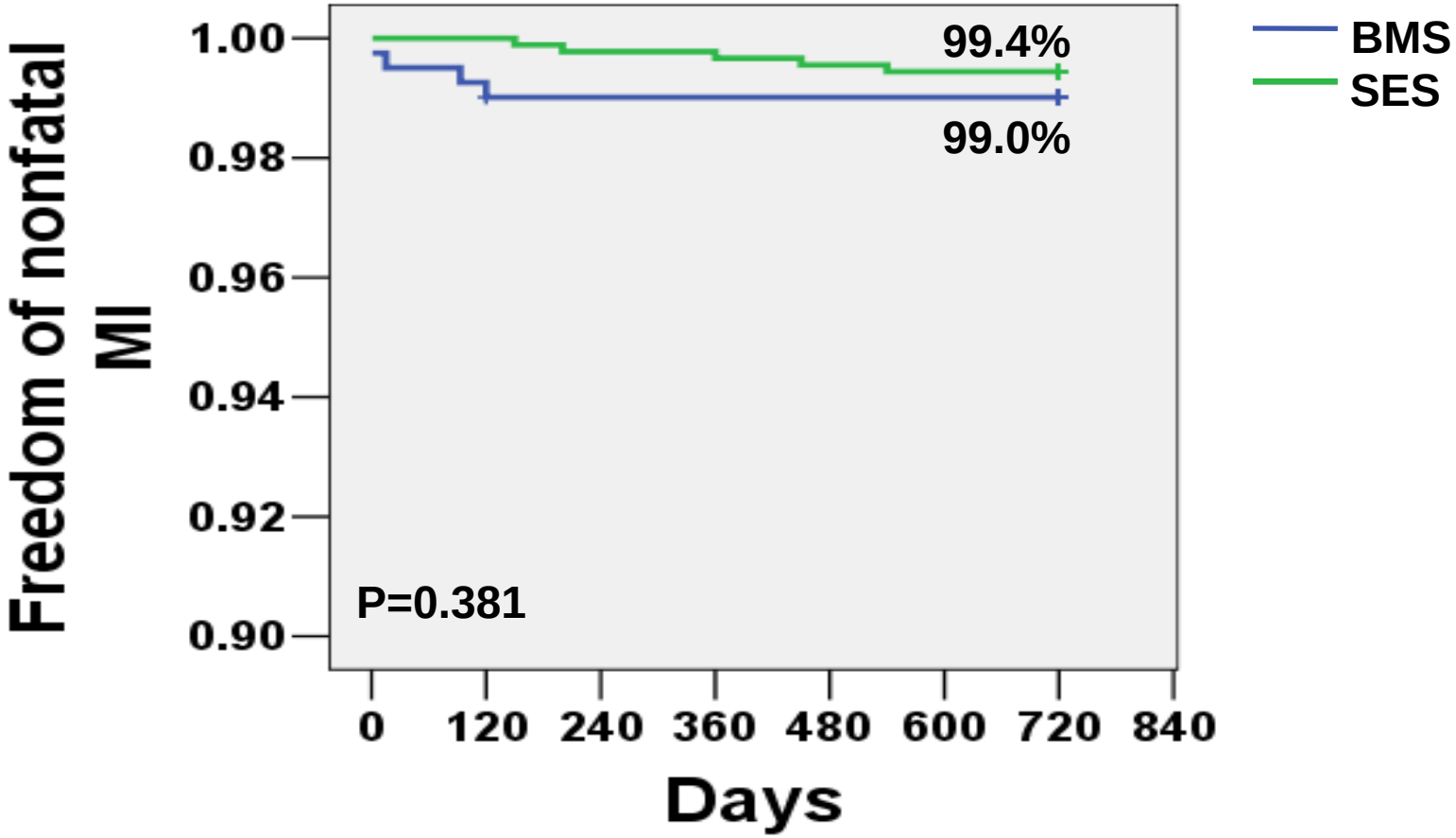

Figure 2. Kaplan–Meier Curves for the Survival of Patients without nonfatal MI.

The survival rates at 720 days are shown. P values were calculated with the use of the log-rank test (unadjusted).

Variable	BMS	DES
All cause death n(%)	7(1.7)	6(0.7)
Cardiac	4	3
No cardiac	3	3
Nonfatal MI n(%)	4(1.0)	5(0.6)
Death / Nonfatal MI n（%）	11(2.7)	11(1.2)
Stent thrombosis n（%）	4(1.0)	7(0.8)
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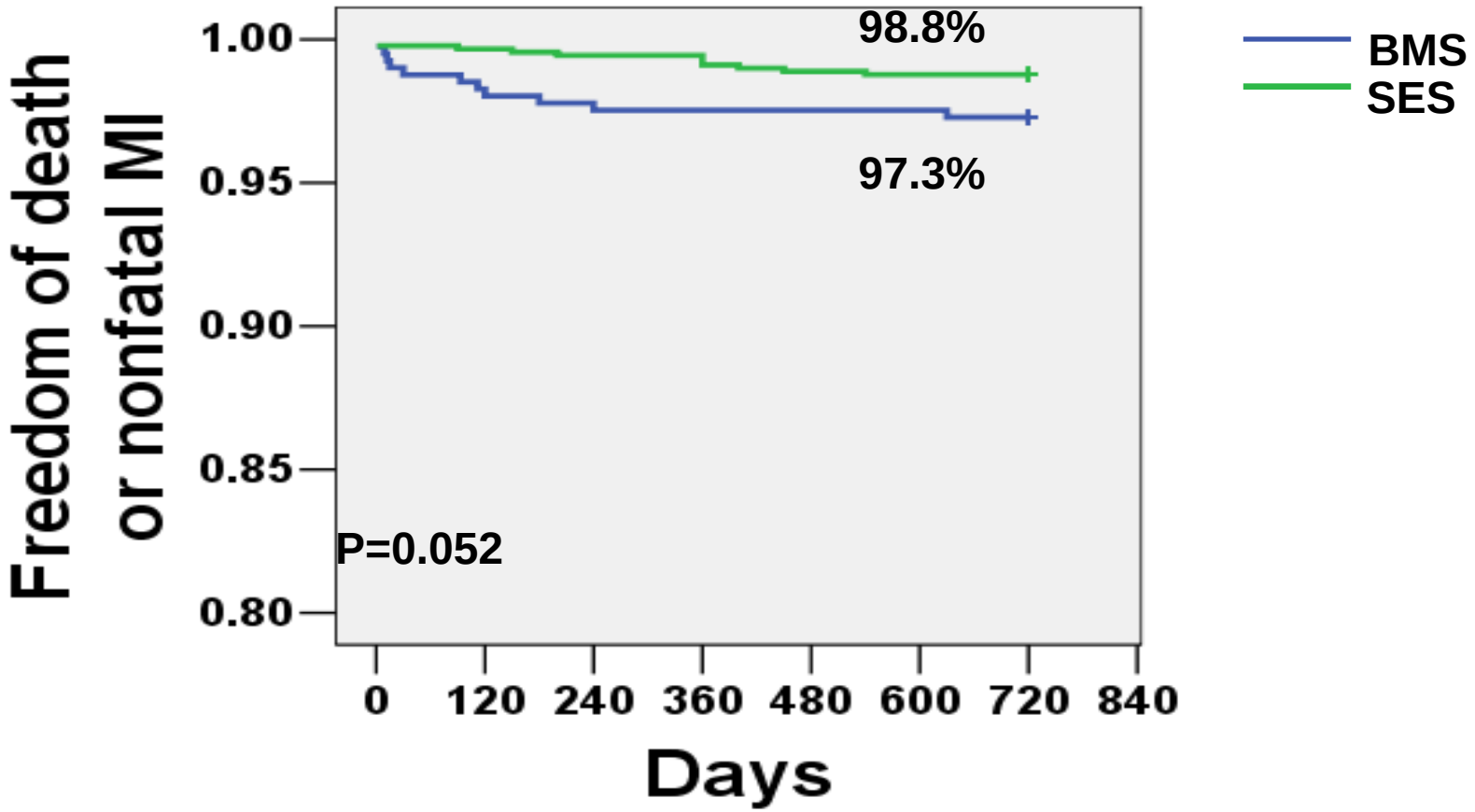

Figure 3. Kaplan–Meier Survival Curves for Patients Who are freedom from death or nonfatal MI.

The survival rates at 720 days are shown. P values were calculated with the use of the log-rank test (unadjusted).

Variable	BMS	DES
All cause death n(%)	7(1.7)	6(0.7)
Cardiac	4	3
No cardiac	3	3
Nonfatal MI n(%)	4(1.0)	5(0.6)
Death / Nonfatal MI n（%）	112.7)	11(1.2)
Stent thrombosis n（%）	4(1.0)	7(0.8)
LST	2(0.5)	5(0.6)

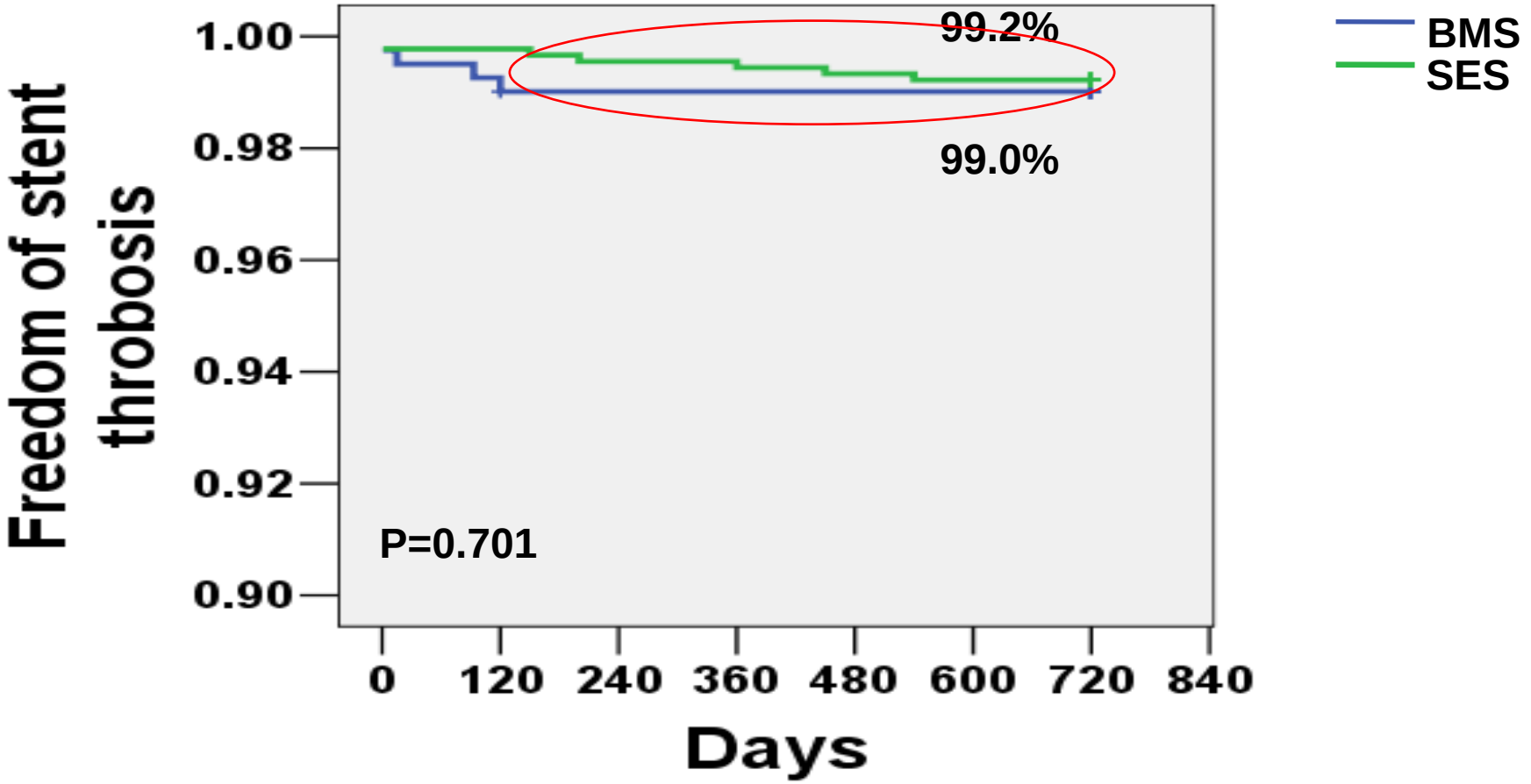

Figure 4. Kaplan–Meier Curves for the Survival of Patients without Stent Thrombosis as Defined by the ARC.
The survival rates at 720 days are shown. The P value was calculated with the use of the log-rank test (unadjusted).

Conclusion

- **In 1302 patients treated with a BMS or SES we found:**
  - No difference in mortality
  - No difference in MI
  - No difference in stent thrombosis
  - There are no late thrombosis after 120 days post PCI procedure in BMS group

Limitations

- No randomized trial
- There are inherent limitations about using the retrospective ,historical control study
- The study does not have complete follow-up data on compliance with dual antiplatlet therapy after hospital discharge