



TRITON TIMI-38 STENT ANALYSIS

Prasugrel Compared to Clopidogrel in Patients with Acute Coronary Syndromes Undergoing PCI with Stenting: the TRITON - TIMI 38 Stent Analysis

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Disclosure Statement:

The TRITON-TIMI 38 trial was supported by a research grant to the Brigham and Women's Hospital from Daiichi Sankyo Co. Ltd and Eli Lilly & Co.

Main Trial Design

ACS (STEMI or UA/NSTEMI) & Planned PCI

ASA ↓ **N= 13,608**

Double-blind

CLOPIDOGREL
300 mg LD/ 75 mg MD

PRASUGREL
60 mg LD/ 10 mg MD

Duration of therapy: 6-15 months

1° endpoint: CV death, MI, Stroke
2° endpoint: Stent Thrombosis
Safety endpoints: TIMI major bleeds, Life-threatening bleeds



TRITON TIMI-38 STENT ANALYSIS

Trial Organization

Trial Leadership: TIMI Study Group

Eugene Braunwald, Chairman,
Elliott M. Antman, PI, Carolyn H. McCabe, Director, Stephen D.
Wiviott, Gilles Montalescot, Sabina A. Murphy, Susan McHale

Sponsors: Daiichi Sankyo and Eli Lilly

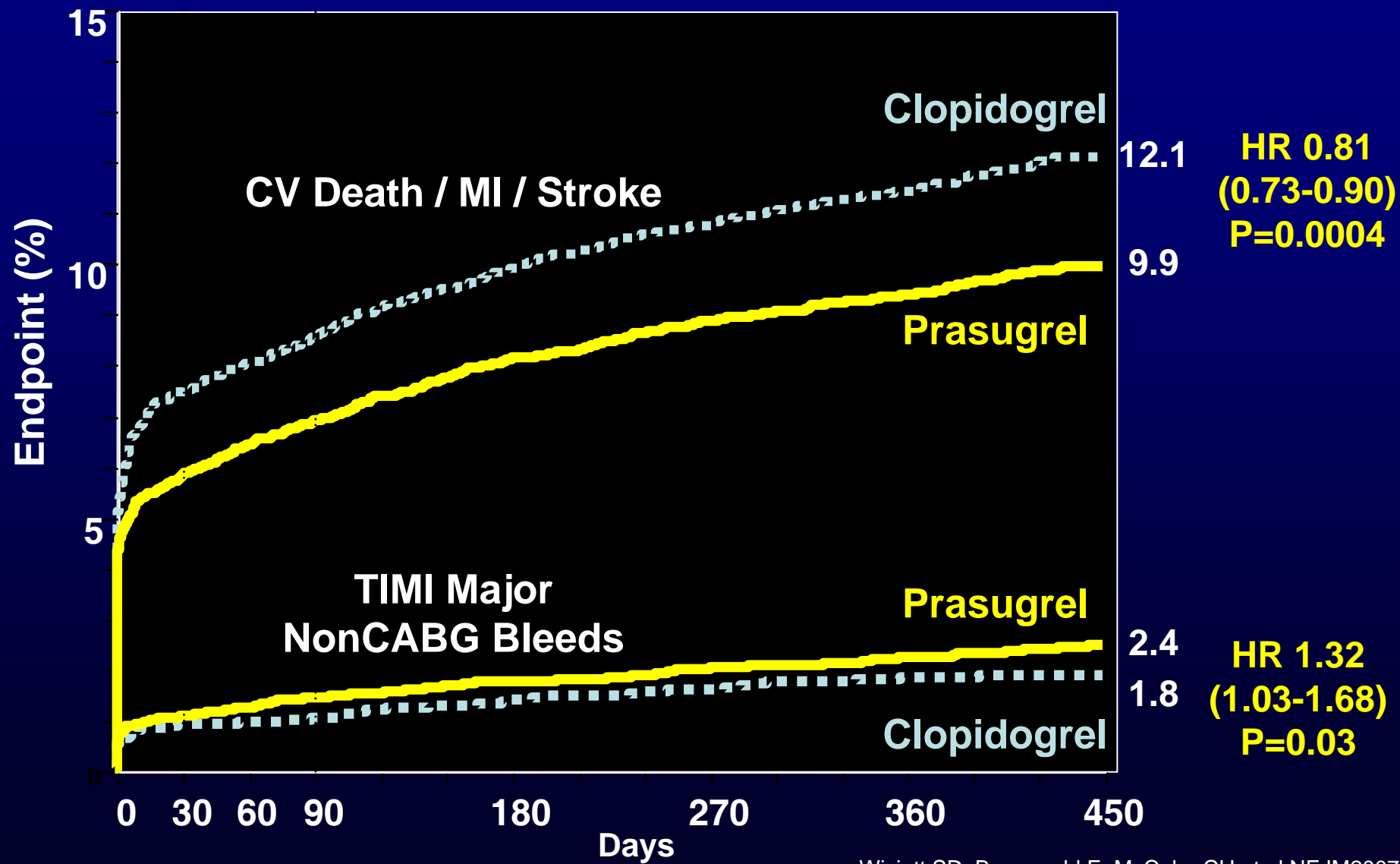
J. Anthony Ware, Jeffrey Riesmeyer, William Macias,
James Croaning, Govinda Weerakkody, Francis Plat,
Tomas Bocanegra

Data Center and Site Management: Quintiles Inc

Data Safety Monitoring Board

David Williams (Chair) , Christophe Bode, Spencer King,
Ulrich Sigwart, David DeMets

Main Trial: Primary Results



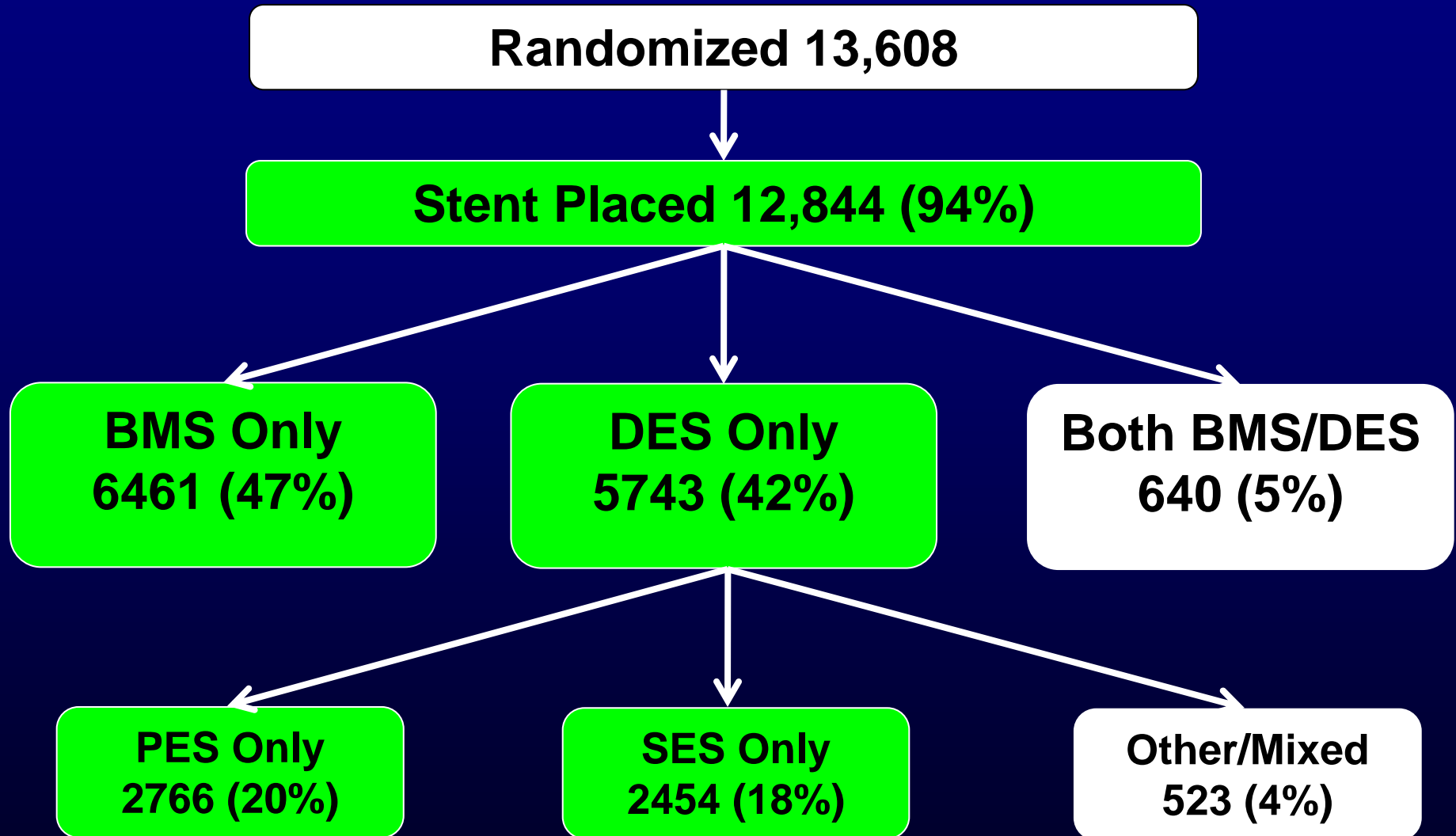


To compare the efficacy and safety of **PRASUGREL** and **CLOPIDOGREL** in 12,844 patients with at least one stent as part of the index procedure with respect to:

- Stent Thrombosis (ARC definitions)
- Ischemic Events, Bleeding
- Overall and stratified by stent type received



Patient Population





Baseline Characteristics

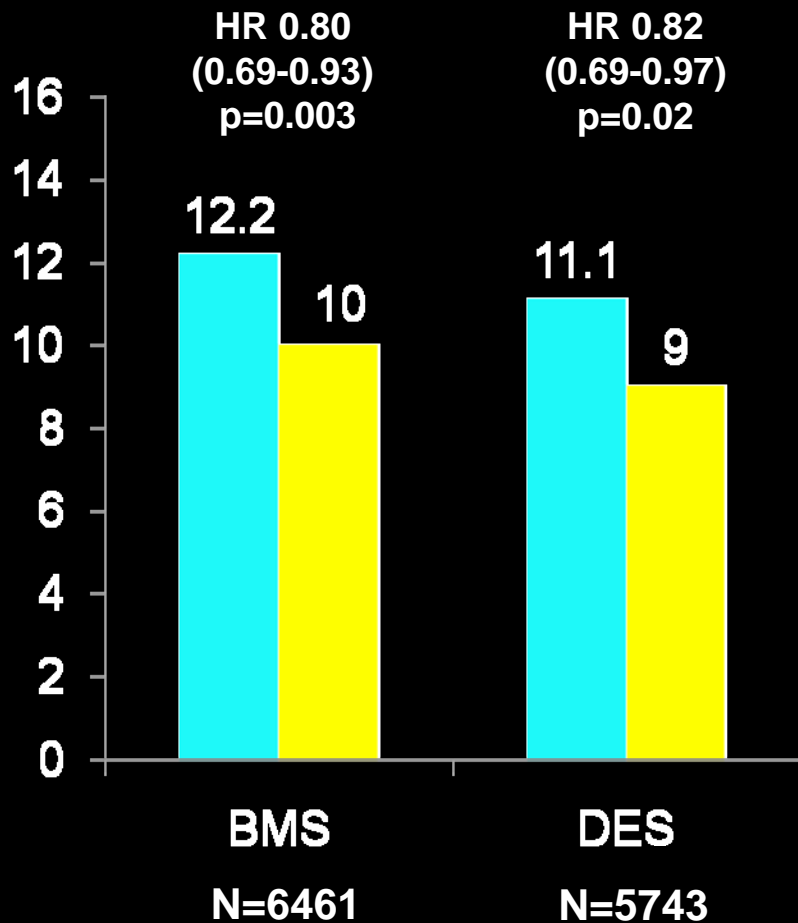
	Any Stent (N=12844) 94 %
UA/NSTEMI	75
STEMI	25
Age, median (IQR)	60 (53,69) y
≥75 y	13
Female	26
Diabetes	23
Smoker	38
North America	32
Prior MI	17
CrCl (ml/min)	
≥60	89
<60	11



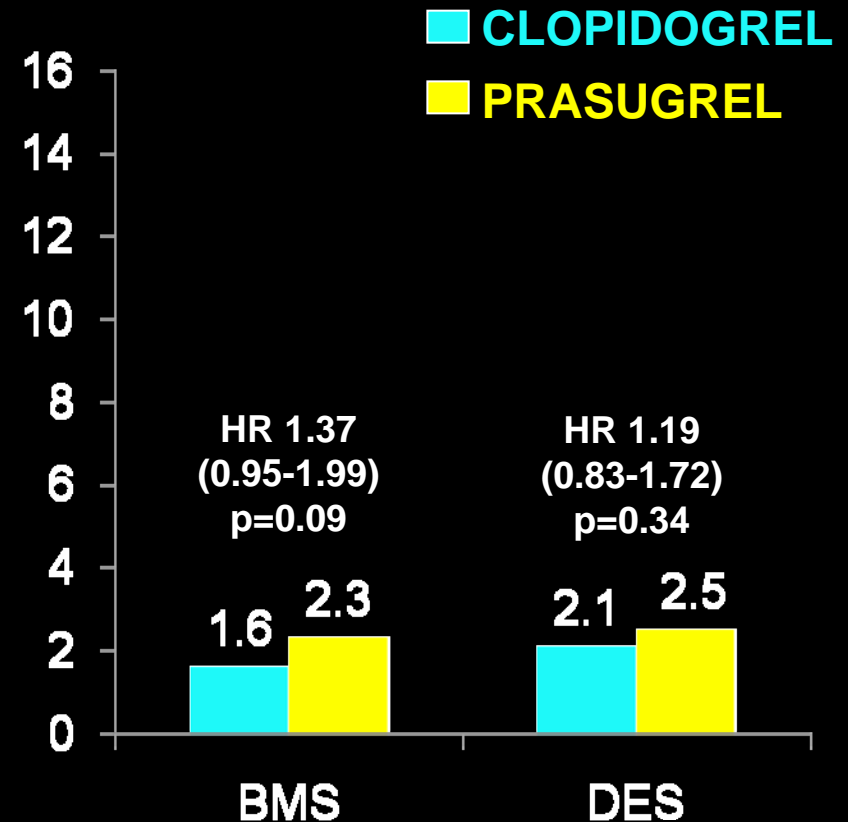
Key Efficacy, Safety EP: Stratified by Stent Type

% of Subjects

CVD/MI/CVA



Non-CABG TIMI Major Bleeding



Blinded CEC review of using source documents incl imaging reports:

Definite: total occlusion w/in or < 5 mm of the stent or thrombus w/in or < 5 mm of the stent AND a clinical syndrome < 48 h.

Probable: unexplained death ≤ 30 days or MI in stented territory w/o angiographic confirmation ST AND w/o alternative cause

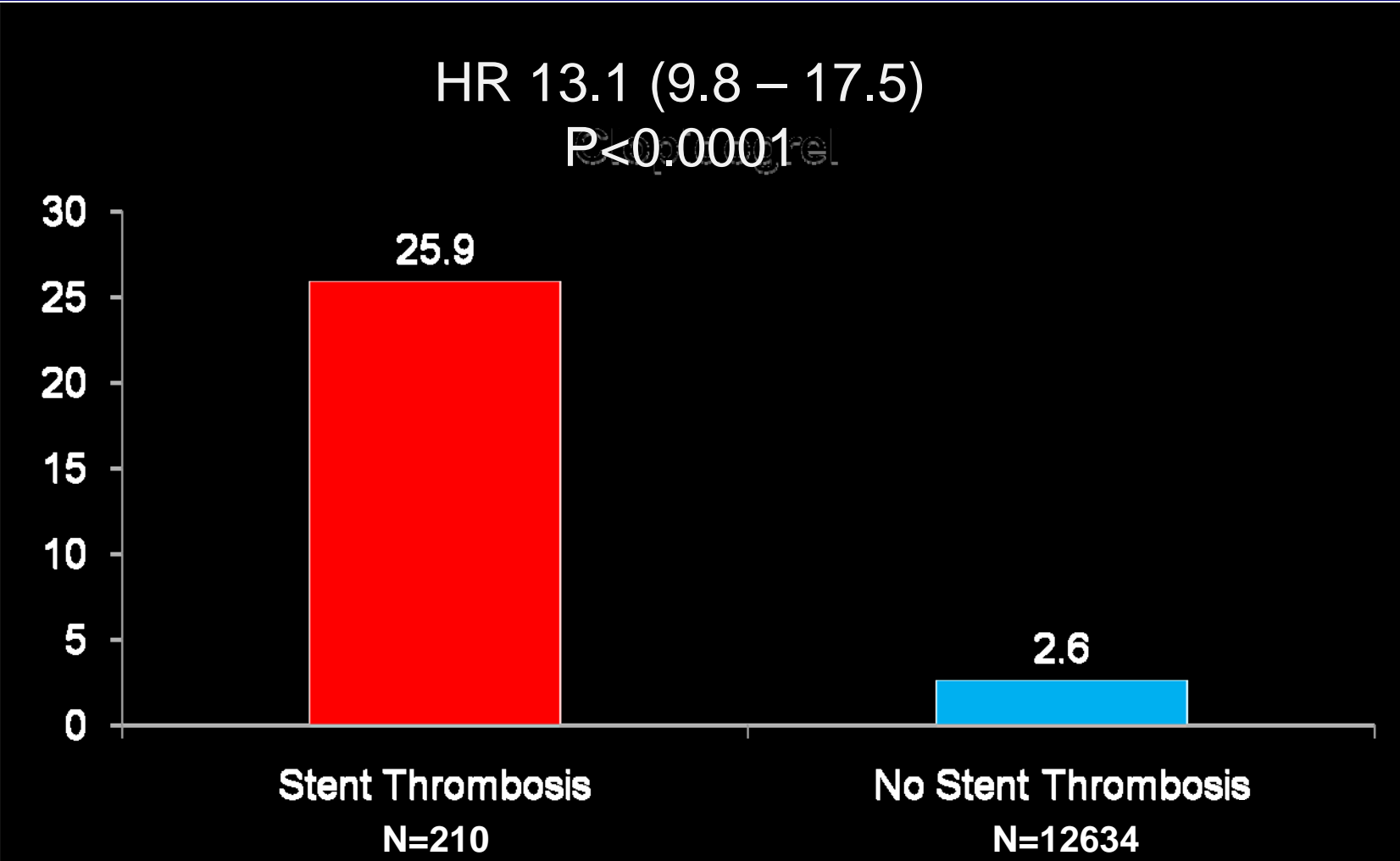
Possible: unexplained death > 30 days following stenting

Early: 0 – 30 days after randomization

Late > 30 days after randomization (landmark analysis)

Death Following ST

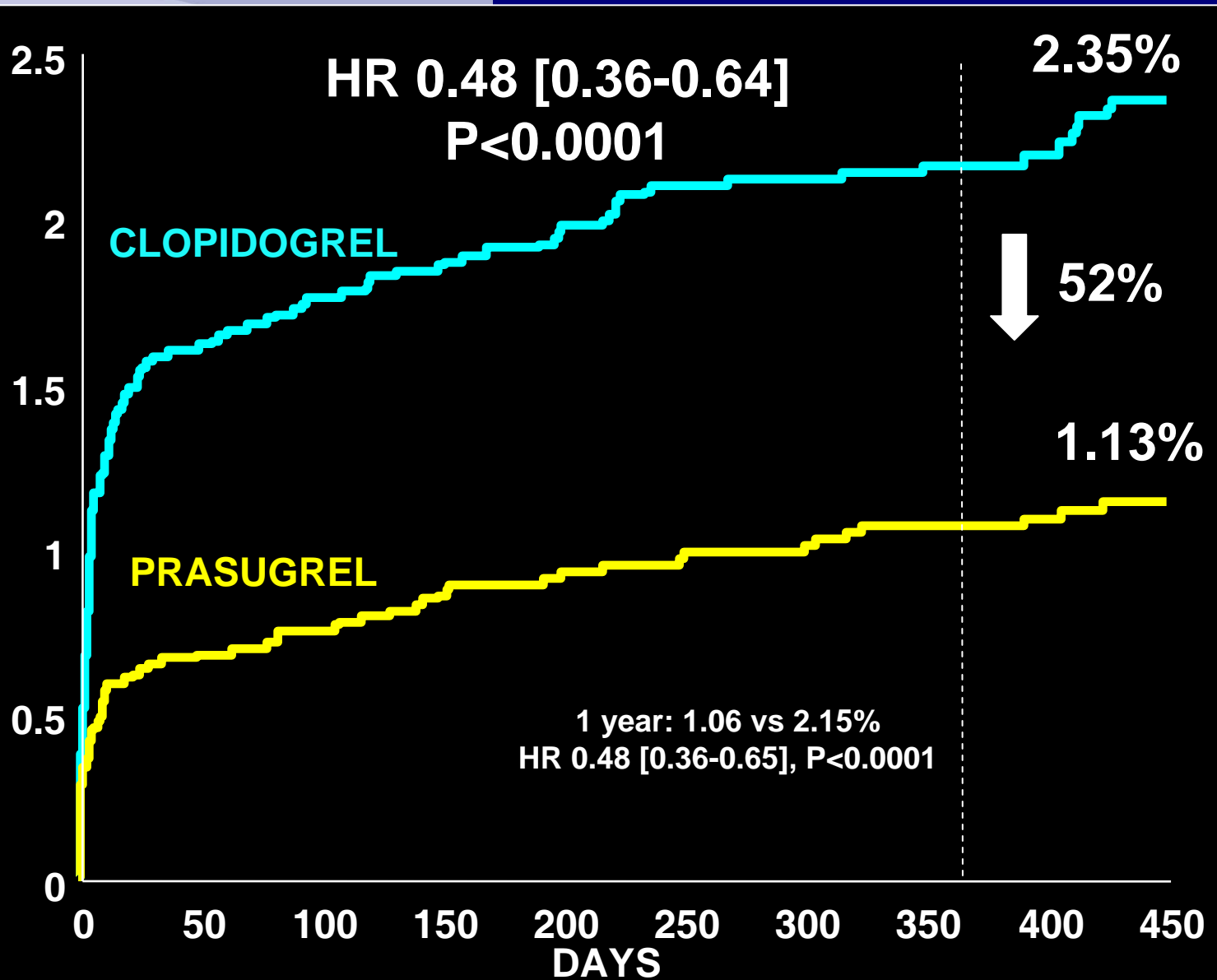
Mortality During Follow up (%) Post-Stent Thrombosis





Definite/Probable ST: Any Stent (N=12844)

% of Subjects

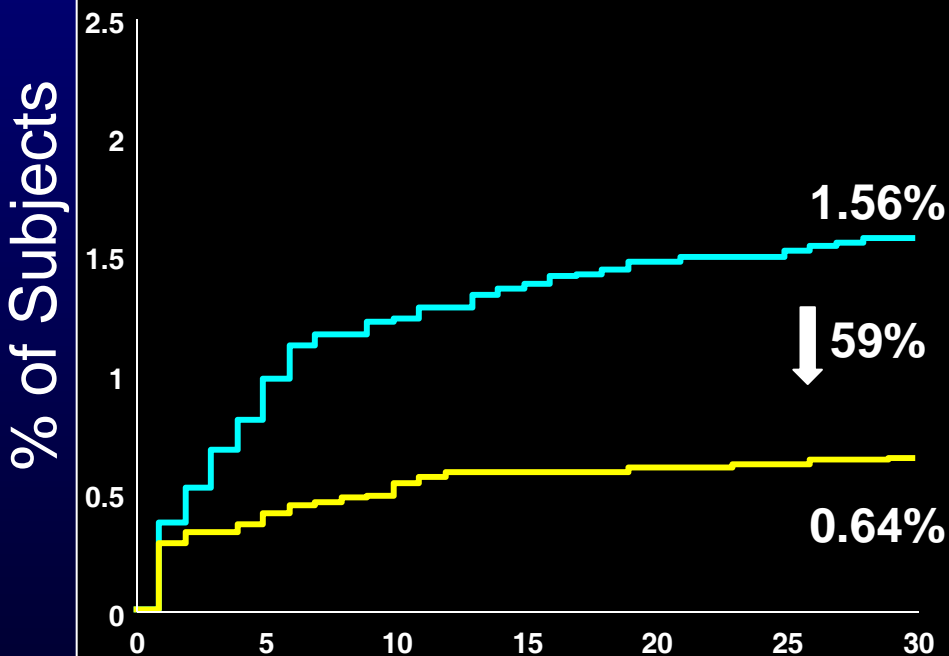




Definite/Probable ST: Any Stent (N=12844)

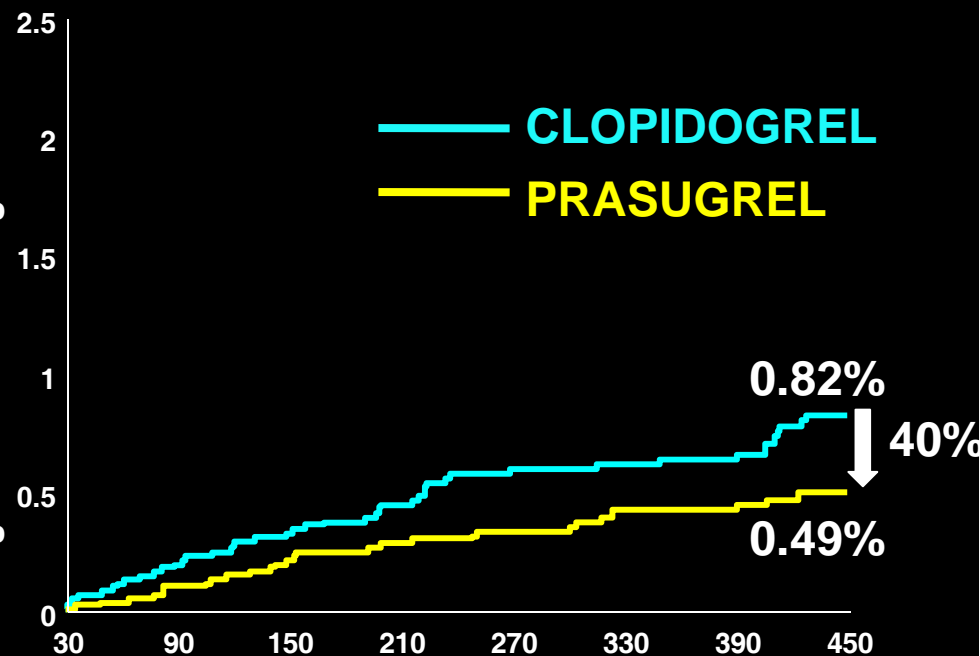
EARLY ST

HR 0.41 [0.29-0.59]
P<0.0001



LATE ST

HR 0.60 [0.37-0.97]
P=0.03



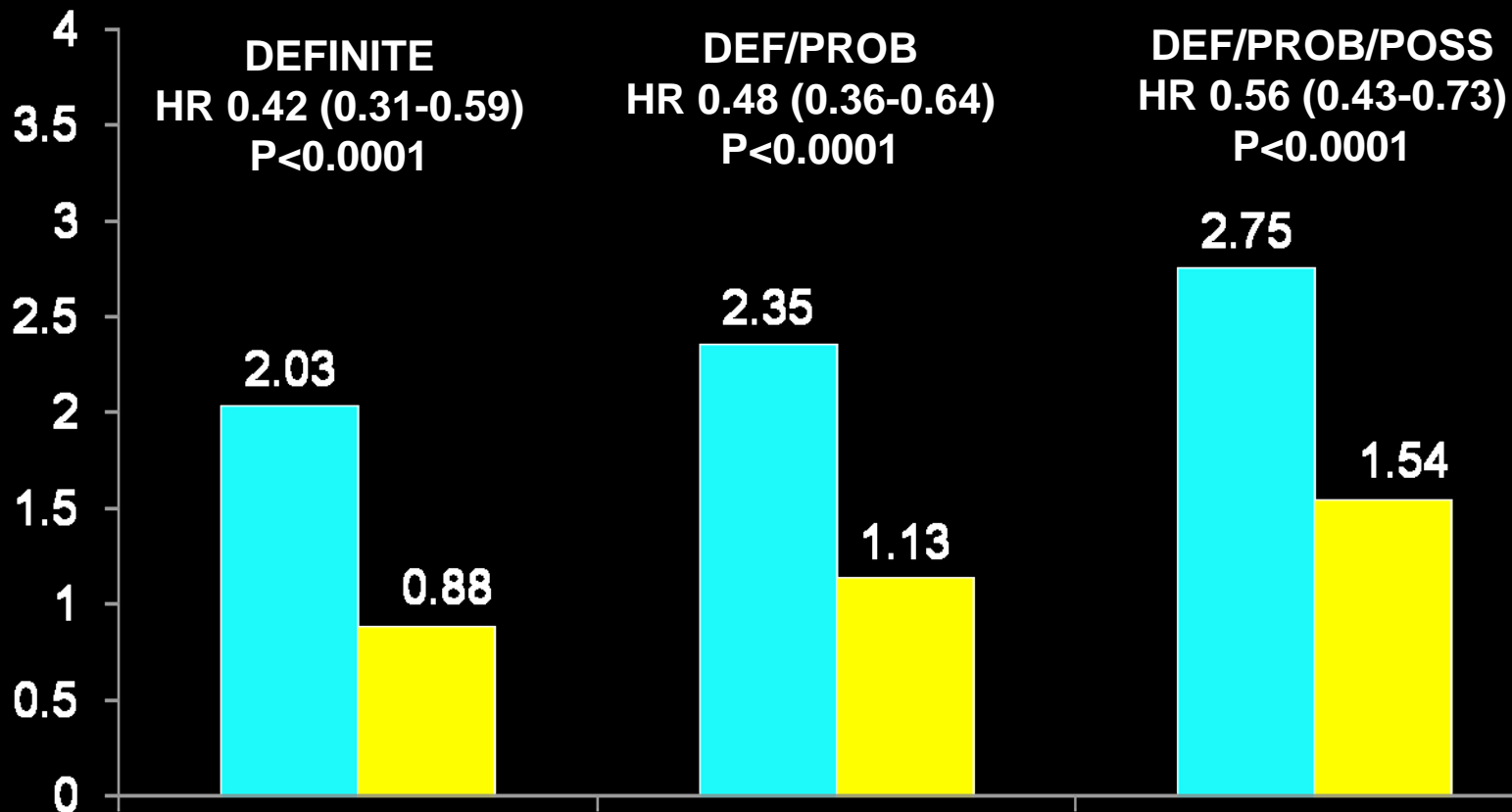
DAYS



Stent Thrombosis By ARC Category (N=12844)

% of Subjects

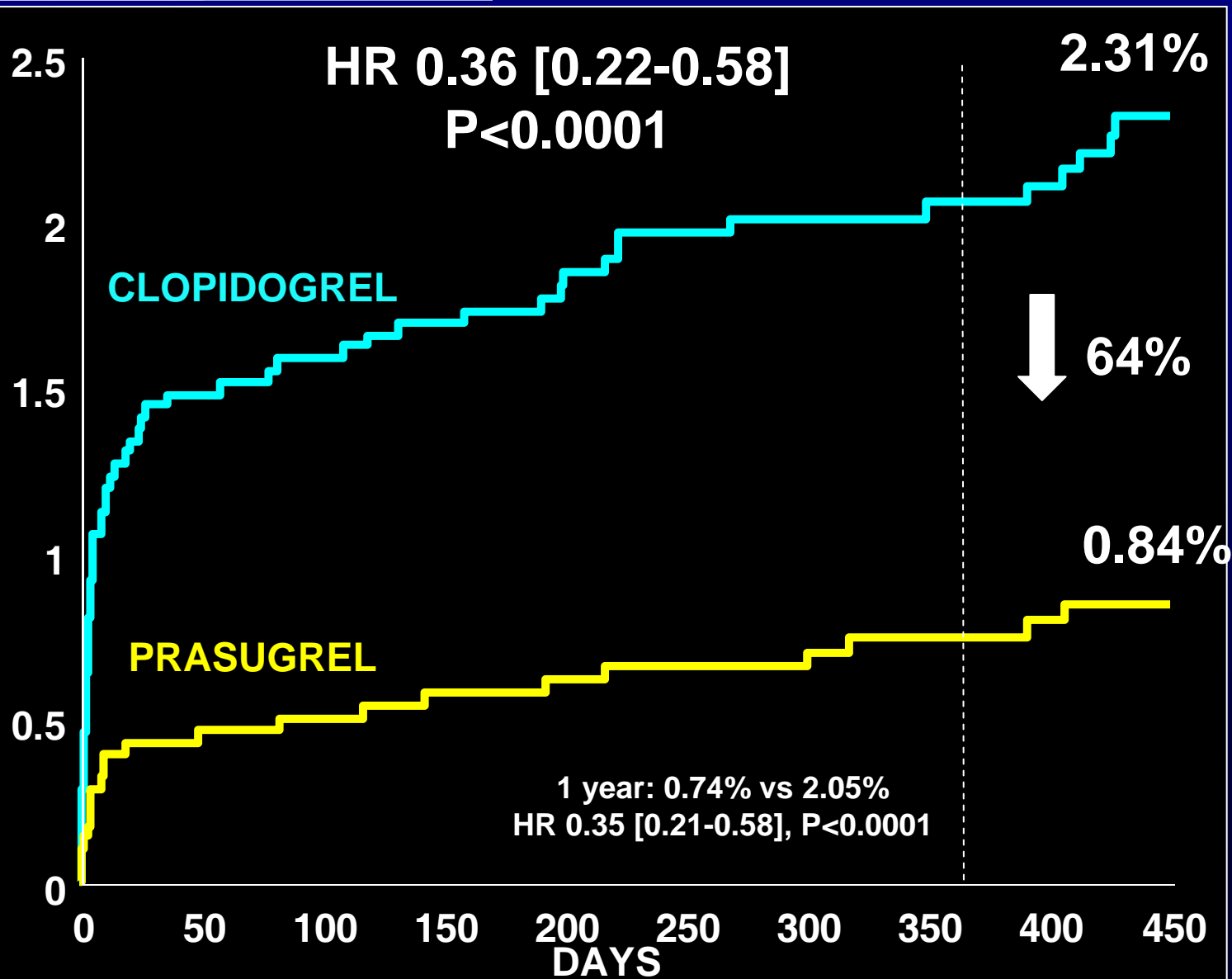
CLOPIDOGREL
PRASUGREL





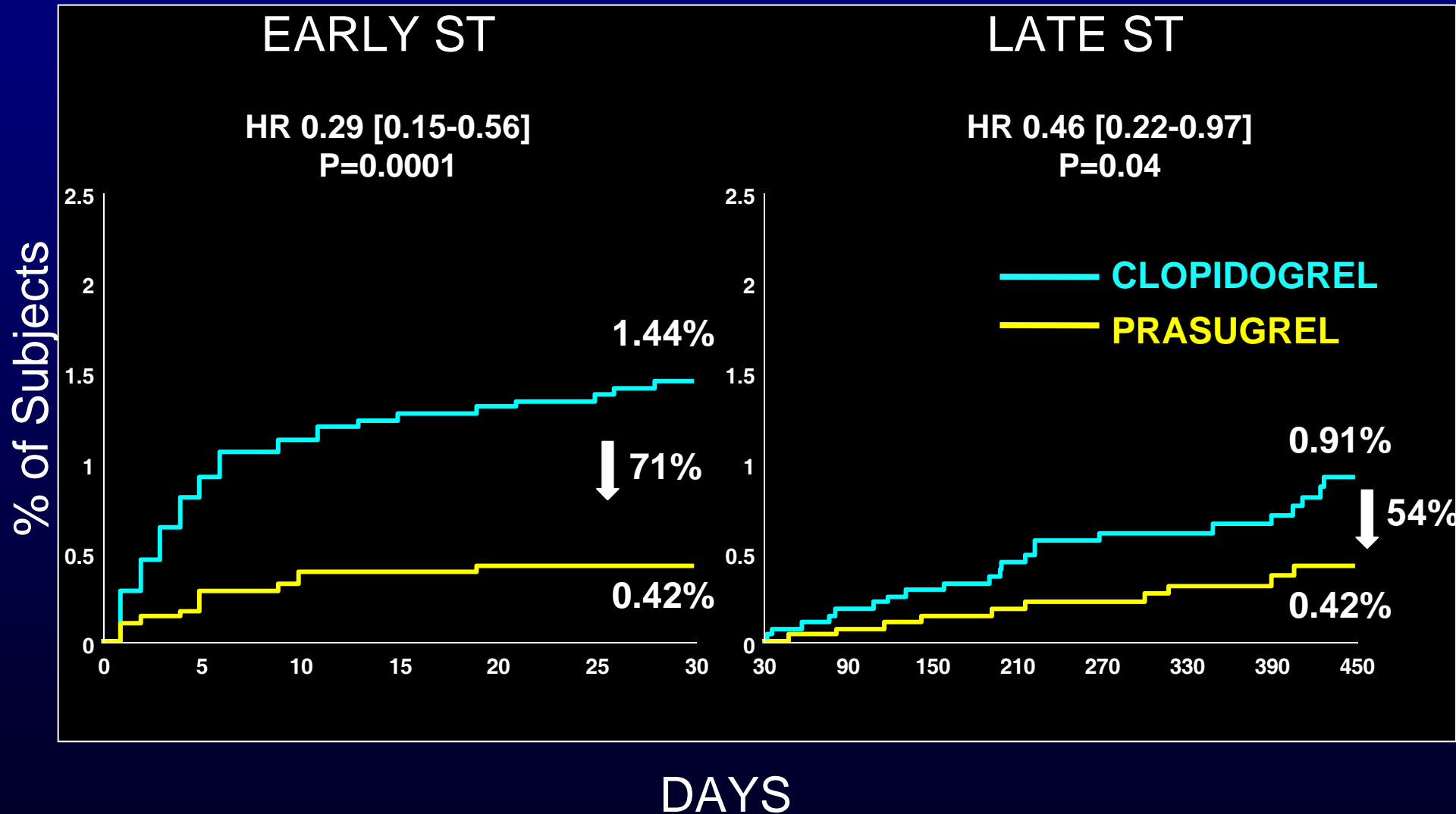
Definite/Probable ST: DES Only (N=5743)

% of Subjects

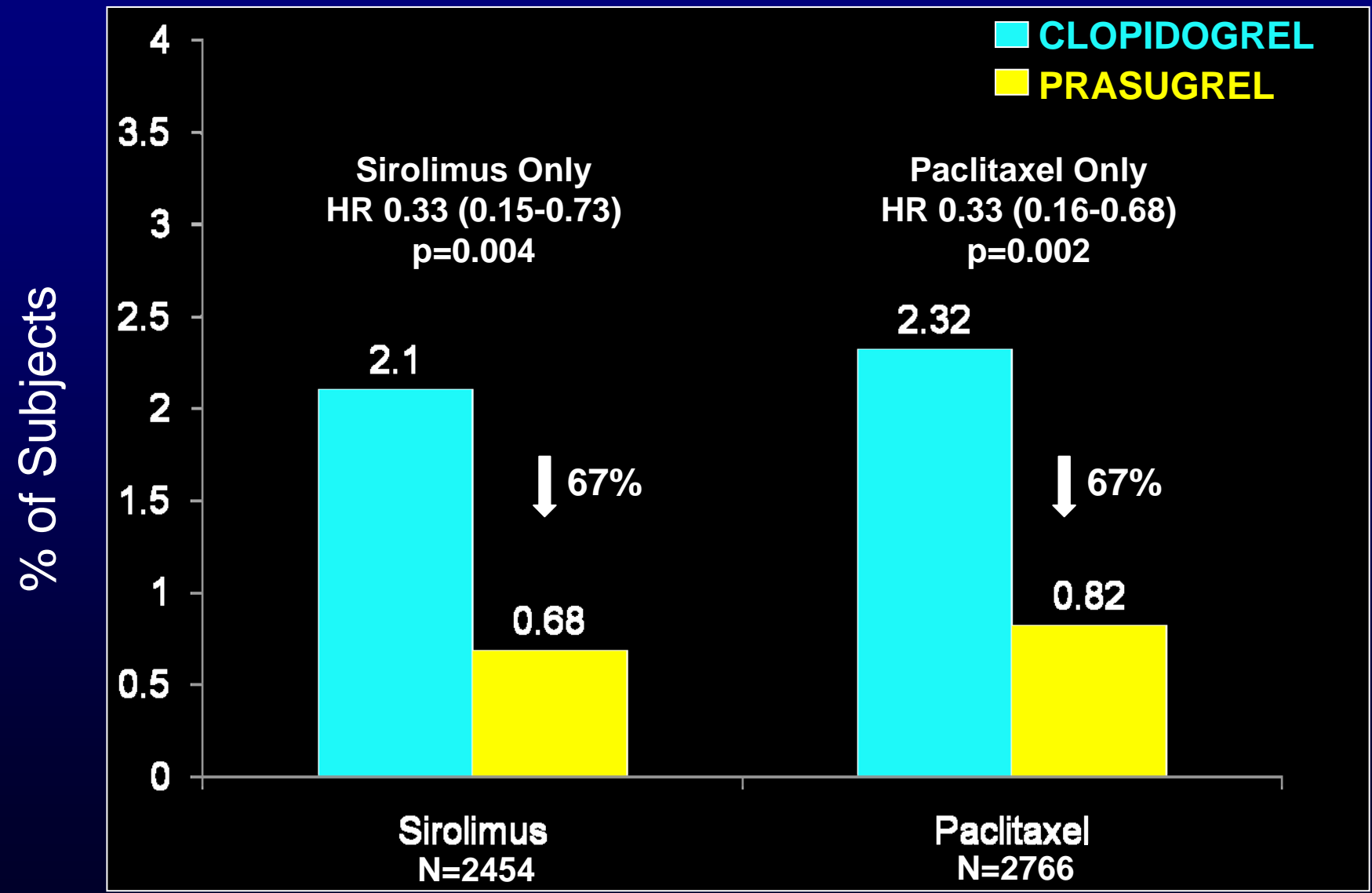




Definite/Probable ST: DES Only (N=5743)

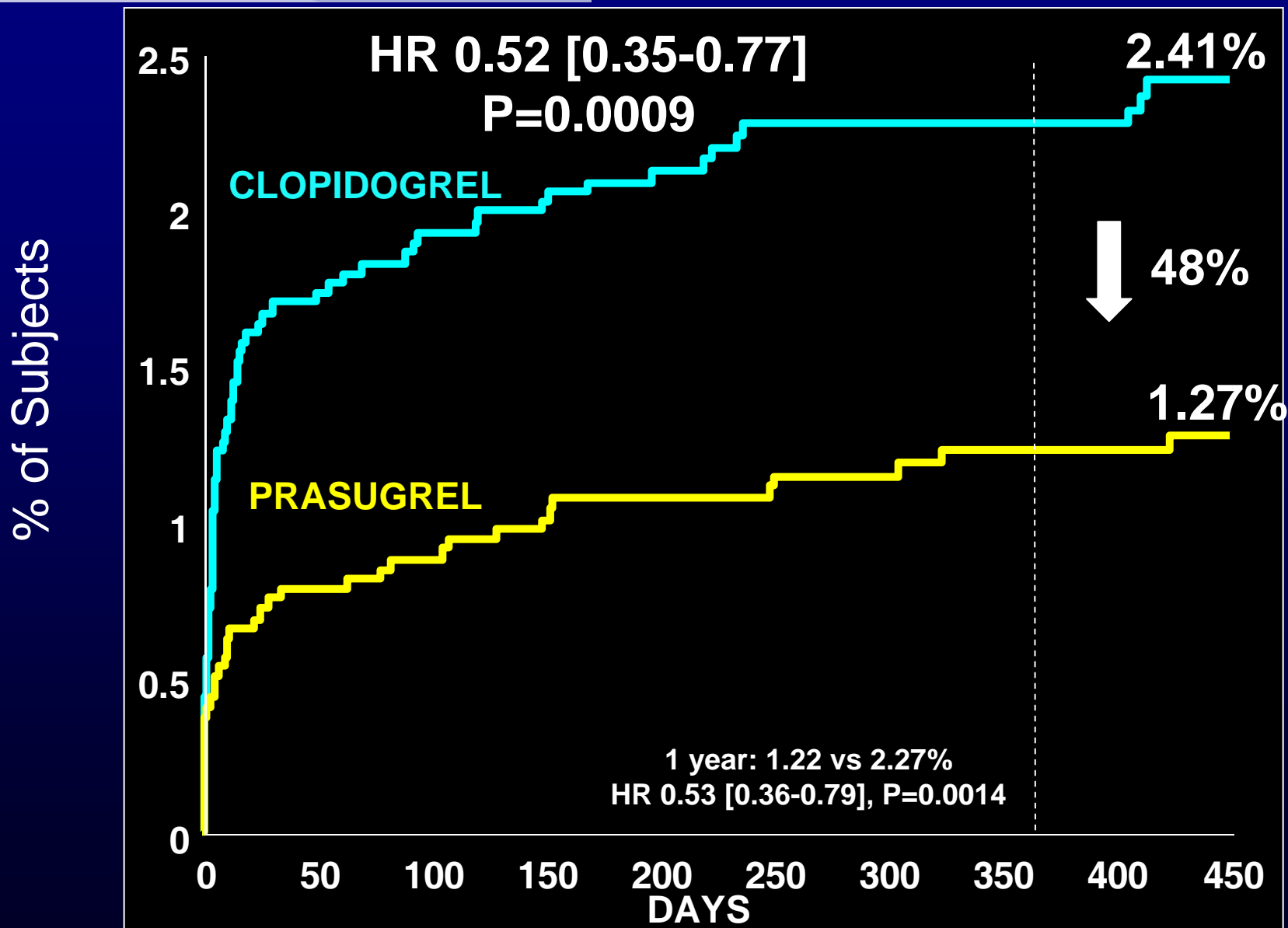


Stent Thrombosis DES Subtypes Trial Duration



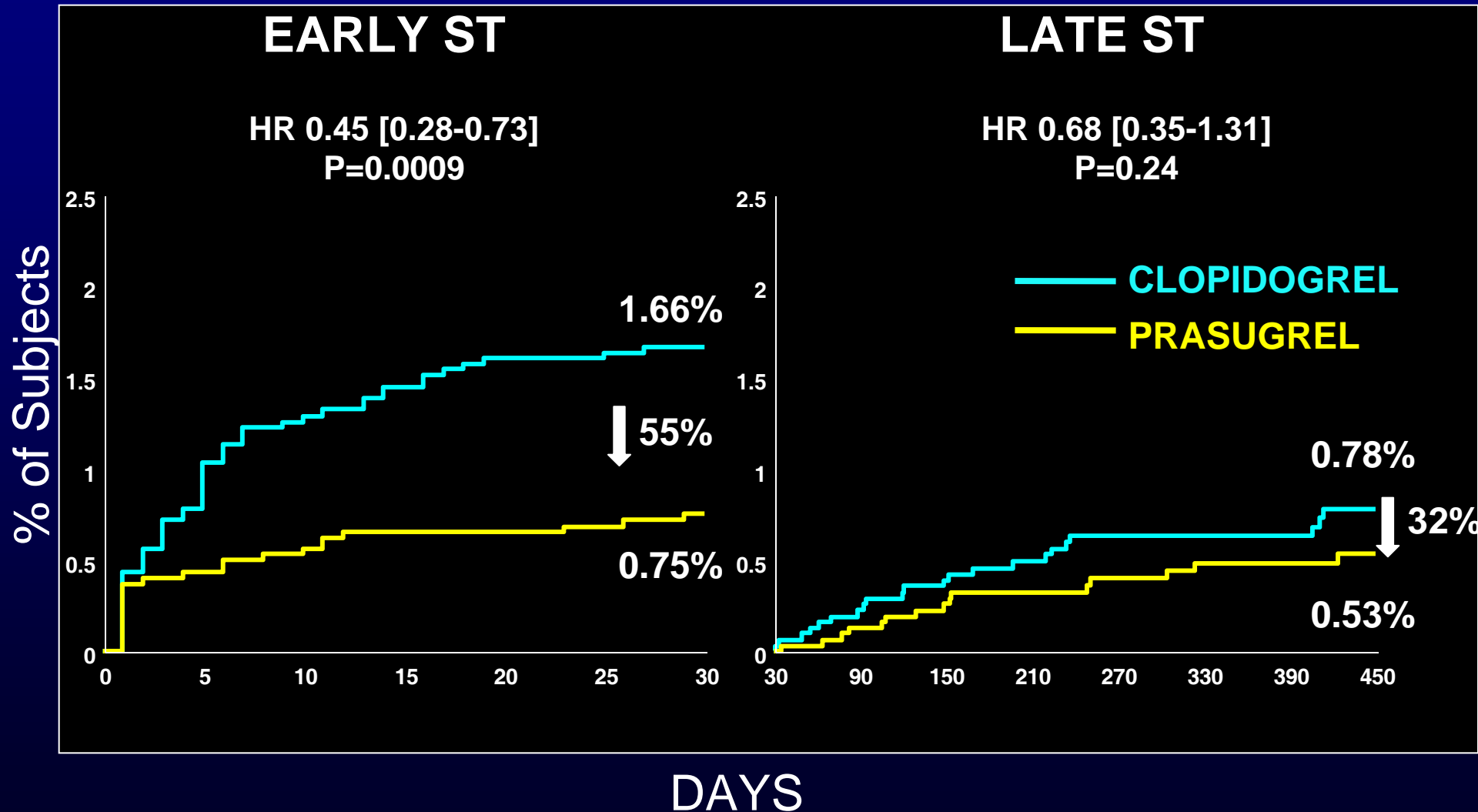


Definite/Probable ST: BMS Only (N=6461)





Definite/Probable ST: BMS Only (N=6461)

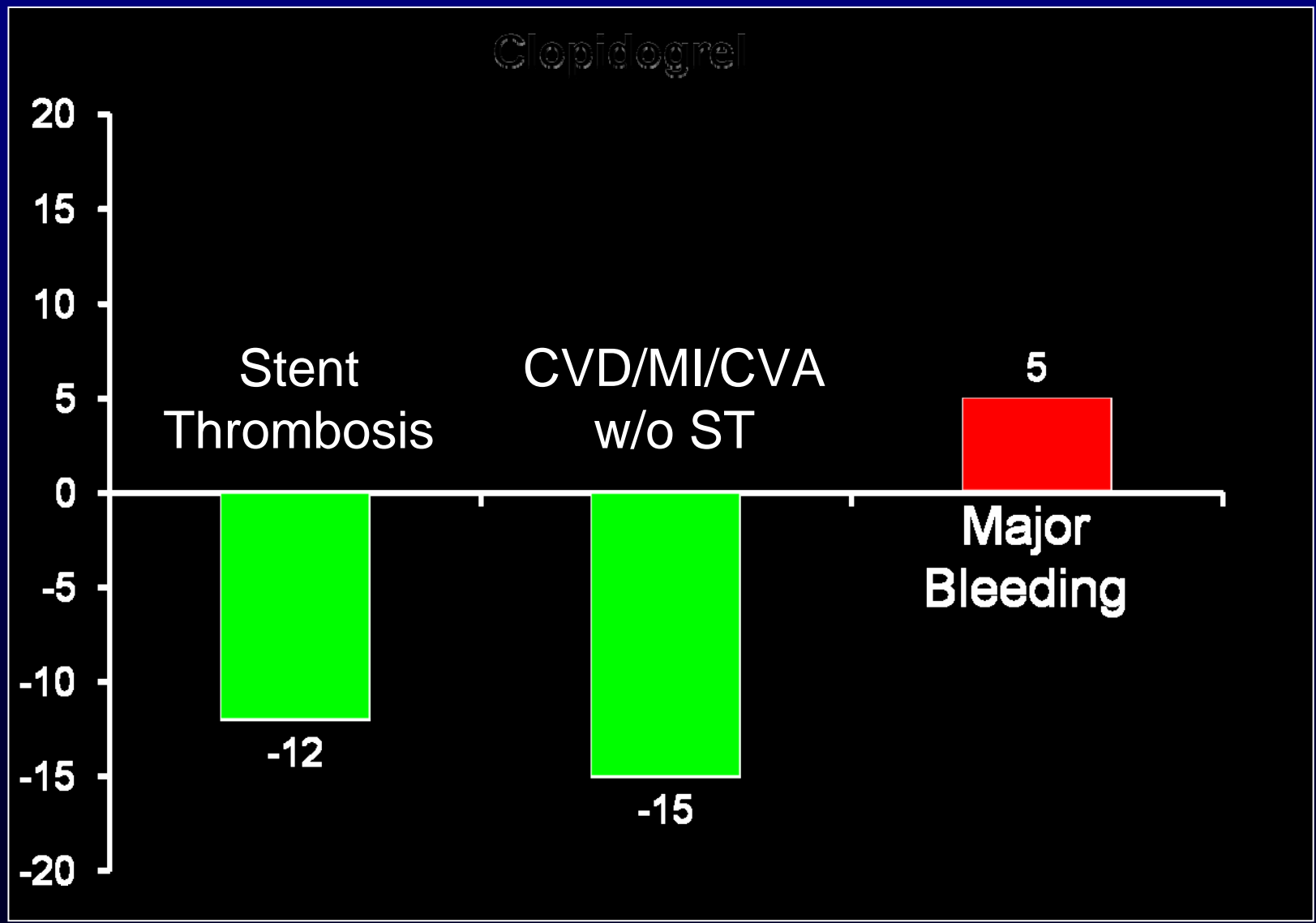


Intensive antiplatelet therapy with **PRASUGREL** in stented patients compared to **CLOPIDOGREL**:

- Substantial reduction in ST:
 - Regardless of stent type or ST definition
 - Early and Late
 - A broad range of clinical/procedural characteristics
- Fewer ischemic events, more major bleeding

Balance of Efficacy and Safety (Stented Population)

Events per 1000 patients treated





TRITON TIMI-38 STENT ANALYSIS

Conclusions/Implications

Intensive oral antiplatelet therapy for reduction of ischaemic events including stent thrombosis in patients with acute coronary syndromes treated with percutaneous coronary intervention and stenting (TRITON-TIMI 38): a subanalysis of a randomised trial



THE LANCET

Stephen D Wiviott, Eugene Braunwald, Carolyn H McCabe, Ivan Horvath, Matyas Koltai, Jean-Paul R Herman, Frans Van de Werf, William E Downey, Benjamin M Scirica, Sabina A Murphy, and Elliott M Antman for the TRITON-TIMI 38 Investigators

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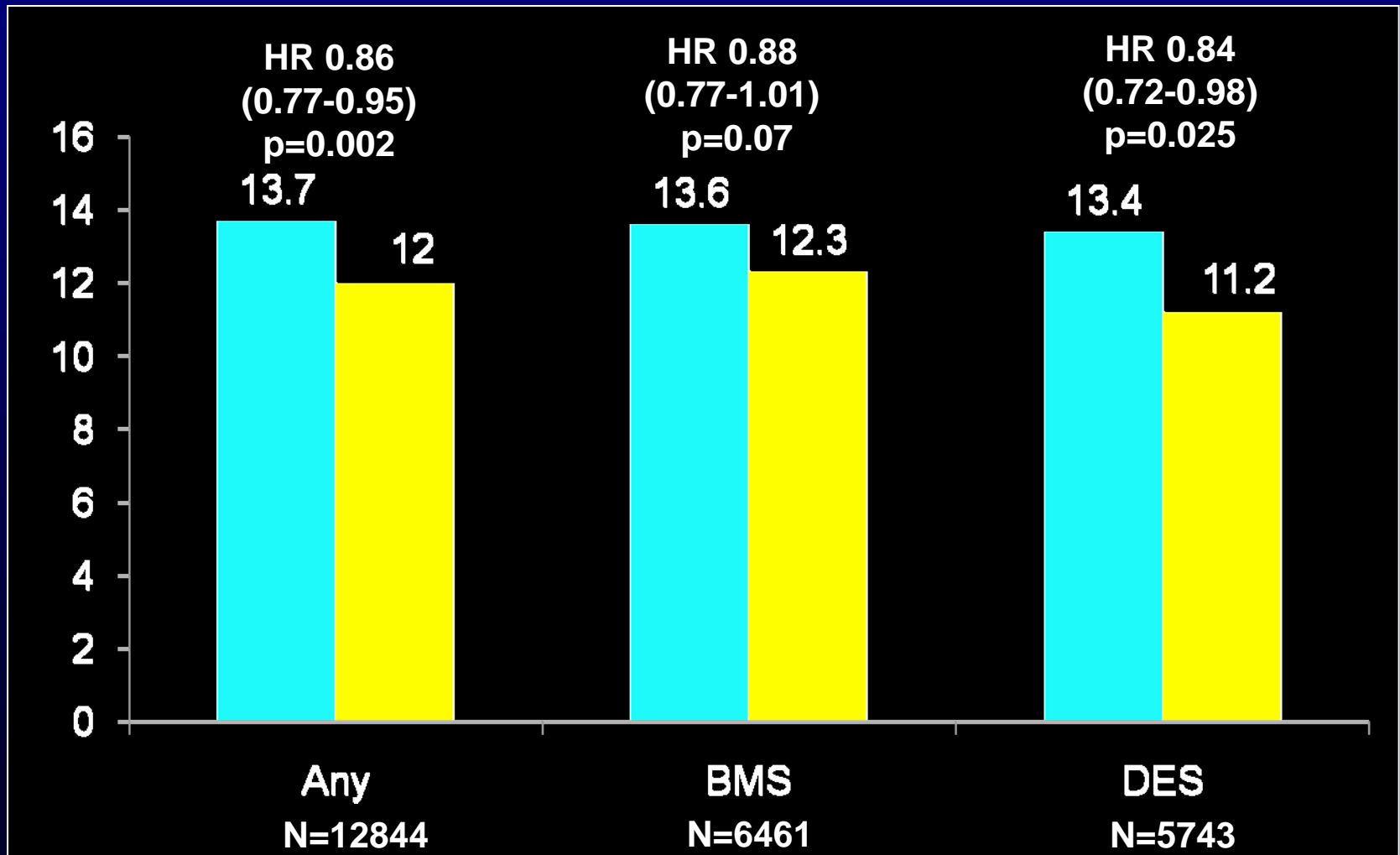
- Stent Thrombosis is a rare, but devastating complication of PCI associated with a high mortality. Efforts to reduce ST have focused on compliance w/ and duration of ASA/clopidogrel
- Our data indicate that an agent w/ more rapid, consistent, and greater inhibition of platelet aggregation (prasugrel) results in major reductions (~50%) in ST across a broad array of clinical procedural characteristics



TRÎTON TIMI-38

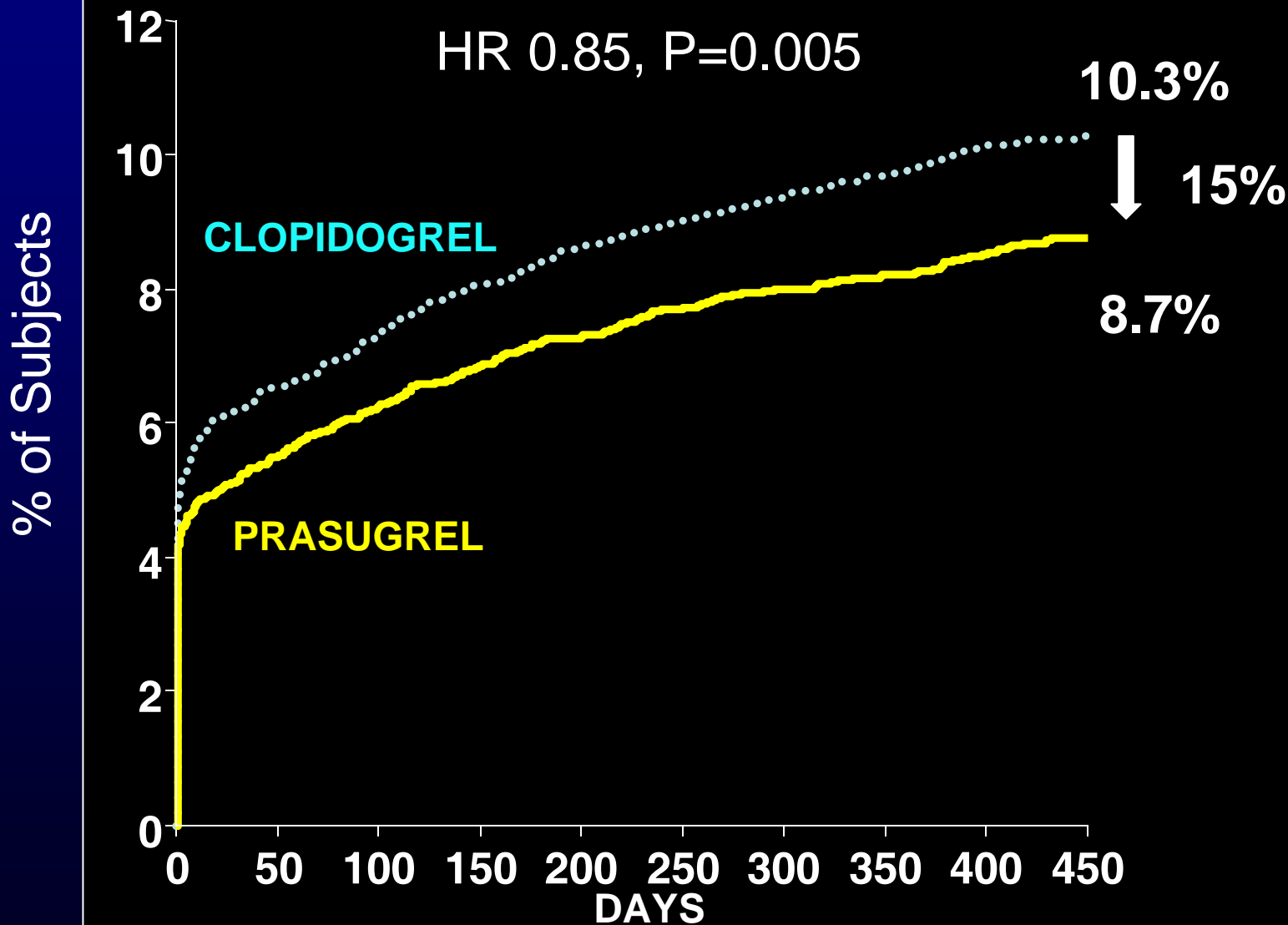
STENT ANALYSIS

Net Clinical Benefit





Primary EP (D/MI/CVA) Not Related to ST





Key Efficacy, Safety EP: Stratified by Stent Type

