

Biolimus-eluting biodegradable polymer-coated stent versus a durable polymer-coated sirolimus-eluting stent in unselected patients receiving percutaneous coronary intervention

SORT-OUT V: 3-year outcome

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I have the following potential conflicts of interest to report:

Cordis, Johnson & Johnson: Research grants.
Terumo: Research grants

Background

- After implantation of the permanent-polymer coated sirolimus-eluting Cypher stent the risk of restenosis is low, but the risk of stent thrombosis is a concern
- Stent thrombosis may be related to the permanent polymer
- The biolimus-eluting Nobori stent has a biodegradable polymer coating, and the long-term risk of major adverse cardiac events after implantation may be reduced

SORT OUT V OBJECTIVE

To compare the efficacy and safety of the sirolimus-eluting Cypher stent and the biolimus-eluting Nobori stent in an all-comer population

ClinicalTrials.gov Identifier: NCT01254981

Primary endpoint

Major Adverse Cardiac Events at 9 months

composite of cardiac death, myocardial infarction, definite stent thrombosis and clinically driven target vessel revascularization

Presented at PCR 2012

Today: 3-year follow-up

Patient Population

Inclusion period: July 2009 to January 2011

Criteria of inclusion

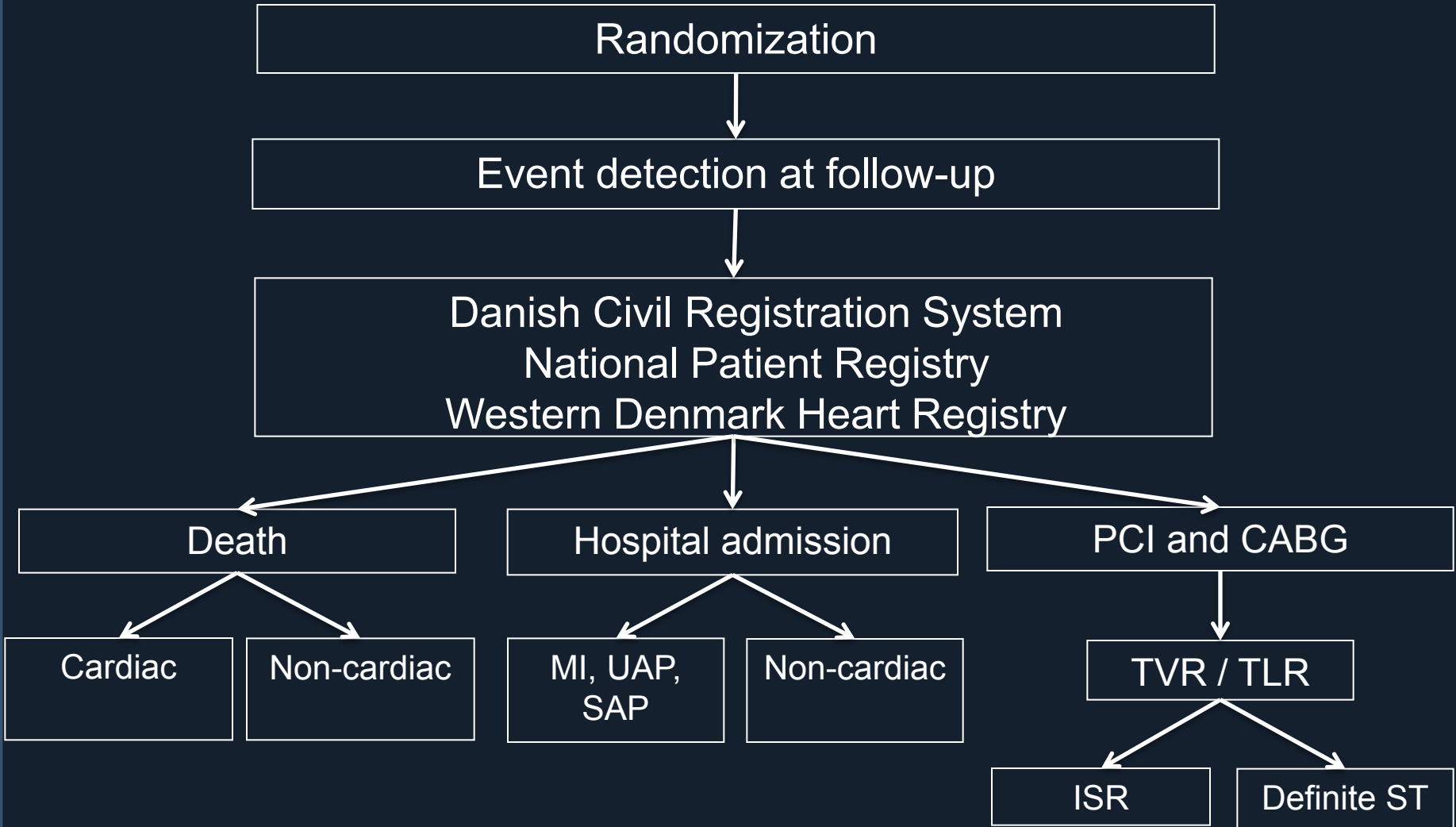
- 18 years of age or older
- Chronic stable coronary artery disease or acute coronary syndromes

Criteria of exclusion

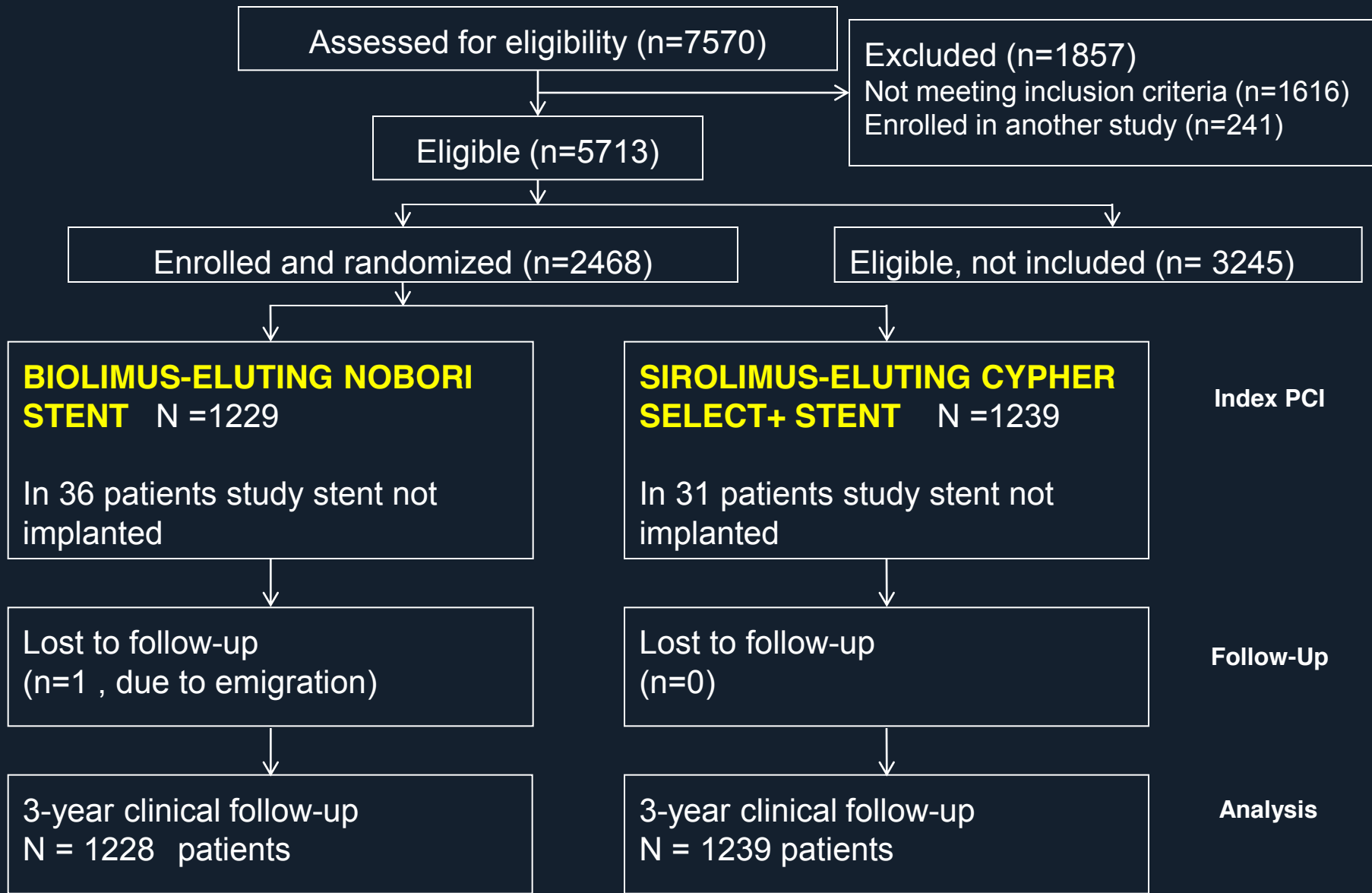
- Life expectancy less than one year
- Allergy to aspirin, clopidogrel, sirolimus, or biolimus
- Participation in another randomized trial
- Unacceptable risk by 12-month dual antiplatelet treatment
- Unable to provide written informed consent

No restrictions were placed on number of treated lesions or treated vessels or lesion length

Clinical event detection



Consort flow diagram



Patient Characteristics

	BIOLIMUS-ELUTING NOBORI STENT	SIROLIMUS-ELUTING CYPHER STENT	p
No. of patients	1229	1239	
Age (years)	65.0 ±10.6	65.2 ±10.3	0.51
Male gender	74.6 %	75.1 %	0.79
Diabetes	15.1 %	15.3 %	0.89
Hypertension	57.7 %	54.7 %	0.30
Lipid-lowering therapy	60.0 %	61.1 %	0.81
Current smoker	33.6 %	33.1 %	0.78
Prior CABG	8.1 %	5.9 %	0.04
Prior PCI	17.3 %	16.5 %	0.56
Prior myocardial infarction	17.7 %	17.3 %	0.82
Body mass Index (kg/m ²)	27.5 ± 5.2	27.4 ± 5.2	0.66

Patient Characteristics

	BIOLIMUS-ELUTING NOBORI STENT	SIROLIMUS-ELUTING CYPHER STENT	p
No. of patients	1229	1239	
Indication for PCI			0.71
Stable angina	49.5 %	48.1 %	
NSTEMI / unstable angina	30.3 %	31.0 %	
STEMI	18.3 %	18.3 %	
Other	2.0 %	2.6 %	

Lesion Characteristics

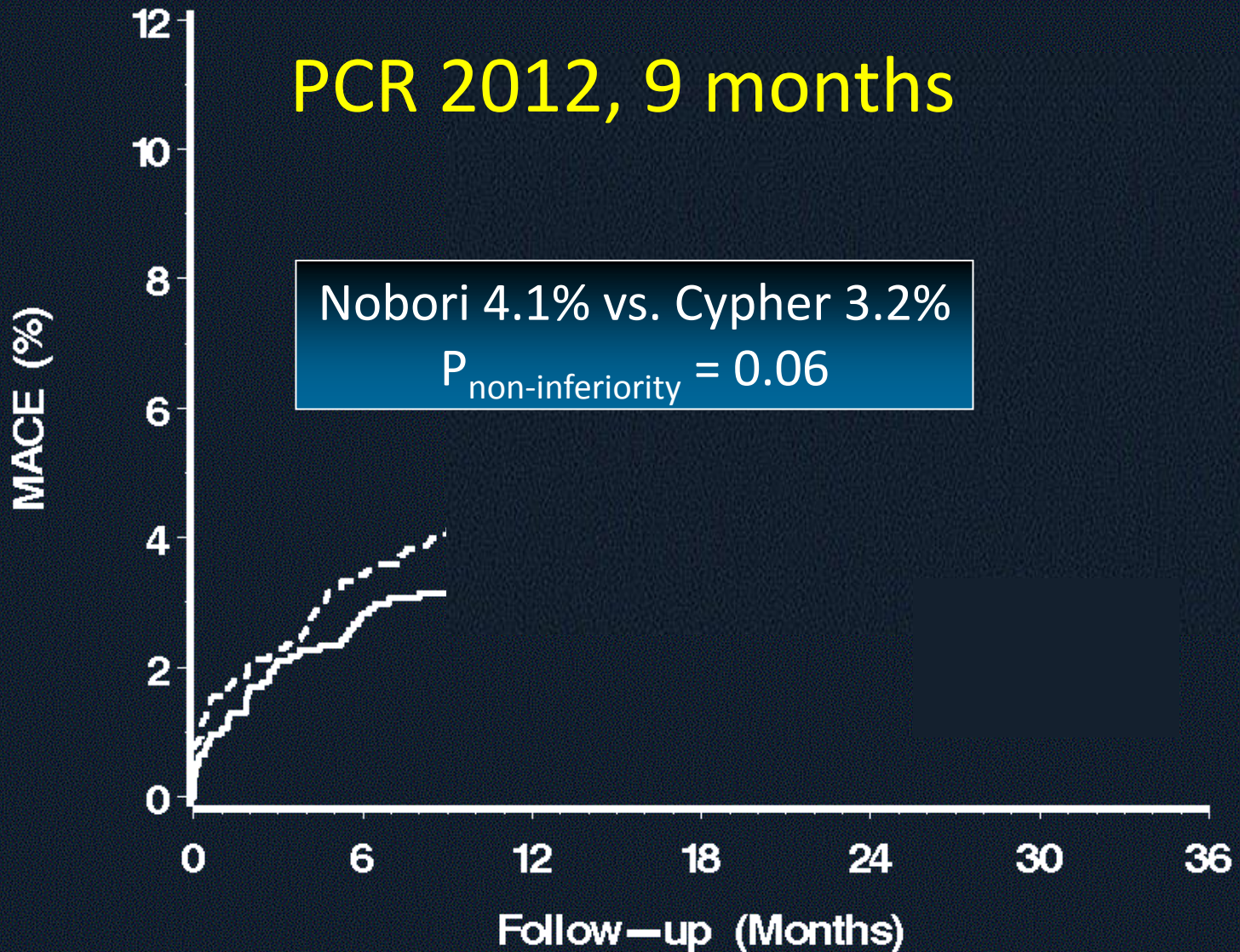
	BIOLIMUS-ELUTING NOBORI STENT	SIROLIMUS-ELUTING CYPHER STENT	p
No. of lesions	1,532	1555	
Target lesion location			0.34
Left main artery	1.4	1.4	
Left anterior descending artery	40.7	40.9	
Left circumflex artery	23.2	22.5	
Right coronary artery	33.2	34.4	
Saphenous vein graft	1.6	0.8	
Lesion type B2/C	61.0	58.8	0.25
Bifurcation lesions	15.0	15.1	0.98
Chronic total occlusions	6.0	7.2	0.21
Lesion length > 18 mm	34.1	33.6	0.80
Reference vessel size (mm)	3.2 (3.0 - 3.5)	3.3 (3.0 - 3.6)	0.03

Procedural Characteristics

	BIOLIMUS-ELUTING NOBORI STENT	SIROLIMUS-ELUTING CYPHER STENT	p
No. of lesions per patient	1.25	1.26	0.71
No. of stents			
Per patient, median	1.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)	0.77
> 1 stent	37.1 %	37.6 %	0.80
Total stent length (mm)	22.0 (14.0 - 32.0)	23.0 (13.0 - 33.0)	0.22
Direct stenting	21.6 %	22.4 %	0.60
Maximum pressure (atm)	16.0 (14.0 - 20.0)	18.0 (15.0 - 20.0)	<.0001
Stent delivery failure	2.9 %	2.6 %	0.60
Use of GP IIb/IIIa inhib.	15.9 %	16.9 %	0.51

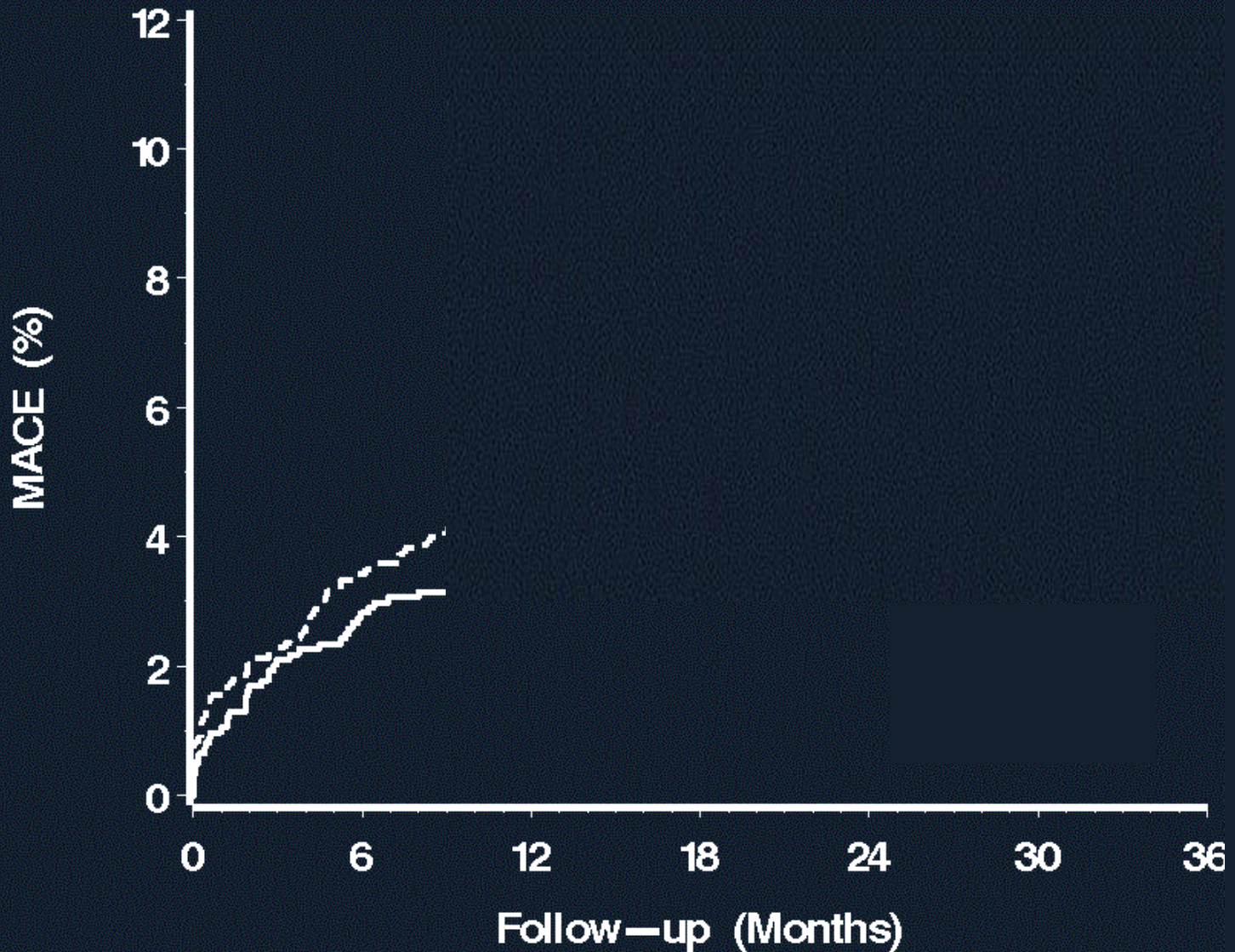
1° Endpoint: Major Adverse Cardiac Events

(Cardiac death, myocardial infarction, definite stent thrombosis, target vessel revascularization)



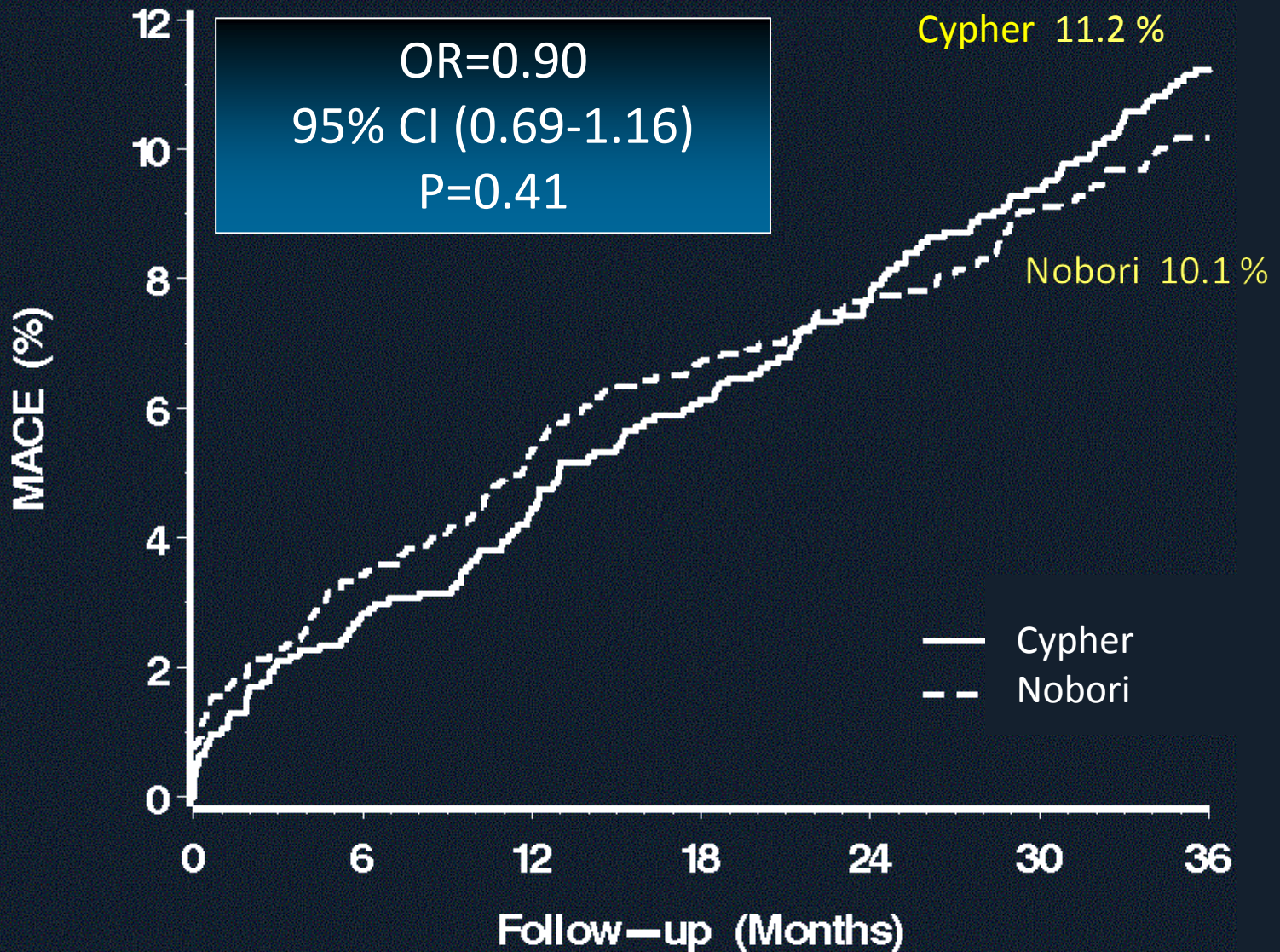
Major Adverse Cardiac Events, 3 year

(Cardiac death, myocardial infarction, definite stent thrombosis, target vessel revascularization)

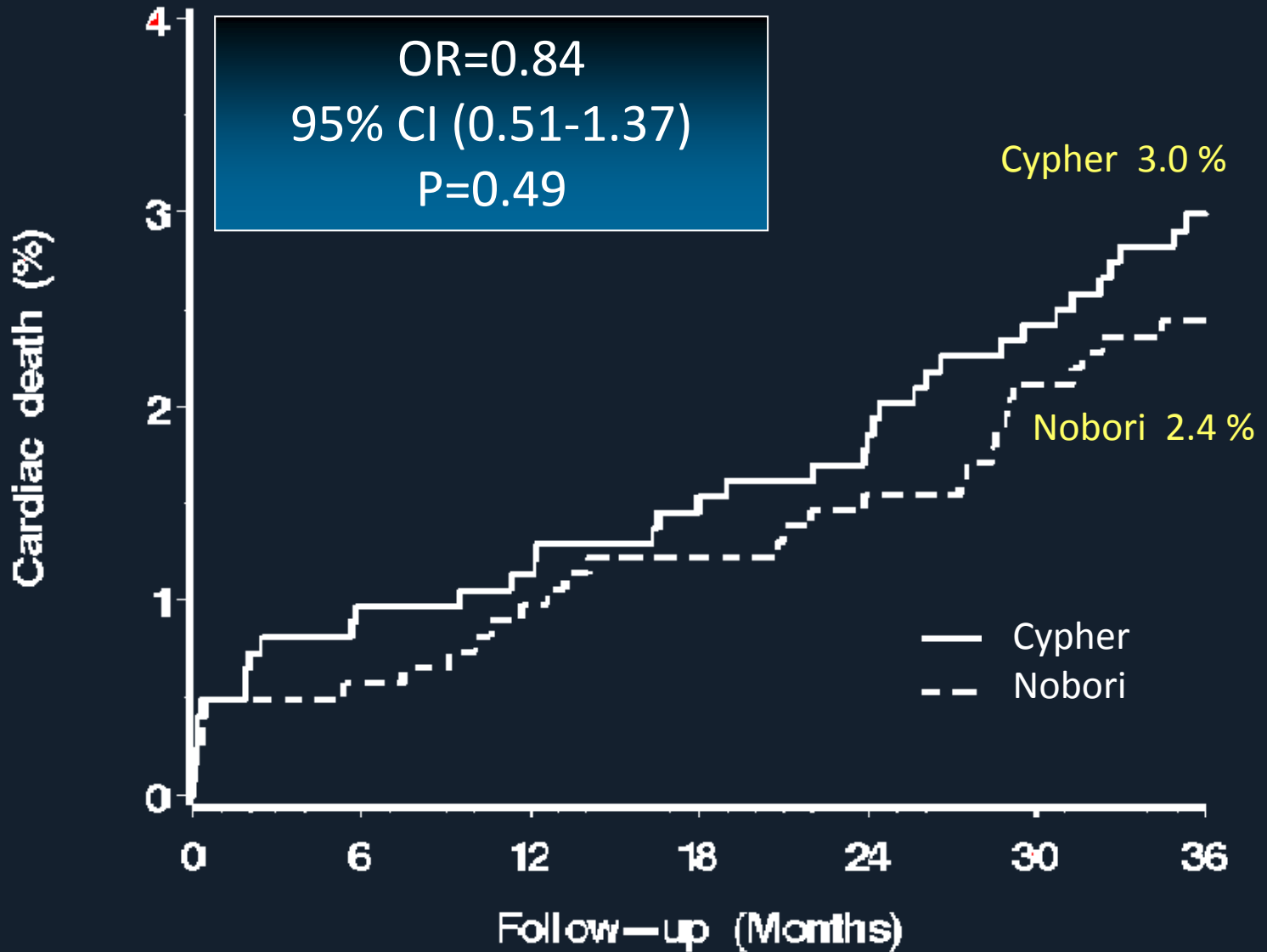


Major Adverse Cardiac Events, 3 year

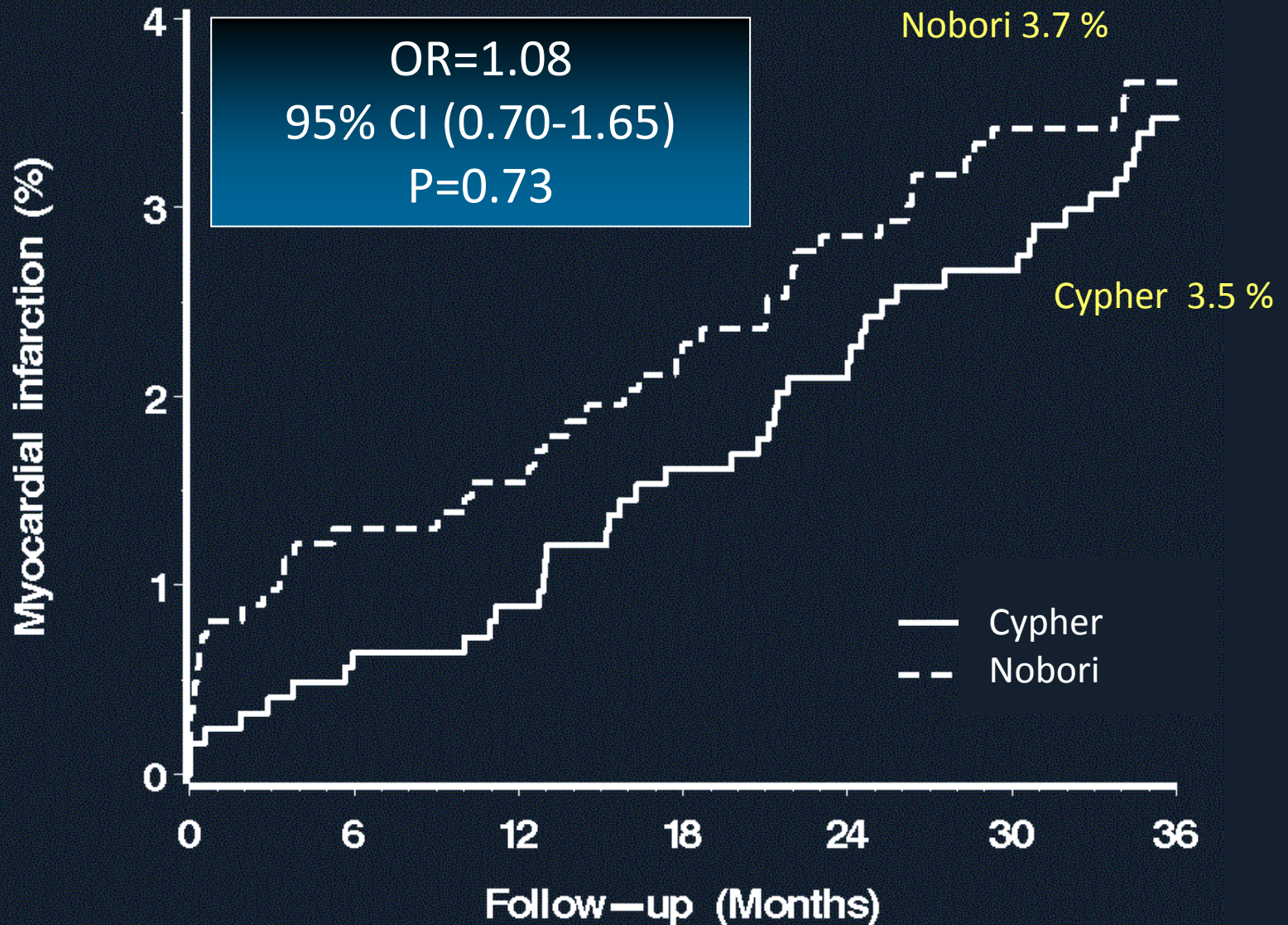
(Cardiac death, myocardial infarction, definite stent thrombosis, target vessel revascularization)



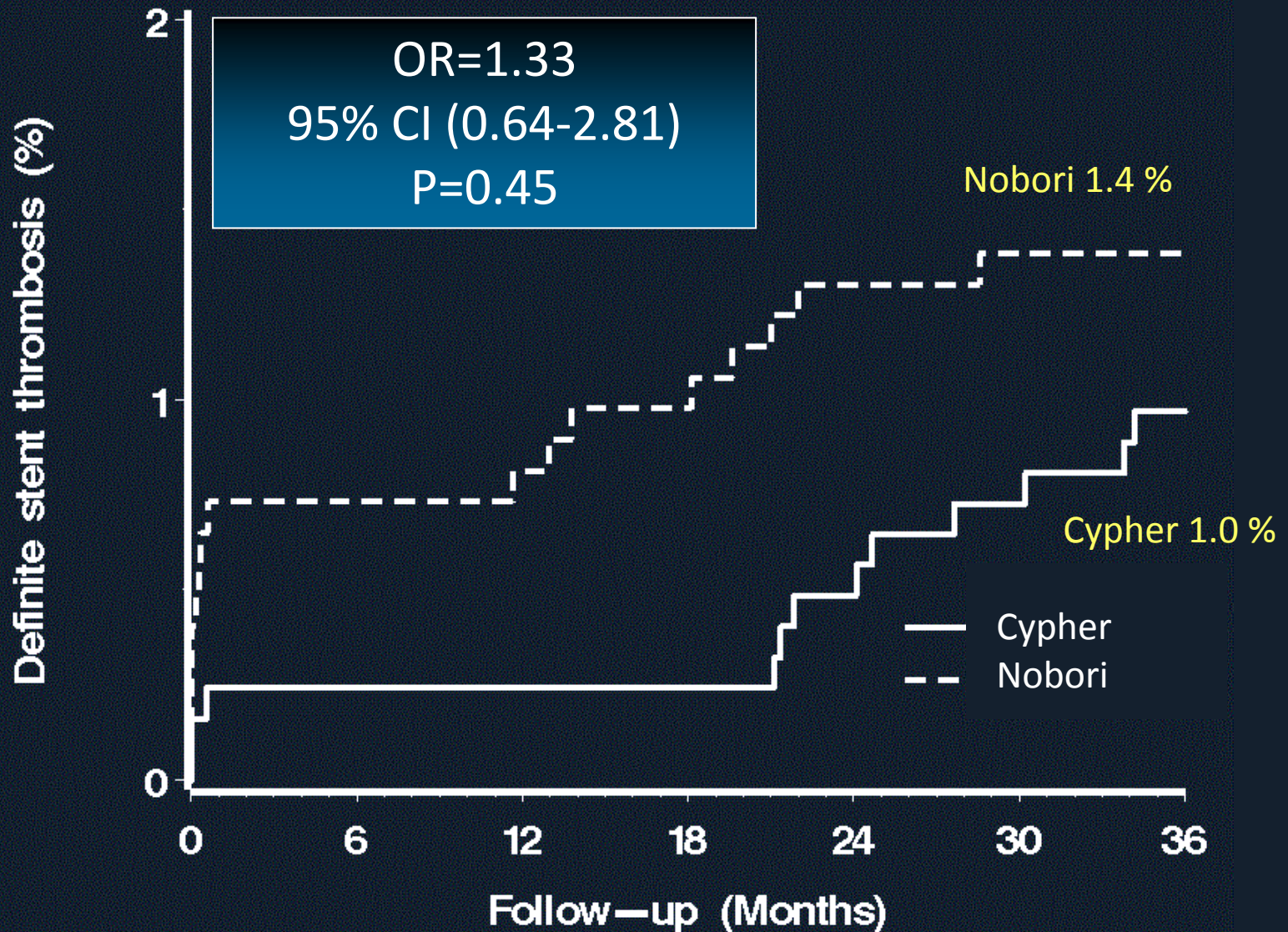
Cardiac Death, 3 year



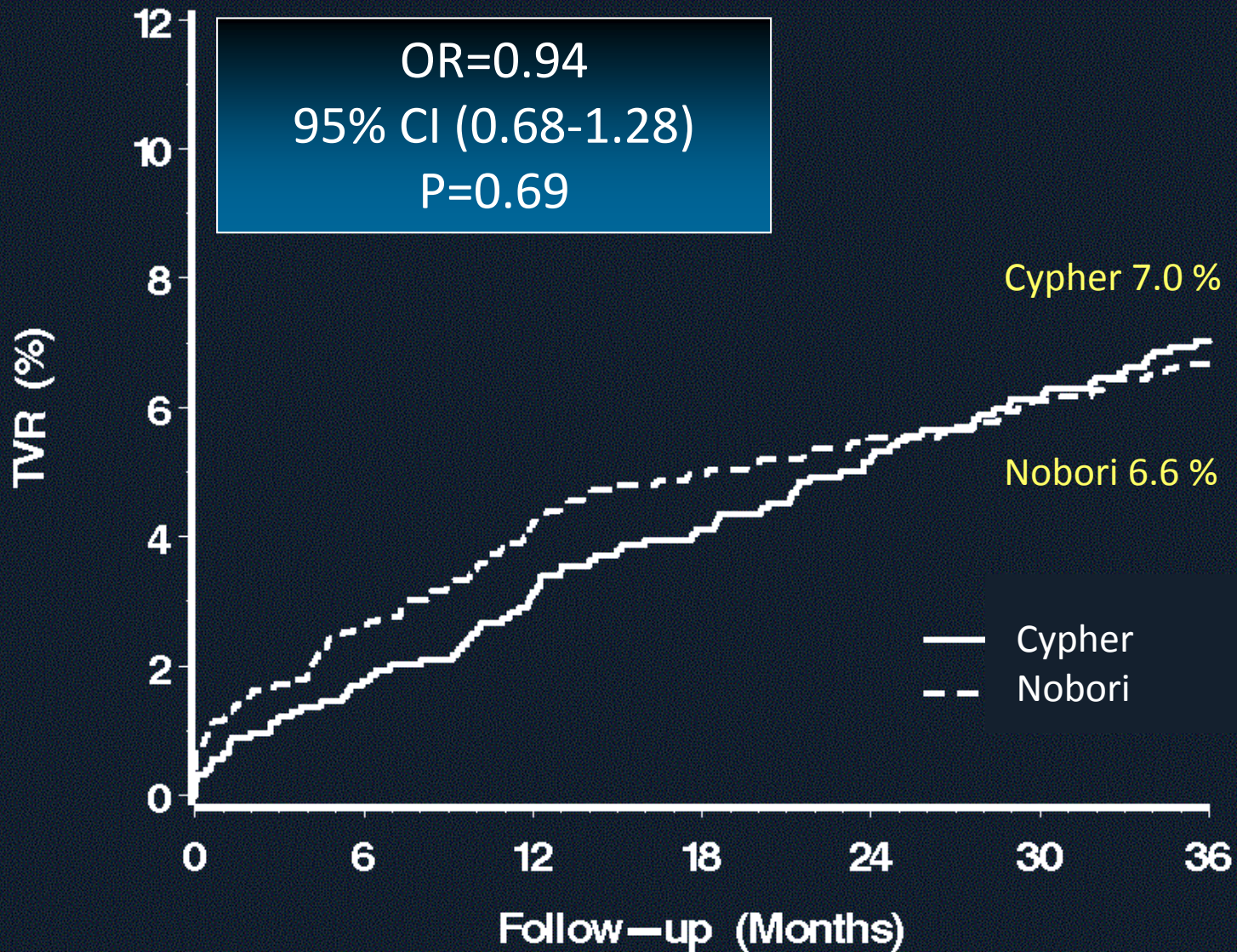
Myocardial Infarction, 3 year



Definite Stent Thrombosis, 3 year



Target Vessel Revascularization, 3 year



Conclusion

- At 9 month the biolimus-eluting Nobori stent was not found to be non-inferior to the sirolimus-eluting Cypher stent
- No difference in MACE, or the individual components of MACE, were observed at 3 year

SORT OUT Study Organization

- Steering Committee

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 - L. O. Jensen

 - P. Thayssen

 - H. H. Tilsted

 - J. Ravkilde

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- Clinical Event Committee

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 - B. L. Noergaard

- DSMB

 - M. Madsen

 - H. T. Soerensen

- Coordinating Center

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Aarhus, Denmark

- Participating centers

 - Aarhus University Hospital, Skejby

 - Aalborg University Hospital

 - Odense University Hospital