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Nothing to disclose

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INCIDENCE AND PREDICTORS OF DRUG ELUTING STENT THROMBOSIS DURING AND FOLLOWING DISCONTINUATION OF THIENOPYRIDINE TREATMENT

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The population included 3021 consecutive patients treated on 5389 lesions with the implantation of a SES in 2853 lesions and a PES in 2536 lesions, between April 2002 and December 2004. All patients except for 14 of them had clinical FU at 18 months with information regarding time of discontinuation of any antiplatelet theraphy

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End Point: Stent Thrombosis - *Definitions*

Subacute (0-30 days)

Angiographic documentation of complete or partial stent occlusion with thrombus and target vessel related acute clinical ischaemic event.

OR ST elevation MI in the distribution of the stented vessel.

OR Sudden cardiac death

Late (> 30 days)

Angiographic documentation of complete or partial stent occlusion and target vessel related acute clinical ischaemic event.

OR ST elevation MI in the distribution of the stented vessel

OR Autopsy documentation of complete or partial thrombotic stent occlusion

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Statistical Analysis

- A total sample of 3000 observations was computed to achieve 80% power at a 2-sided 0.05 significance level to detect a hazard ratio (HR) equal to or greater than 2.5 with a Cox regression of the log HR on a binary risk factor with a 20% or greater prevalence.
- Relationship of thrombosis incidence to the time of antiplatelet therapy discontinuation was initially investigated by means of a stratified Cox regression with two time-dependent covariates (thienopyridine administration during the first 6 months and after 6 months) and five stratification factors (center, stent type, intra-aortic balloon pump, glycoprotein IIb/IIIa inhibitors, age coded as ≤60, 60-75, >75 years and family history of coronary artery disease).
- We employed stent type (SES, PES) as a stratification variable (confounder) rather than risk factor because, although we cannot exclude a direct and different thrombogenic effect of a DES (causation or effect), the association with thrombosis incidence is surely spurious in this study being a consequence of a different employment of the two type of stents with uncorrectable bias of different operators in stent selection

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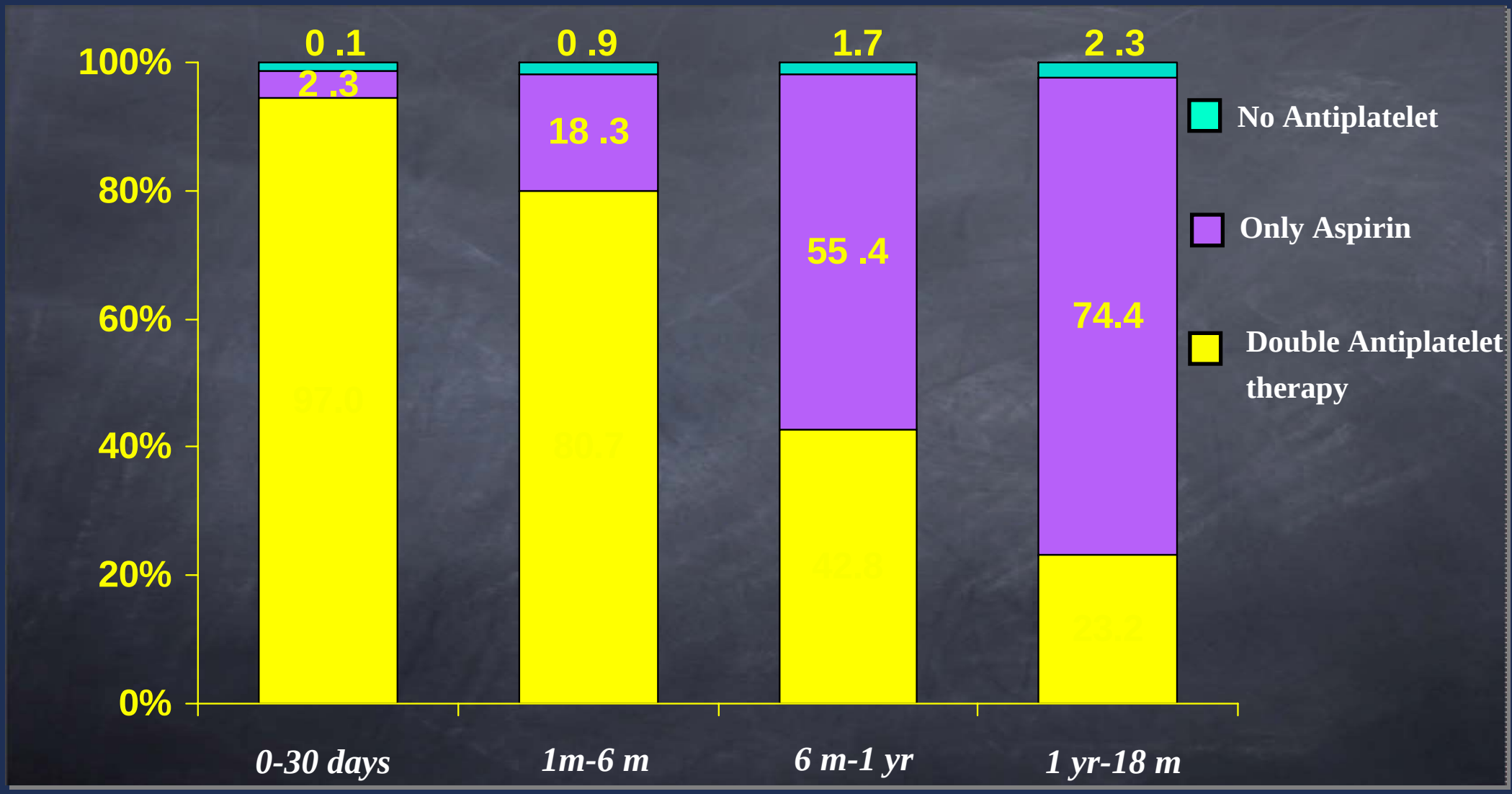
Patients on double antiplatelets, only aspirin and no antiplatelets in different time periods



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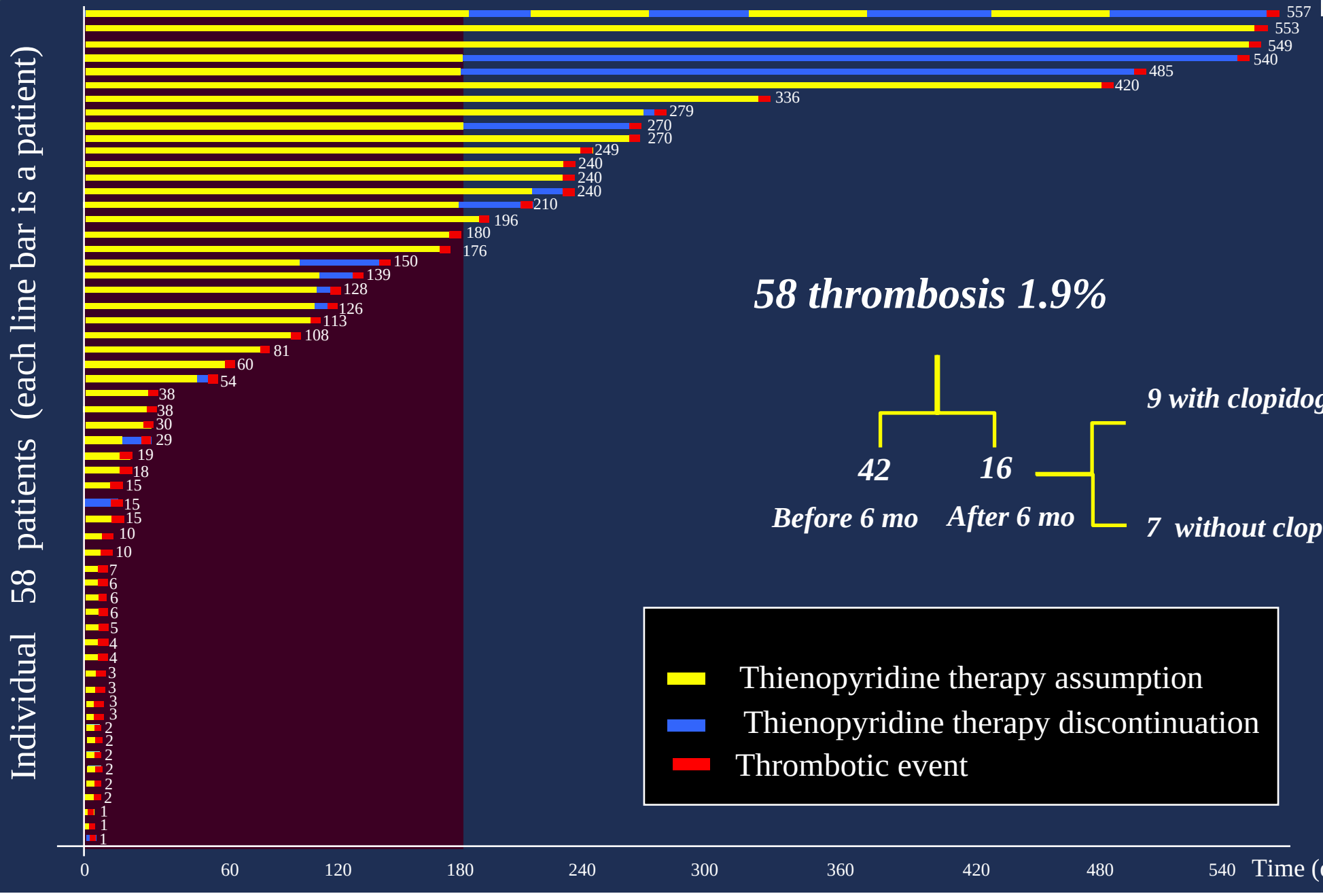
Relationship between thrombosis and antiplatelet therapy discontinuation



58 thrombosis 1.9%

42 — ***Before 6 mo***

16 — ***After 6 mo***

9 with clopidogrel

7 without clopidogrel

Thienopyridine therapy assumption

Thienopyridine therapy discontinuation

Thrombotic event

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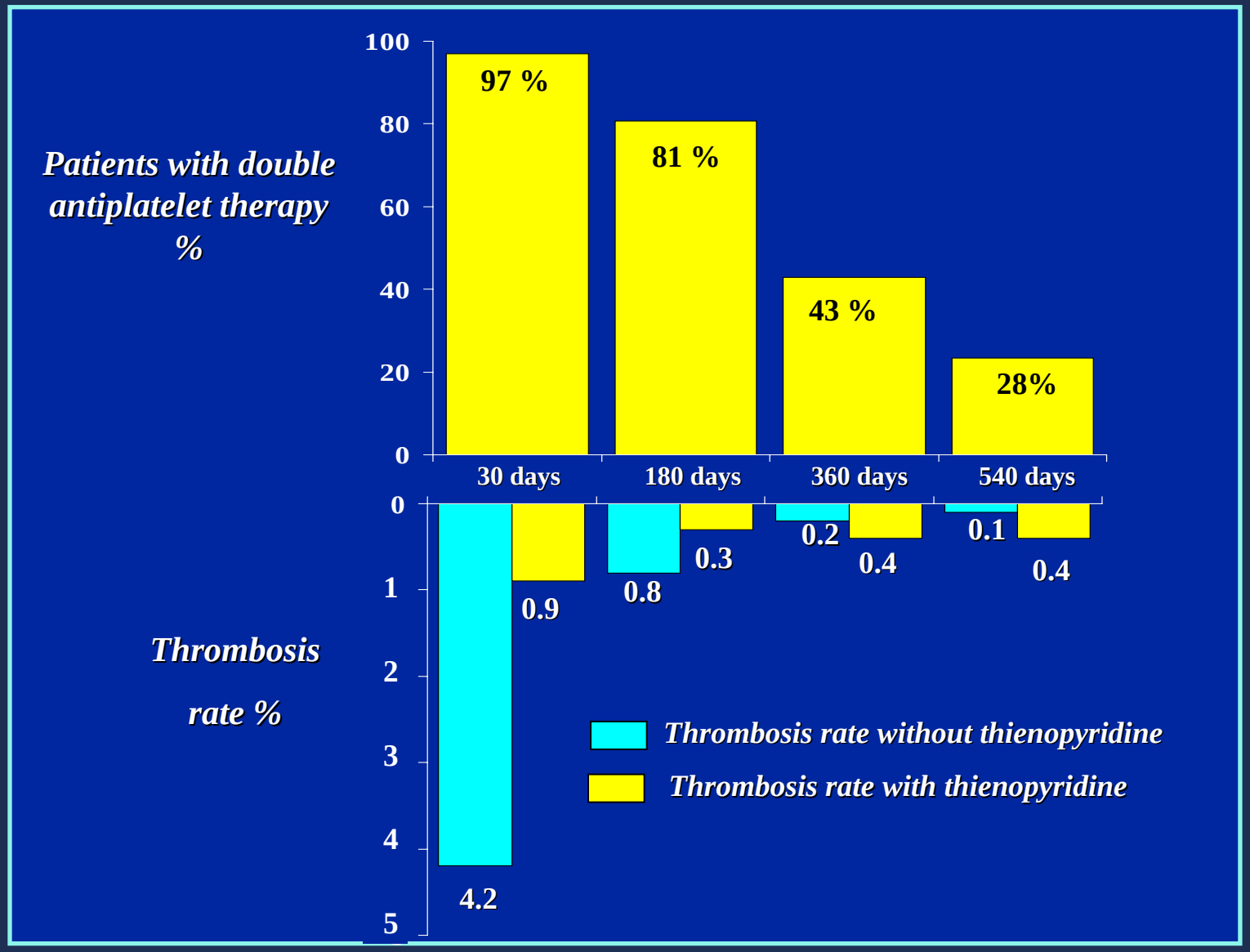
Occurrence of stent thrombosis in patients assuming thienopyridine in 4 different time periods



While the prevalence of stent thrombosis is higher in patients not taking double antiplatelets in the first 6 months, after 180 days there is an increasing proportion of patients with thrombosis while taking double antiplatelet therapy

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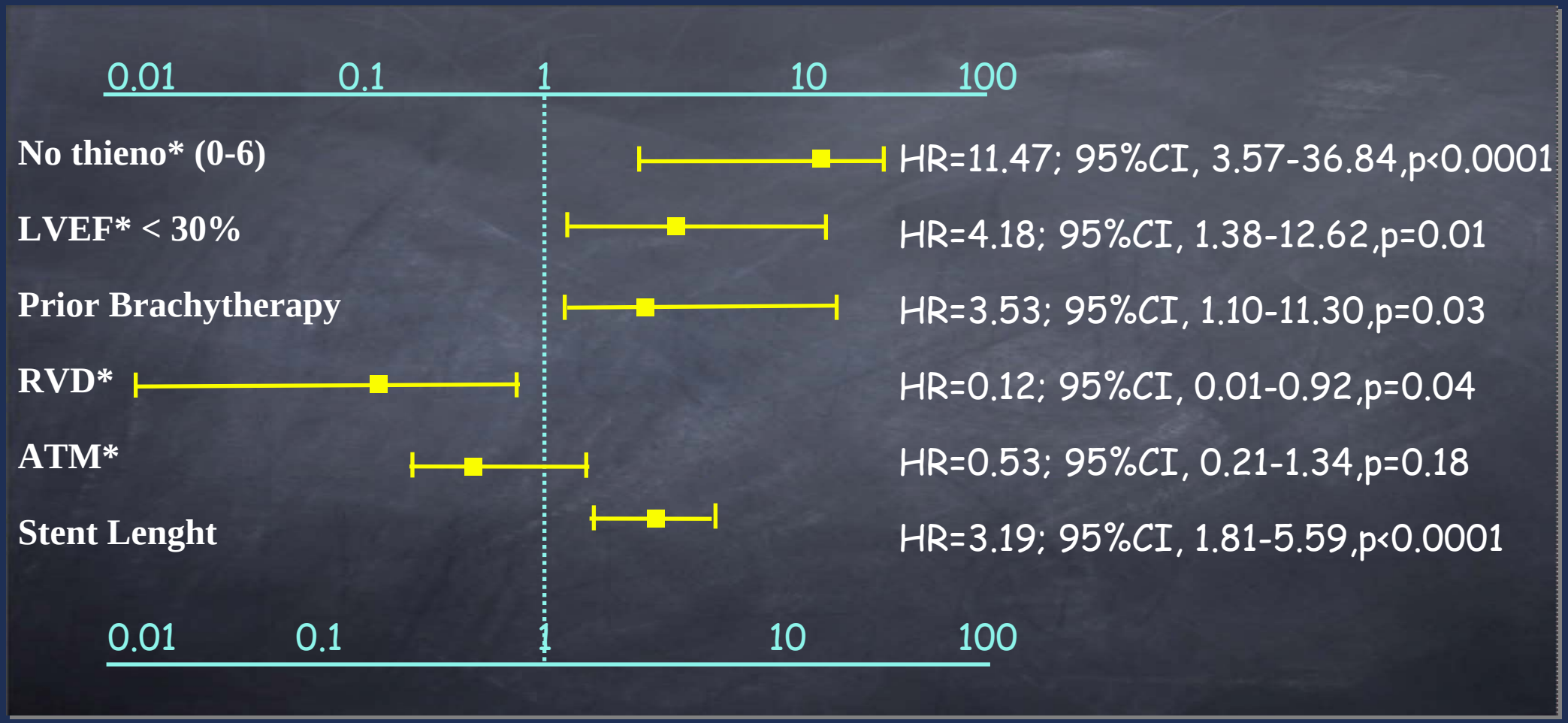
Predictors of stent thrombosis

period 0-6 months



* Abbreviations: thieno=thienopyridine; LVEF=left ventricle ejection fraction; RVD=reference vessel ejection fraction; ATM= final stent atm inflation.

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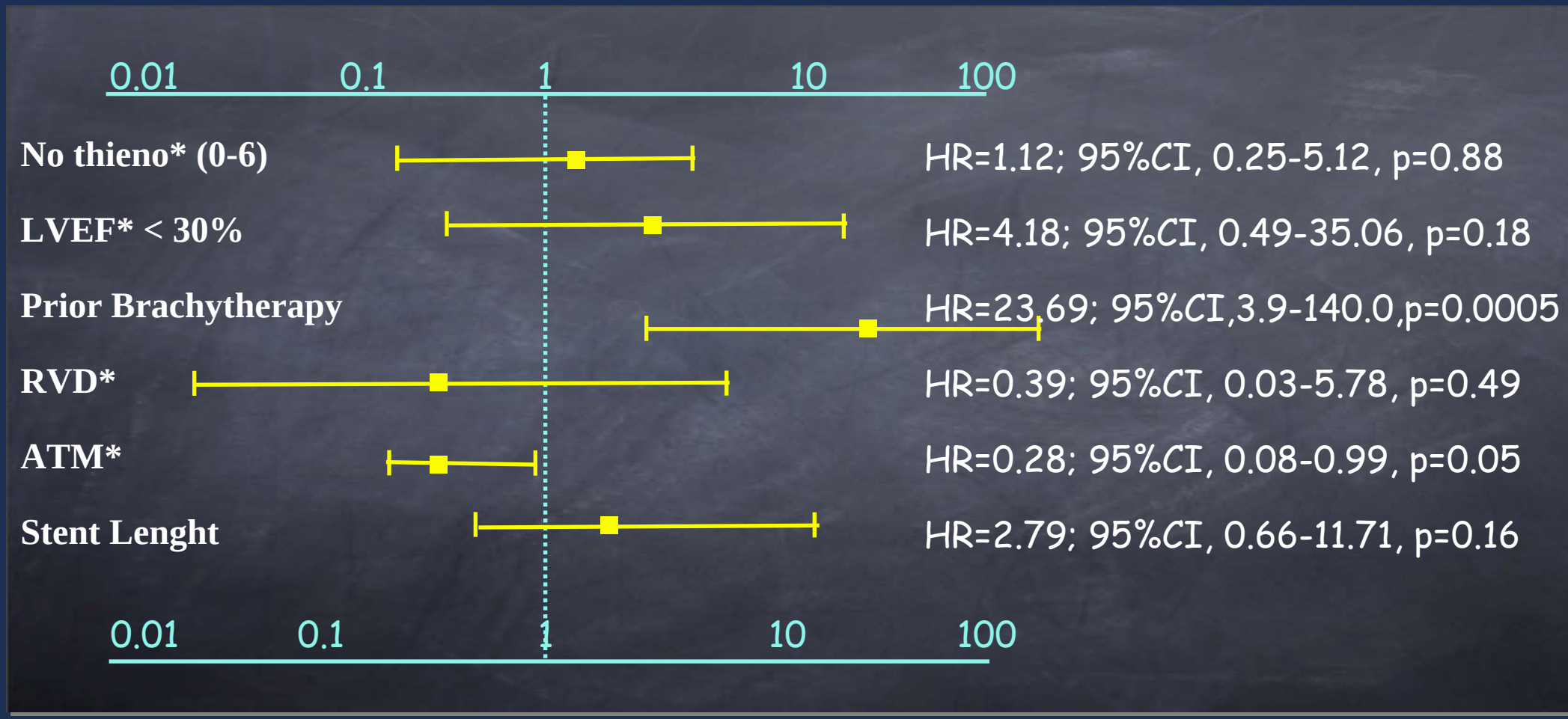
Predictors of stent thrombosis

period 6-18 months



* Abbreviations: thieno=thienopyridine; LVEF=left ventricle ejection fraction; RVD=reference vessel ejection fraction; ATM= final stent atm inflation.

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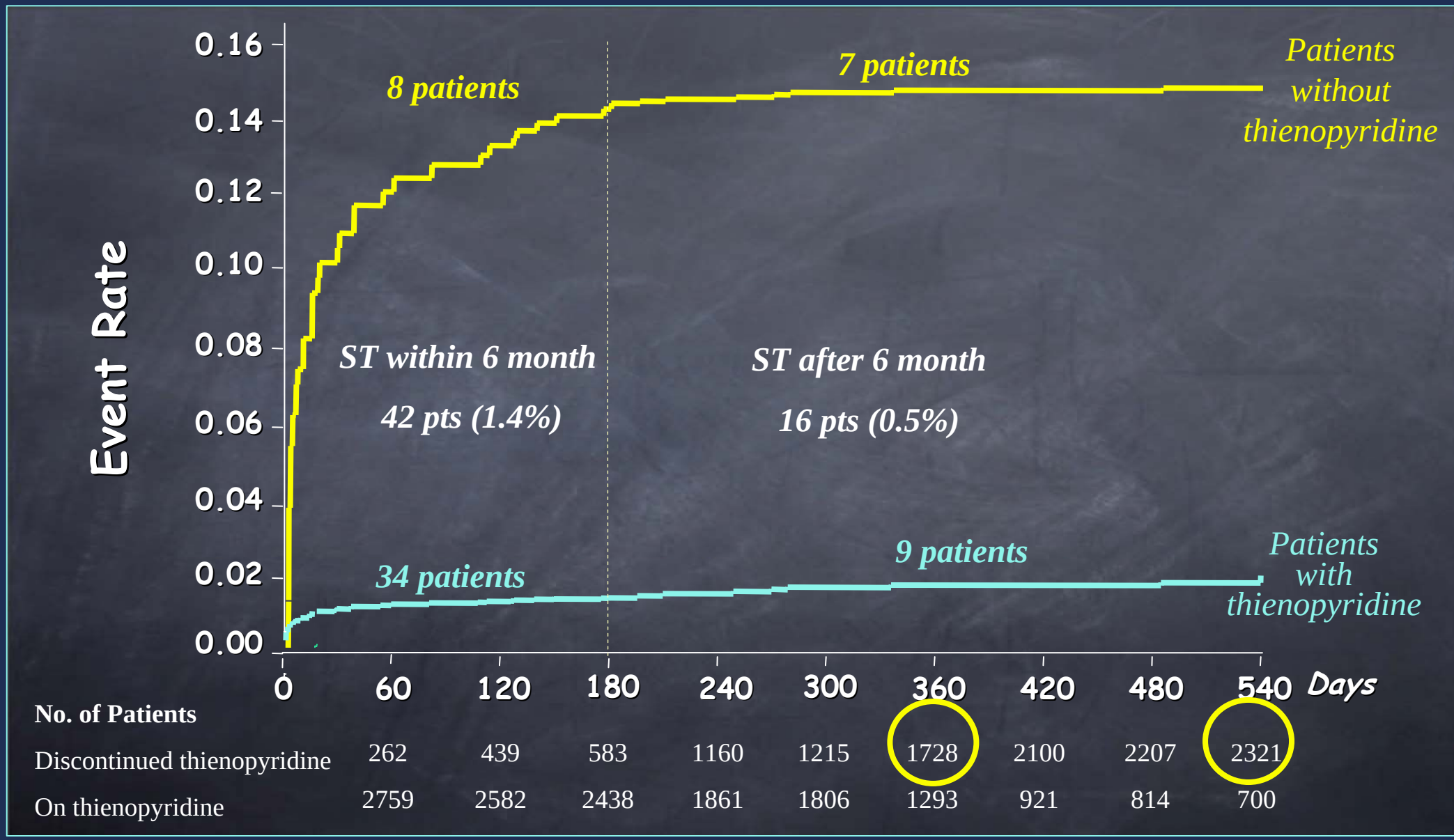
Aalen-Nelson estimate of the cumulative hazard function



No. of Patients									
Discontinued thienopyridine	262	439	583	1160	1215	1728	2100	2207	2321
On thienopyridine	2759	2582	2438	1861	1806	1293	921	814	700

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Characteristics of patients that had thrombosis after 6 months with double antiplatelet therapy

	Time in days	*Renal Failure*	*Brachyth erapy*	*LVEF <30%*	*Stent length*	*RVD*	*DM*	*Bifurcation*	*ATM*
Pt 1	196	No	No	No	24	3.04	No	No	20
Pt 2	240	No	No	No	16	3.5	No	Yes	14
Pt 3	240	No	No	No	16	3.5	Yes	No	14
Pt 4	249	No	No	Yes	66	2.87	No	No	14
Pt 5	270	No	Yes	No	28	3	Yes	No	20
Pt 6	336	No	Yes	No	28	4.00	No	No (SVG)	24
Pt 7	420	No	No	No	36	3.00	No	No	14
Pt 8	540	No	No	No	20	3.26	No	No	14
Pt 9	540	No	No	No	23	2.39	No	No	16

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Conclusions

1. The overall incidence of ST was 1.9%.
2. Half of the patients experienced ST during the first 30 days from stent implantation.
3. Discontinuation of dual antiplatelet therapy was the most powerful predictor of ST during the first six months after stent implantation. Discontinuation of thienopyridine treatment after 6 months from stenting did not increase the risk of ST.