

DES Thrombosis

A Real World Experiences from a Single Center

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Background

- The DES randomized trials and real-world registries revealed that DES significantly reduced the need for revascularization
- Long term safety remains to be approached following DES compared to BMS implantation in daily clinical practice

Objective

- To evaluate whether the use of DES is associated with increased rates of thrombosis ,death, or MI compared with BMS
- To confirm whether the use of DES is associated with reduction in revascularization compared with BMS in general clinical practice in China

Methods

- Consecutive patients with PCI in Fu Wai Hospital from April 2004 to December 2006 were enrolled into analysis
- Patients assigned to DES or BMS groups based on treatment at index procedure
- All patients were scheduled for routinely clinical follow-up at 1m, 6m, 12m, 24m, 36m...
- Primary outcomes: death, MI, thrombosis, TLR, TVR according to ARC definition were compared between two groups

Drug-Eluting and Bare Metal Stenting in Fu Wai Hospital

**N=8,487 PCI Patients in
Fu Wai Hospital**
April 1, 2004 - December 31, 2006
At median of follow-up 1.9 (1-4) yrs

14 stent implantation failed

**N=8,473
PCI Patients with stent**

885 patients with both
stent types excluded

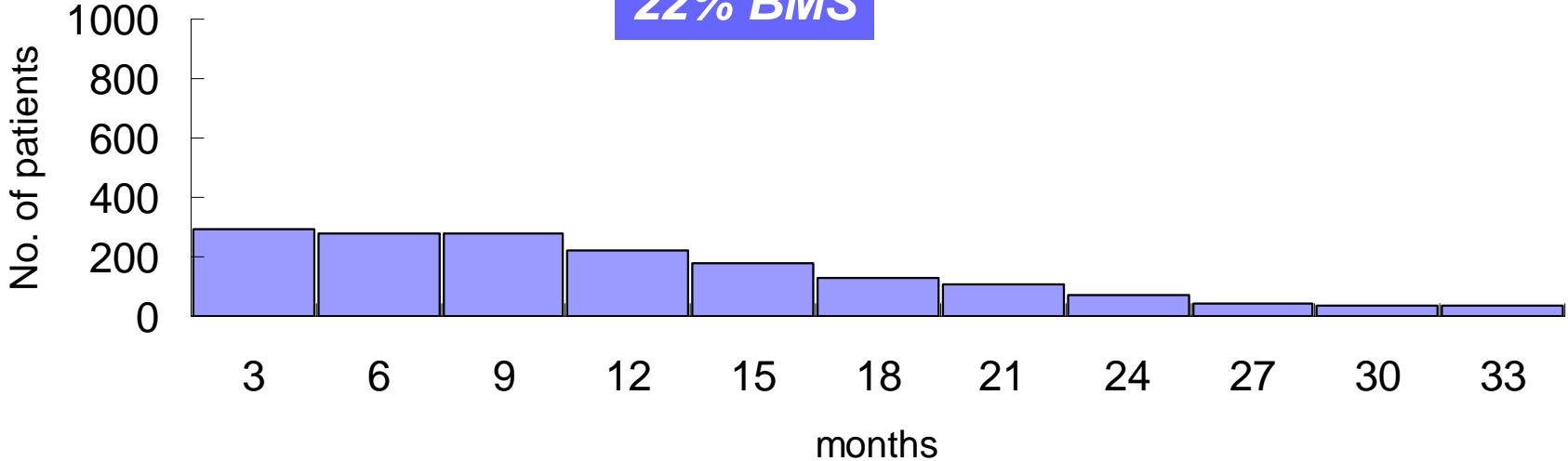
**N=1,667
BMS Only Patients**

**N=5,921
DES Only Patients**

Mean follow-up rate 98%

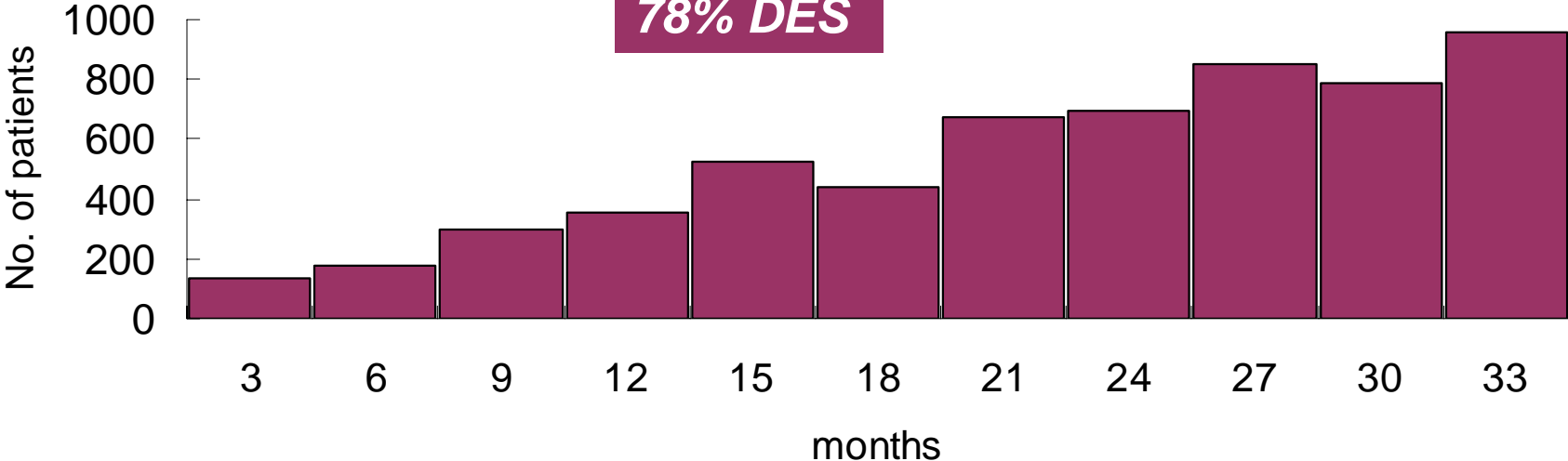
BMS (1667 patients)

22% BMS



DES (5921 patients)

78% DES



Baseline Characteristics <1>

	DES (n = 5921)	BMS (n = 1667)	p value
Age – yrs	57.8 ± 10.6	59.1 ± 11.5	<0.001
Female (%)	20.5	19.9	0.61
Prior MI (%)	40.9	54.0	<0.001
Q – MI (%)	85.4	89.7	0.001
0-24hr PCI (%)	3.8	23.4	<0.001
24-72hr PCI (%)	0.6	1.9	0.001
UAP (%)	53.4	66.8	<0.001
LVEF (%)	59.7 ± 21.4	59.1 ± 22.1	0.80

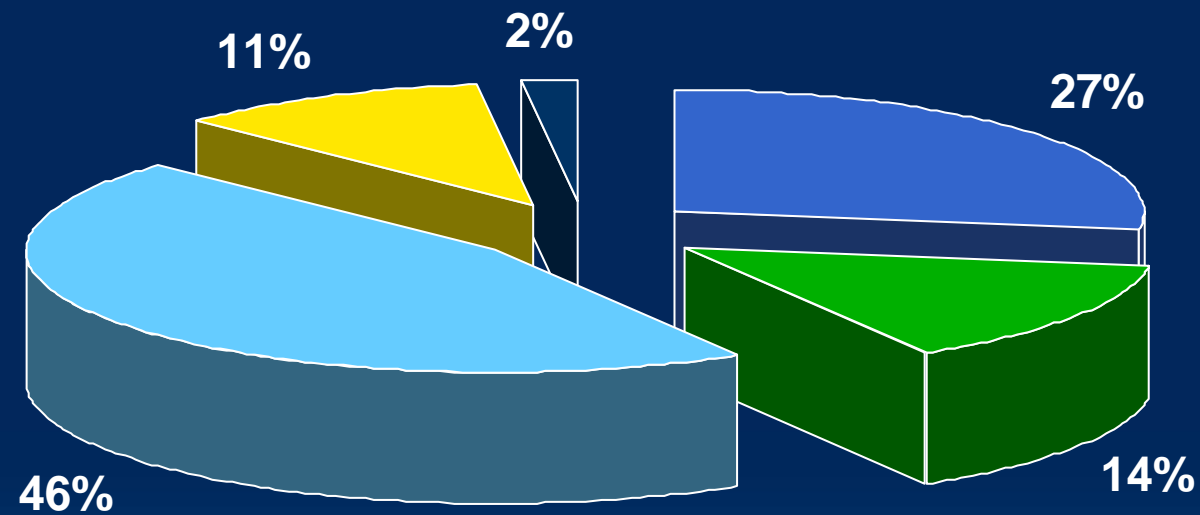
Baseline Characteristics <2>

	DES (n = 5921)	BMS (n = 1667)	p value
Diatetes Mellitus(%)	23.1	18.2	<0.001
Hyperlipidemia (%)	36.2	28.1	<0.001
Hypertension (%)	58.2	55.7	0.08
Current Smoker (%)	48.9	51.4	0.07
Family History (%)	5.6	5.0	0.34
Cerebral Vascular Disease (%)	1.9	2.5	0.17
Peripheral Vascular Disease (%)	0.9	0.9	0.93
Prior CABG (%)	2.3	2.0	0.51
Prior PCI (%)	21.5	15.3	<0.001

Procedural Characteristics

	DES (n = 5921)	BMS (n = 1667)	p value
Number of lesions treated	1.56 ± 0.77	1.39 ± 0.66	<0.001
Left Anterior Descending (%)	47.0	33.7	<0.001
Circumflex (%)	22.1	23.3	0.23
Right Coronary Artery (%)	26.4	41.2	<0.001
Left Main (%)	4.0	1.4	<0.001
Saphenous Vein Graft (%)	0.3	0.4	0.76
Arterial Graft (%)	0.2	0.0	0.06
Reference Vessel Diameter (mm)	3.04 ± 1.27	3.25 ± 1.15	<0.001
Lesion Length (mm)	22.8 ± 14.1	10.6 ± 11.1	<0.001

Proportion of DES per Lesion

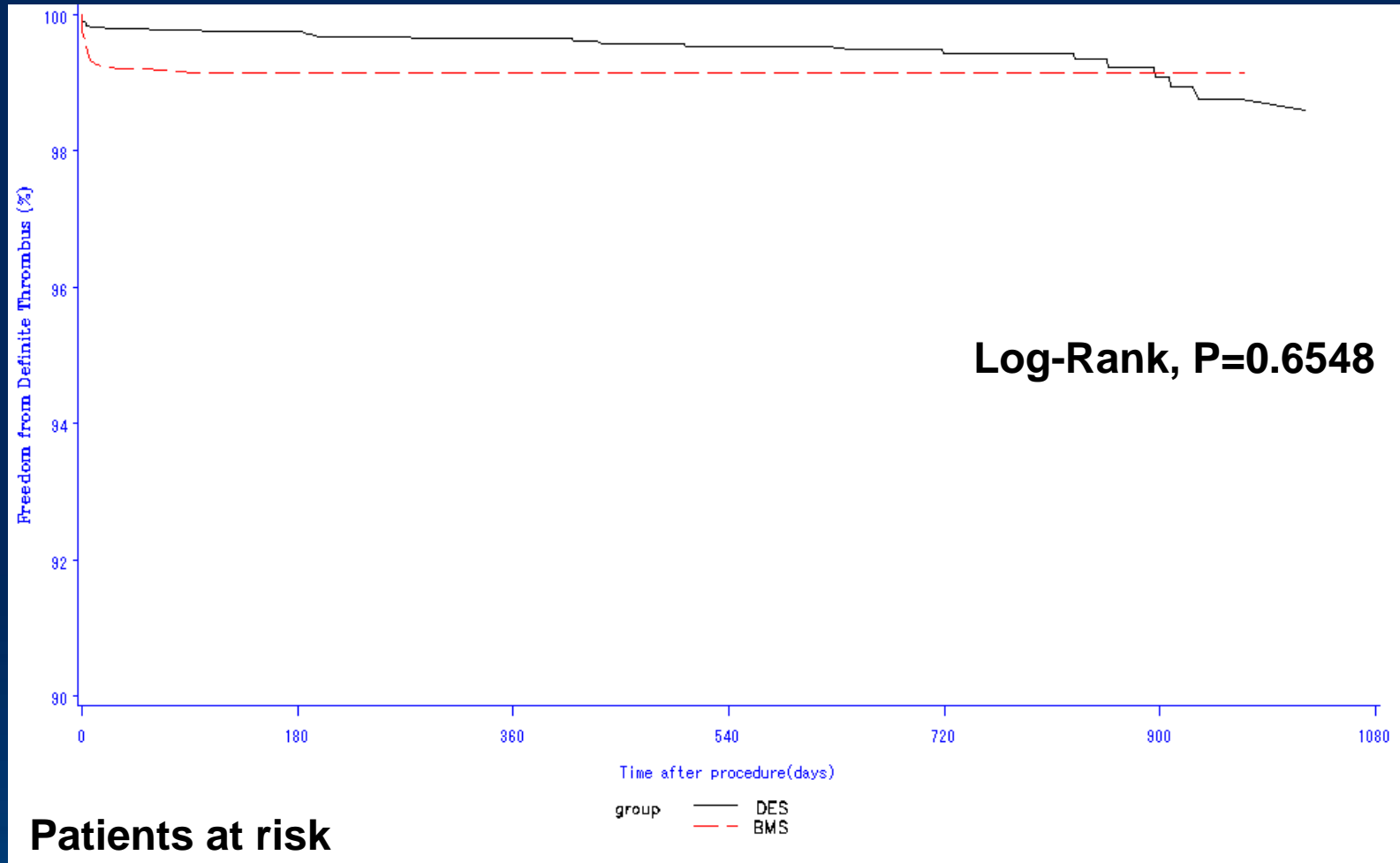


■ CYPHER ■ TAXUS ■ FRIEBIRD ■ EXCEL ■ ENDEAVOR

Stent Thrombosis by ARC Definition

	BMS (n=1667)	DES (n=5921)	P-Value
Definite	0.8% (14)	0.5% (32)	0.164
Probable	0.8% (13)	0.8% (46)	0.990
Definite+Probable	1.6% (27)	1.3% (78)	0.351
Possible	0.5% (9)	0.3% (20)	0.237
Definite+Probable+Possible	2.2% (36)	1.7% (98)	0.167
Acute	0.4% (6)	0.2% (9)	0.091
Subacute	0.7% (11)	0.3% (16)	0.018
Early (<= 30 days)	1.0% (17)	0.4% (25)	0.004
Late (31-365 days)	0.7% (12)	0.6% (33)	0.445
Very Late (> 365 days)	0.4% (7)	0.7% (40)	0.240

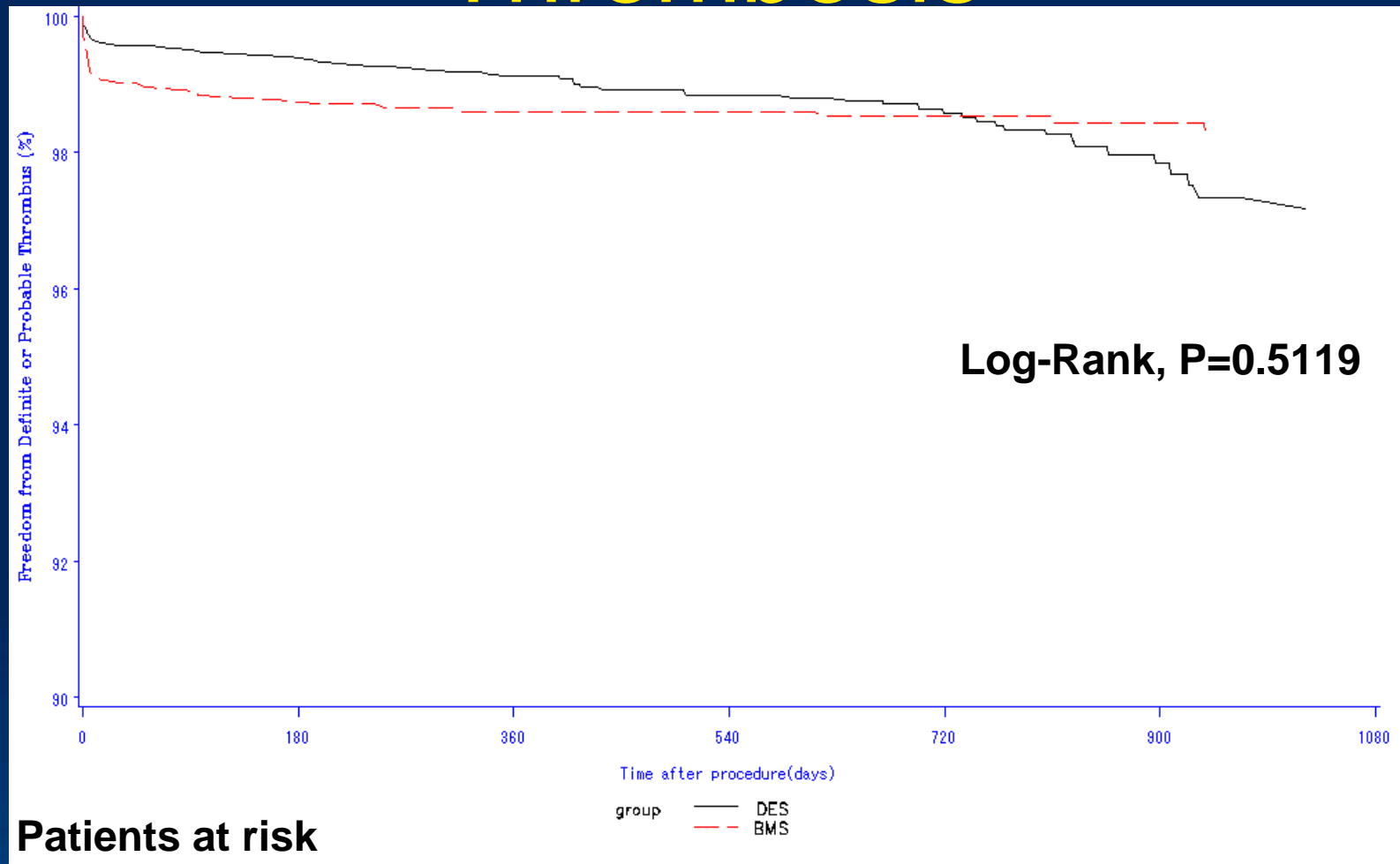
Freedom from Definite Thrombosis



Patients at risk

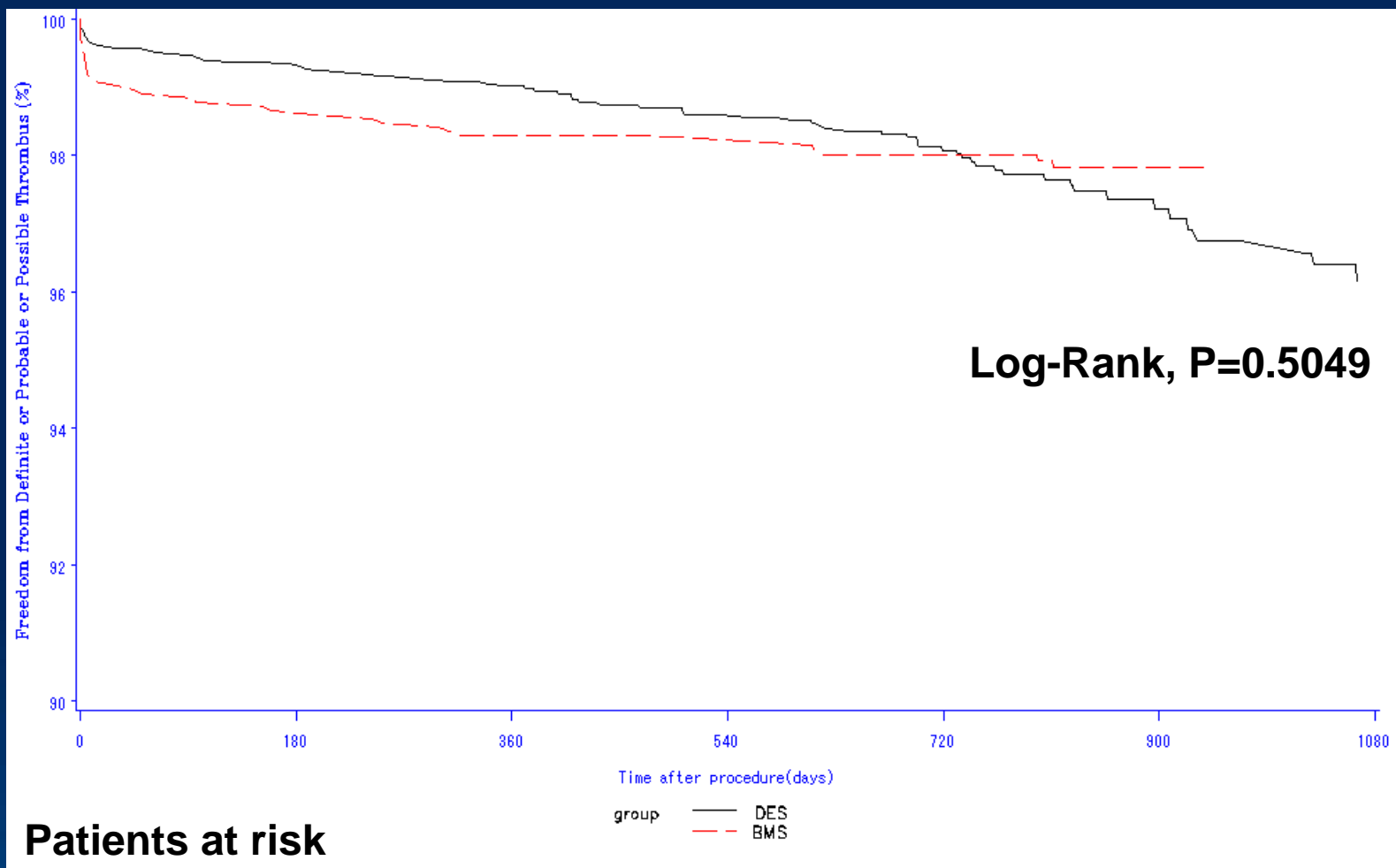
DES	5921	5857	3307	2541	1905	686	295
BMS	1667	1633	1475	1383	1287	833	383

Freedom from Definite/Probable Thrombosis



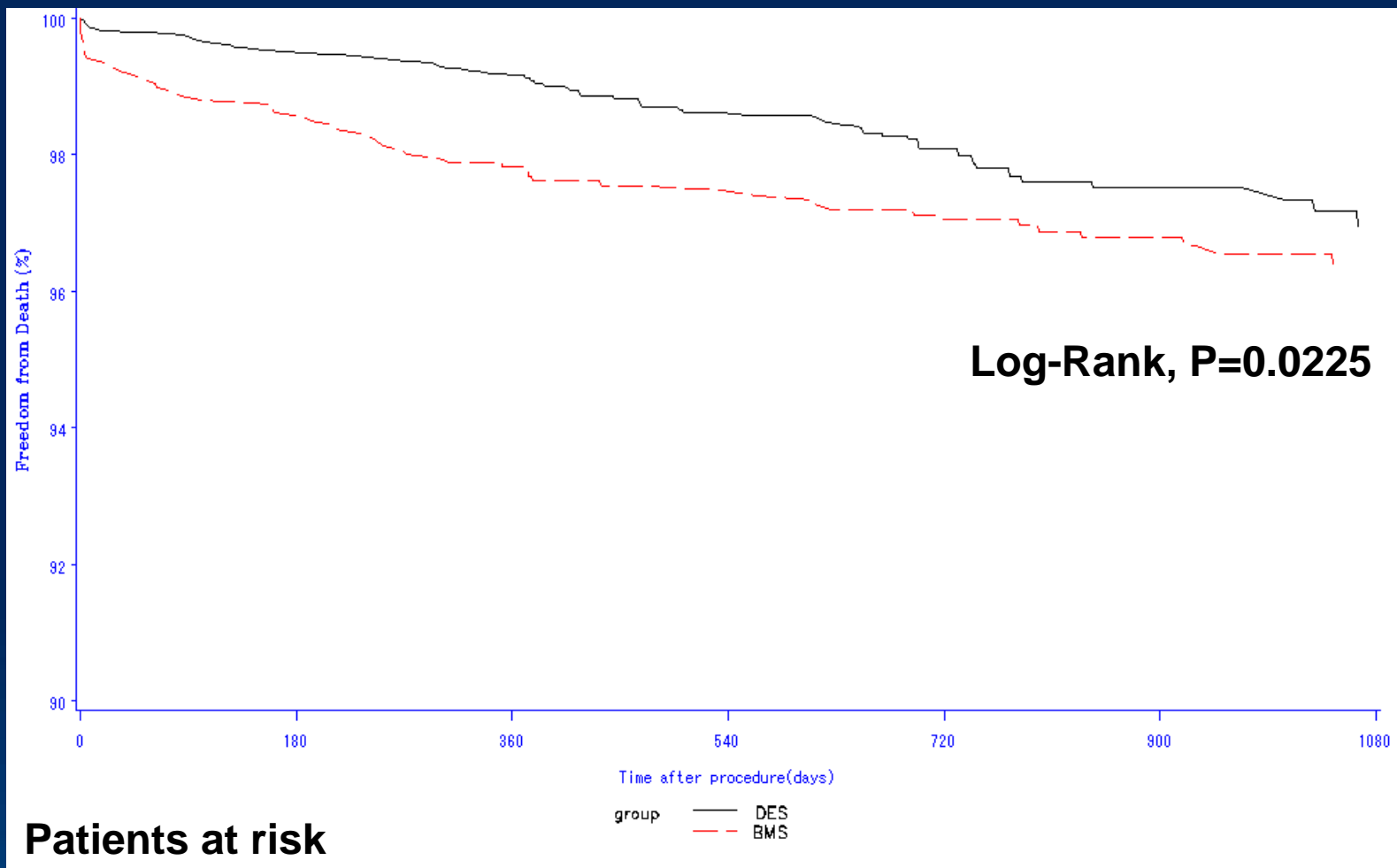
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Freedom from Definite/Probable/Possible Thrombosis



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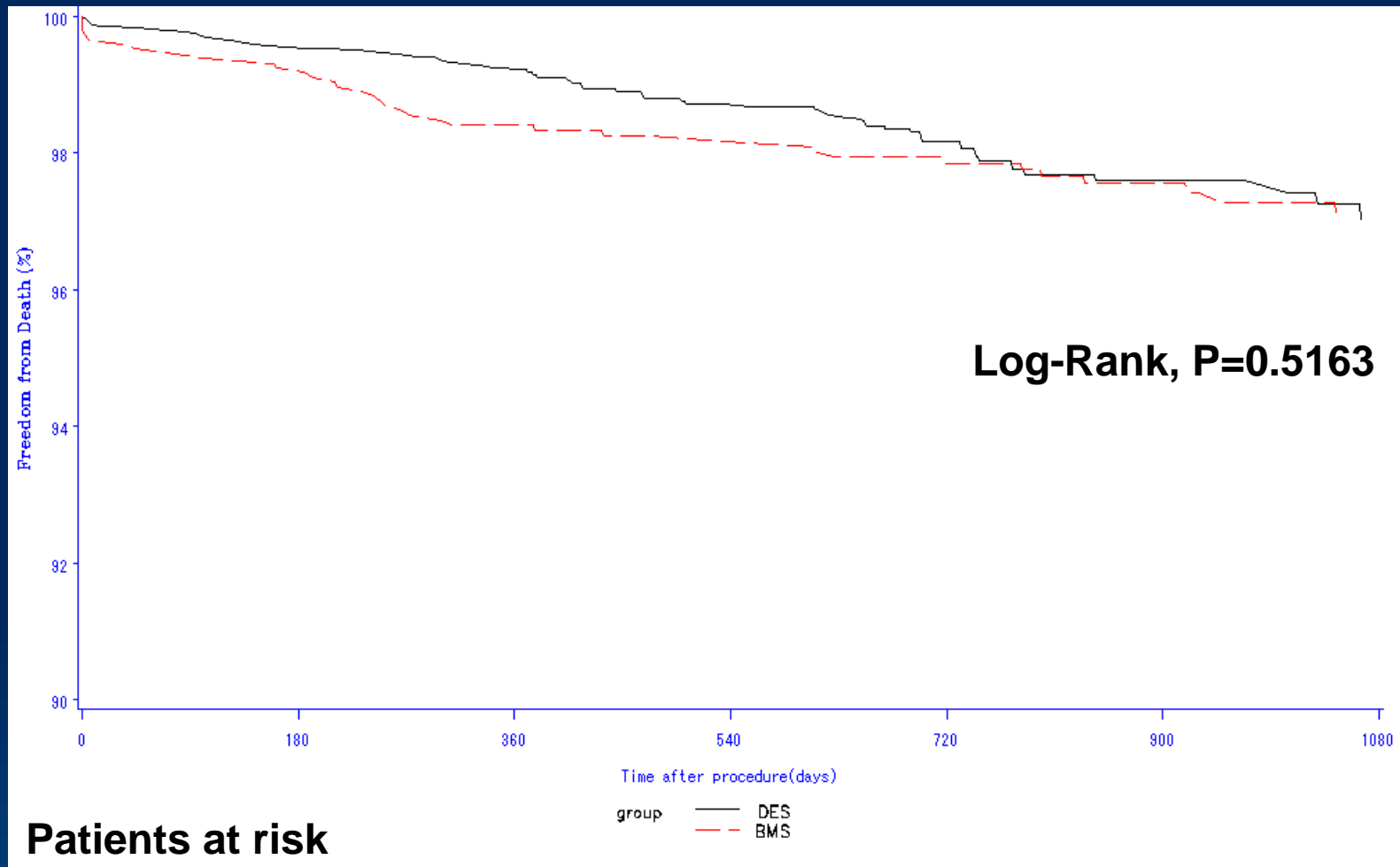
Freedom from Death (All Patients)



Patients at risk

DES	5921	5857	3307	2541	1905	686	295
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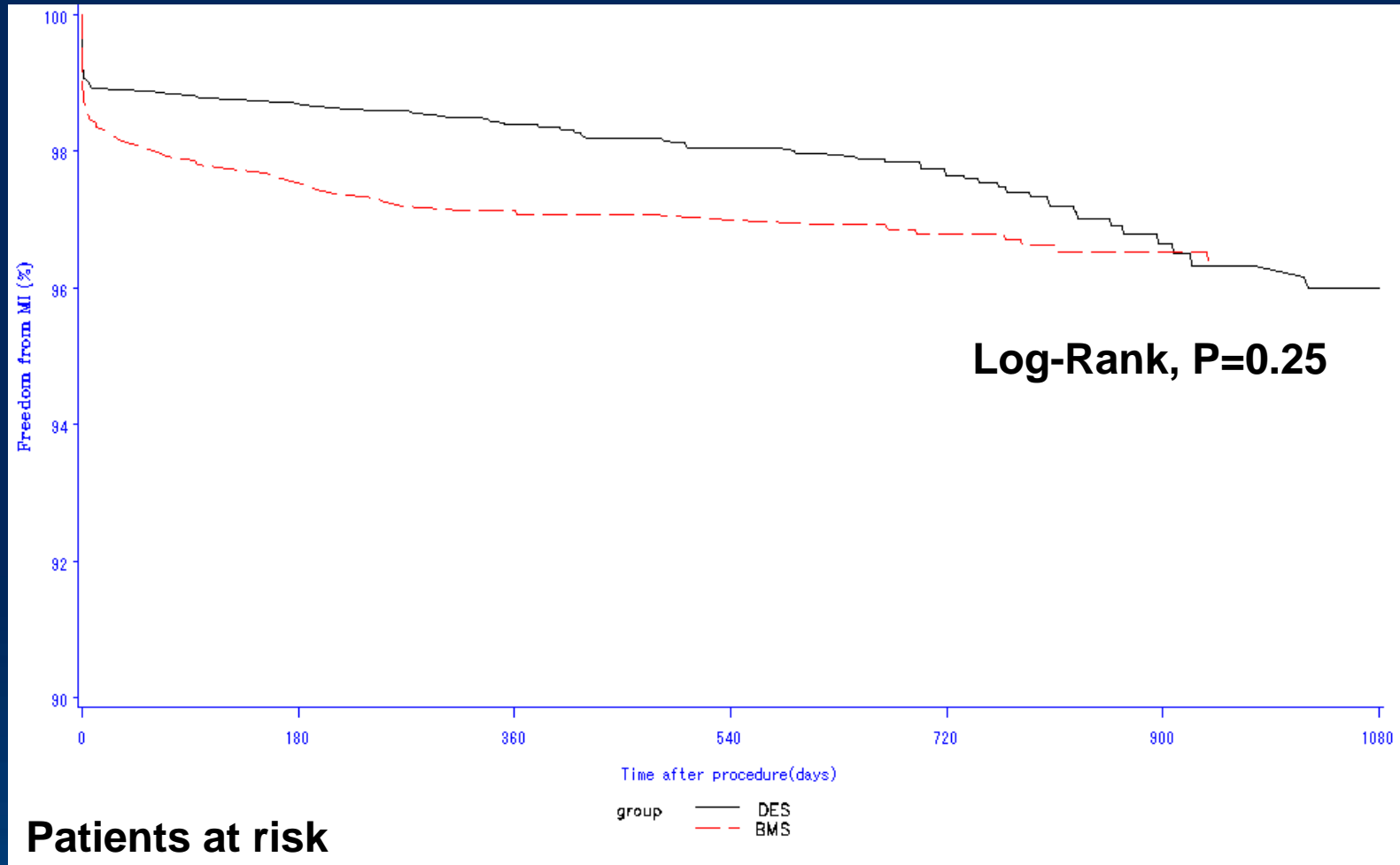
Freedom from Death (Excluding AMI)



Patients at risk

DES	5921	5857	3307	2541	1905	686	295
BMS	1667	1633	1475	1383	1287	833	383

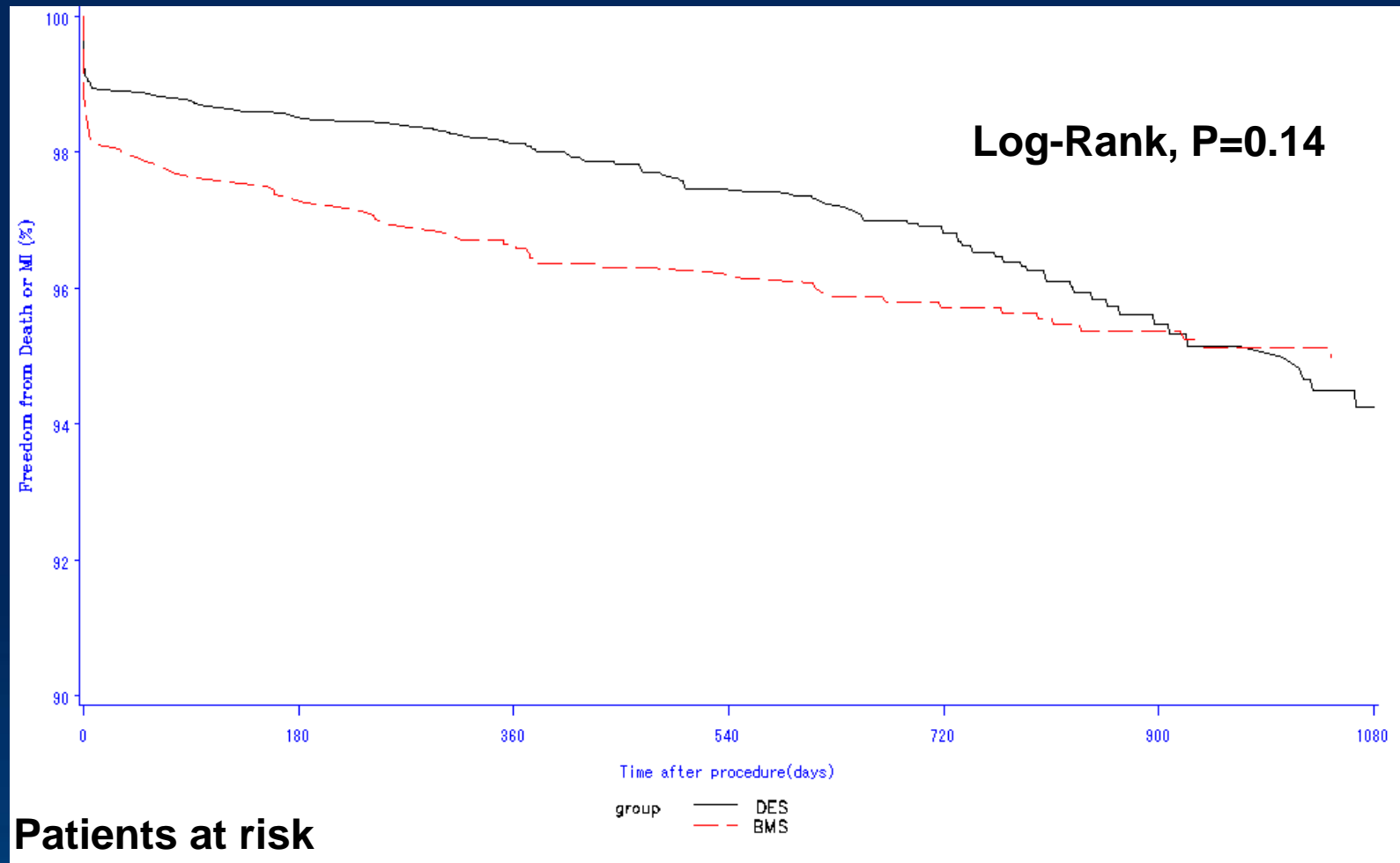
Freedom from MI (All Patients)



Patients at risk

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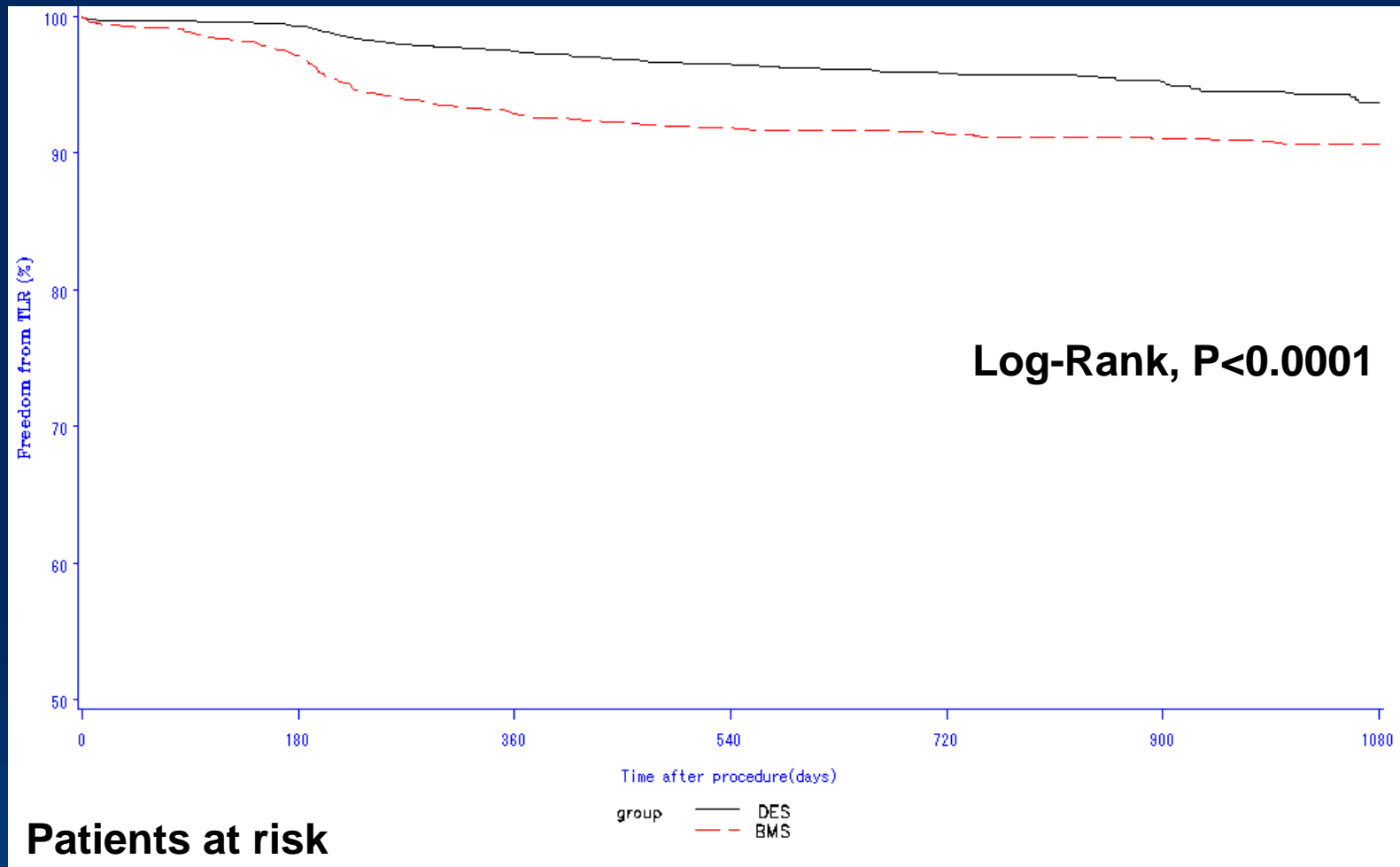
Freedom from Death or MI (All Patients)



Patients at risk

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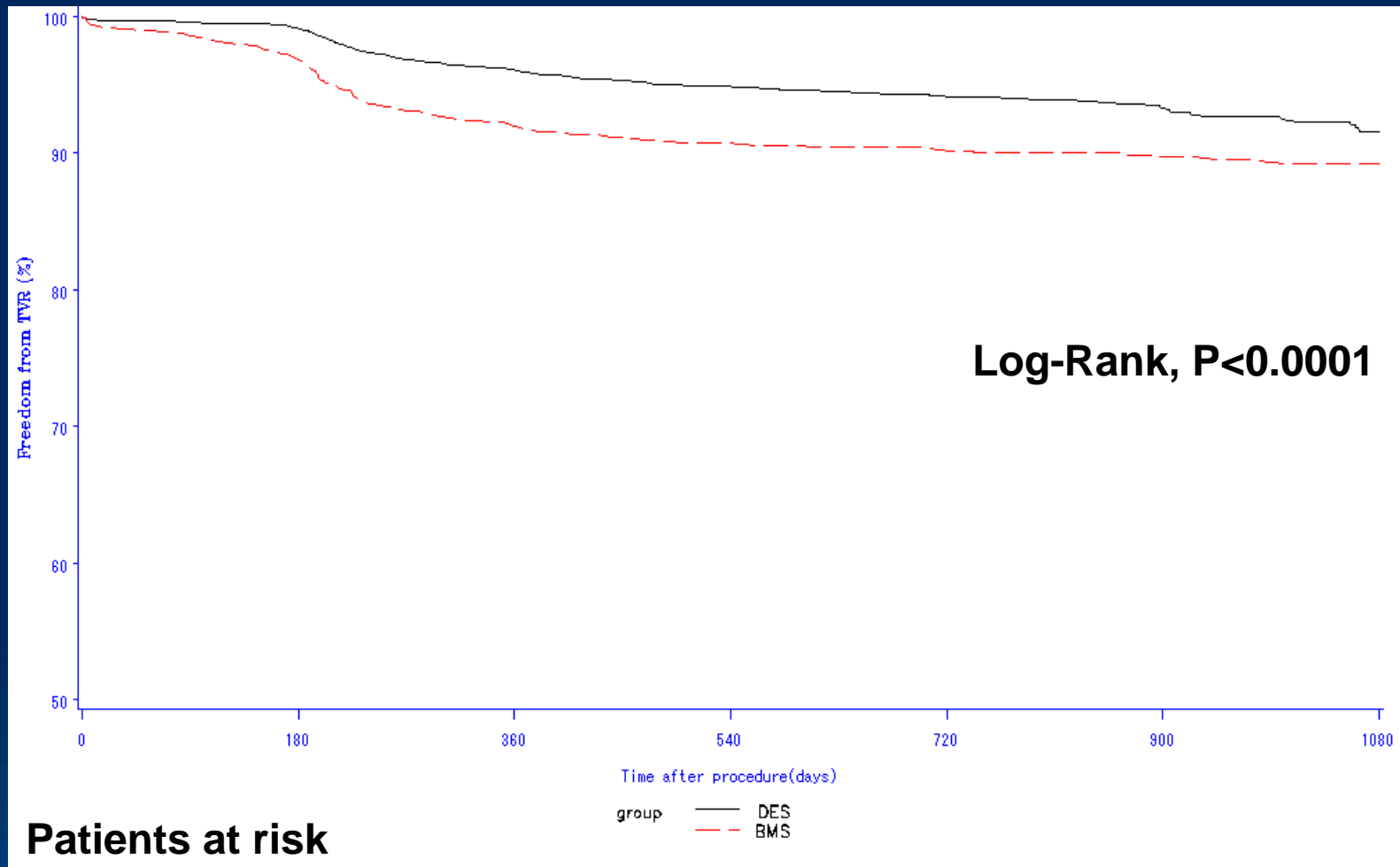
Freedom from TLR (All Patients)



Patients at risk

DES	5921	5857	3307	2541	1905	686	295
BMS	1667	1633	1475	1383	1287	833	383

Freedom from TVR (All Patients)



Patients at risk

DES	5921	5857	3307	2541	1905	686	295
BMS	1667	1633	1475	1383	1287	833	383

Conclusion

The preliminary unadjusted analysis in 7588 patients from a large single-center's database showed

- No increase in rates of thrombosis, death, or myocardial infarction associated with DES as compared to BMS implantation at median of 1.9 years
- A lower rate of revascularization in patients treated with DES compared with BMS

Conclusion (cont.)

- The efficacy and safety of DES were confirmed in daily clinical practice
- Further analysis with propensity score to adjust the unbalances of the baseline data is needed