

**ПРОДЪЛЖИТЕЛНОСТ НА  
ПЕРОРАЛНАТА ДАТ – С КАКВИ  
ДОКАЗАТЕЛСТВА РАЗПОЛАГАМЕ ?**

**Доц. Н. Рунев**

**КПВБ “Проф. Ст. Киркович”**

**МУ - София**



## 2013 ESC guidelines on the management of stable coronary artery disease

The Task Force on the management of stable coronary artery disease of the European Society of Cardiology

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref. <sup>c</sup>
DES is recommended in SCAD patients undergoing stenting if there is no contraindication to prolonged DAPT.	I	A	172
Aspirin is recommended for elective stenting.	I	B	172
Clopidogrel is recommended for elective stenting.	I	A	172
Prasugrel or ticagrelor should be considered in patients with stent thrombosis on clopidogrel without treatment interruption.	IIa	C	-
GP IIb/IIIa antagonists should be considered for bailout situation only.	IIa	C	172
Platelet function testing or genetic testing may be considered in specific or high risk situations (e.g. prior history of stent thrombosis; compliance issue; suspicion of resistance; high bleeding risk) if results may change the treatment strategy.	IIb	C	-
Prasugrel or ticagrelor may be considered in specific high risk situations of elective stenting (e.g. left main stenting; high risk of stent thrombosis; diabetes).	IIb	C	-



## 2013 ESC guidelines on the management of stable coronary artery disease

The Task Force on the management of stable coronary artery disease of the European Society of Cardiology

### Antiplatelet therapy

SAPT, usually aspirin, is recommended indefinitely.	I	A	172,333,501-503
DAPT is indicated after BMS for at least 1 month.	I	A	501,502,504,505
DAPT is indicated for 6 to 12 months after 2nd generation DES.	I	B	504,505
DAPT may be used for more than 1 year in patients at high ischaemic risk (e.g. stent thrombosis, recurrent ACS on DAPT, post MI/diffuse CAD) and low bleeding risk.	IIb	B	334,504,505
DAPT for 1 to 3 months may be used in patients at <u>high bleeding risk or with undeferrable surgery or concomitant anticoagulant treatment.</u>	IIb	C	-

**ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation**

The Task Force for the management of acute coronary syndromes (ACS) in patients presenting without persistent ST-segment elevation of the European Society of Cardiology (ESC)

**Recommendations for oral antiplatelet agents**

Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
Aspirin should be given to all patients without contraindications at an initial loading dose of 150–300 mg, and at a maintenance dose of 75–100 mg daily long-term regardless of treatment strategy.	I	A	107, 108
A P2Y <sub>12</sub> inhibitor should be added to aspirin as soon as possible and maintained over 12 months, unless there are contraindications such as excessive risk of bleeding.	I	A	110, 130, 132
<u>Ticagrelor</u> (180-mg loading dose, 90 mg twice daily) is recommended for all patients at moderate-to-high risk of ischaemic events (e.g. elevated troponins), regardless of initial treatment strategy and including those pre-treated with clopidogrel (which should be discontinued when ticagrelor is commenced).	I	B	132
<u>Prasugrel</u> (60-mg loading dose, 10-mg daily dose) is recommended for P2Y <sub>12</sub> -inhibitor-naïve patients (especially diabetics) in whom coronary anatomy is known and who are proceeding to PCI unless there is a high risk of life-threatening bleeding or other contraindications. <sup>d</sup>	I	B	130
<u>Clopidogrel</u> (300-mg loading dose, 75-mg daily dose) is recommended for patients who cannot receive ticagrelor or prasugrel.	I	A	110, 146, 147

<b>Aspirin</b>	Continue life long
<b>P2Y<sub>12</sub> inhibitor</b>	Continue for 12 months (unless at high risk of bleeding)



## ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

The Task Force on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology (ESC)

**Table 22** Routine therapies in the acute, subacute and long term phase of ST-segment elevation myocardial infarction

Antiplatelet therapy with low dose aspirin (75–100 mg) is indicated indefinitely after STEMI.	I	A	237
In patients who are intolerant to aspirin, clopidogrel is indicated as an alternative to aspirin.	I	B	243
DAPT with a combination of aspirin and prasugrel or aspirin and ticagrelor is recommended (over aspirin and clopidogrel) in patients treated with PCI.	I	A	109, 110
DAPT with aspirin and an oral ADP receptor antagonist must be continued for up to 12 months after STEMI, with a strict minimum of:	I	C	245–247, 283
• 1 month for patients receiving BMS	I	C	
• 6 months for patients receiving DES	IIb	B	
DAPT should be used up to 1 year in patients with STEMI who did not receive a stent.	IIa	C	-

## Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

### Recommended duration of dual antiplatelet therapy

*After percutaneous coronary intervention*

- 1 month after BMS implantation in stable angina;<sup>55,60,94</sup>
- 6–12 months after DES implantation in all patients;<sup>60,94</sup>
- 1 year in all patients after ACS, irrespective of revascularization strategy.



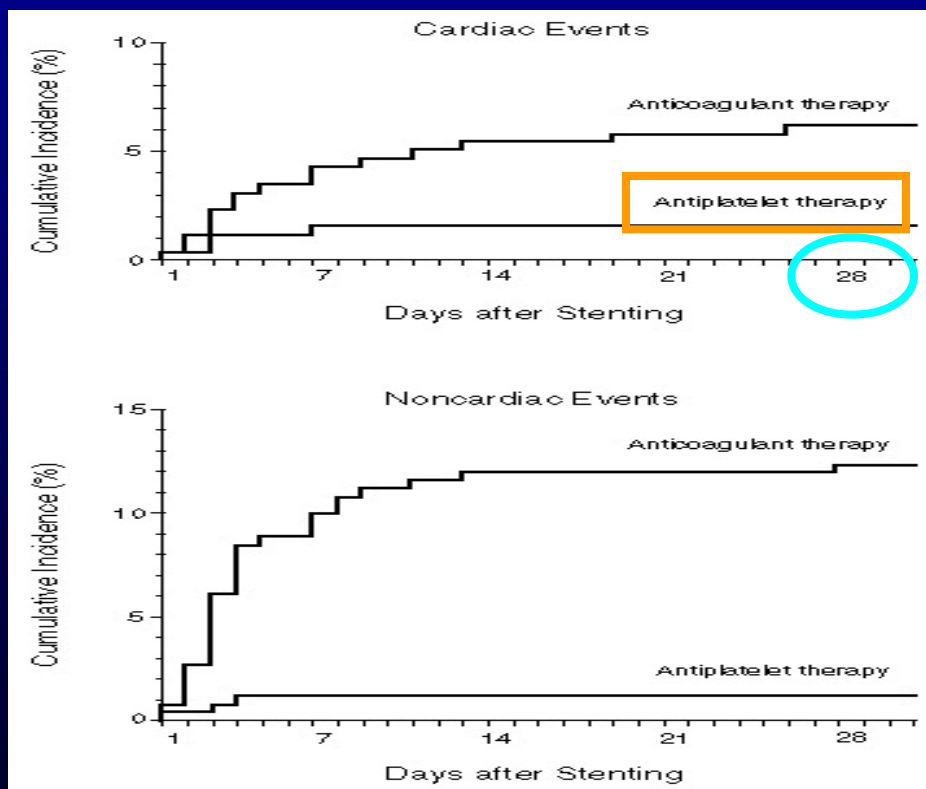
ORIGINAL ARTICLE

**A Randomized Comparison of Antiplatelet and Anticoagulant Therapy after the Placement of Coronary-Artery Stents**

Albert Schömig, M.D., Franz-Josef Neumann, M.D., Adnan Kastrati, M.D., Helmut Schühlen, M.D., Rudolf Blasini, M.D., Martin Hadamitzky, M.D., Hanna Walter, M.D., Eva-Maria Zitzmann-Roth, M.D., Gert Richardt, M.D., Eckhard Alt, M.D., Claus Schmitt, M.D., and Kurt Ulm, Ph.D.

N Engl J Med 1996; 34:1084-1089 | April 25, 1996 | DOI: 10.1056/NEJM199604253341702

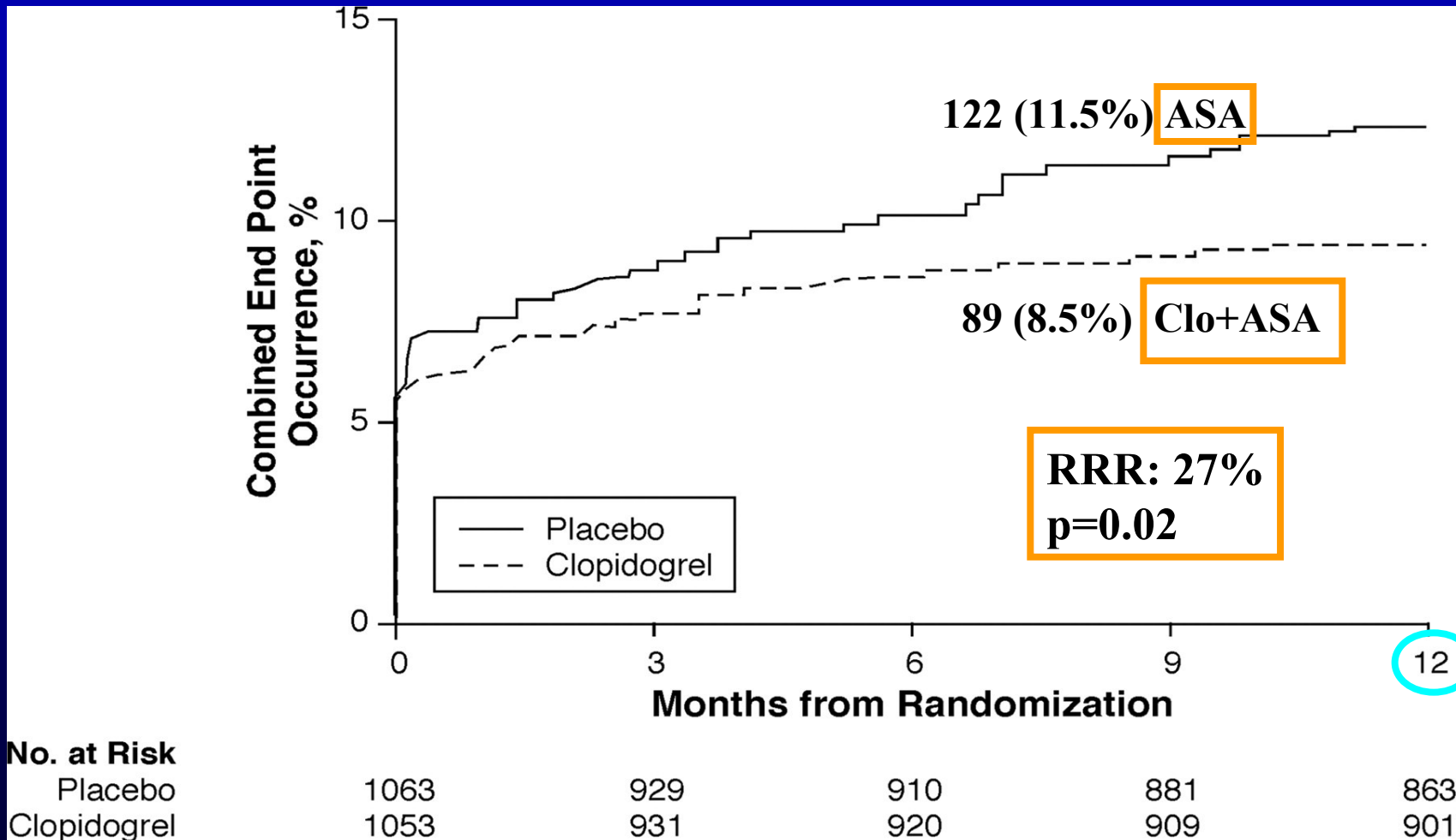
Честота на **сърдечни и несърдечни събития** в двете проучвани групи:  
на **антикоагулант (i.v. Heparin.VKA) vs DAPT (ASA + Ticlopidine)**



# CREDO Trial: Честота на смърт / МИ / инсулт



## на 1-та година (след планова ПКИ)

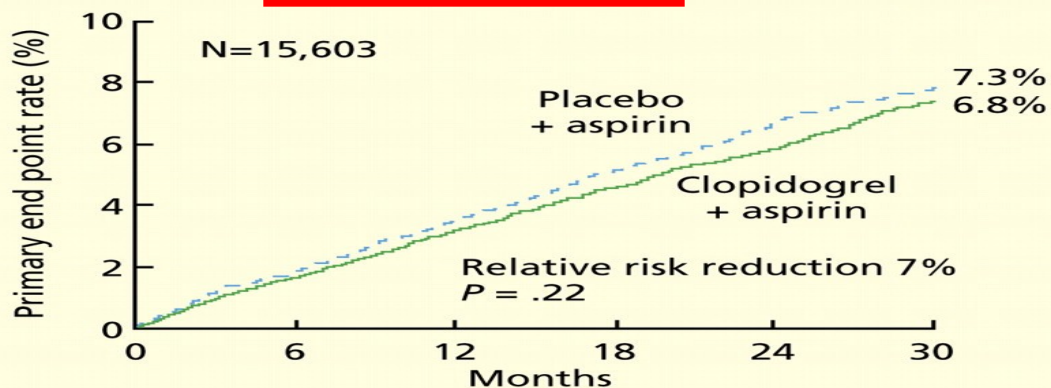


**Сигнификантна редукция на комбинирания краен показател  
между 29-тия ден и 1-та година**

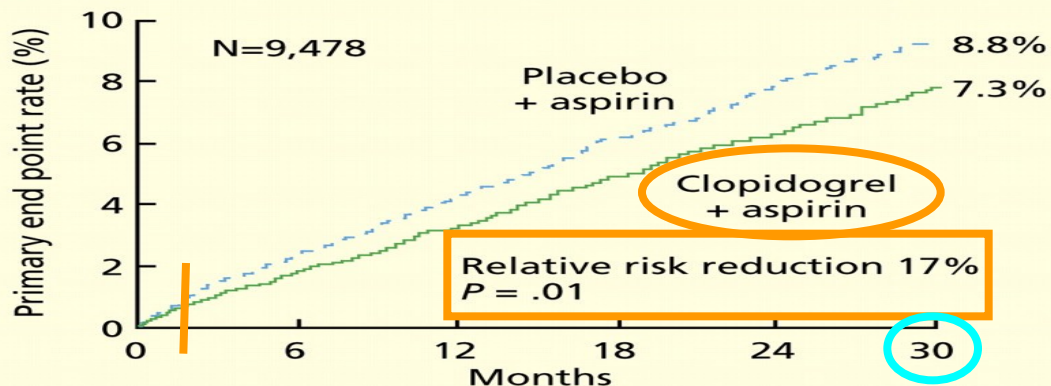


**CHARISMA Trial:** Първична крайна цел (МИ / инсулт / СС смърт) в цялата кохорта (със ССЗ или РФ) и в подгрупата високорискови пациенти с предшестващ МИ / инсулт или симптоматична PAD: **КОНСЕРВАТИВНО ПОВЕДЕНИЕ**

**CHARISMA: No benefit from dual antiplatelet therapy in the overall cohort of stable patients studied...**



**...but possible benefit in subgroup with prior MI, stroke, or symptomatic PAD**

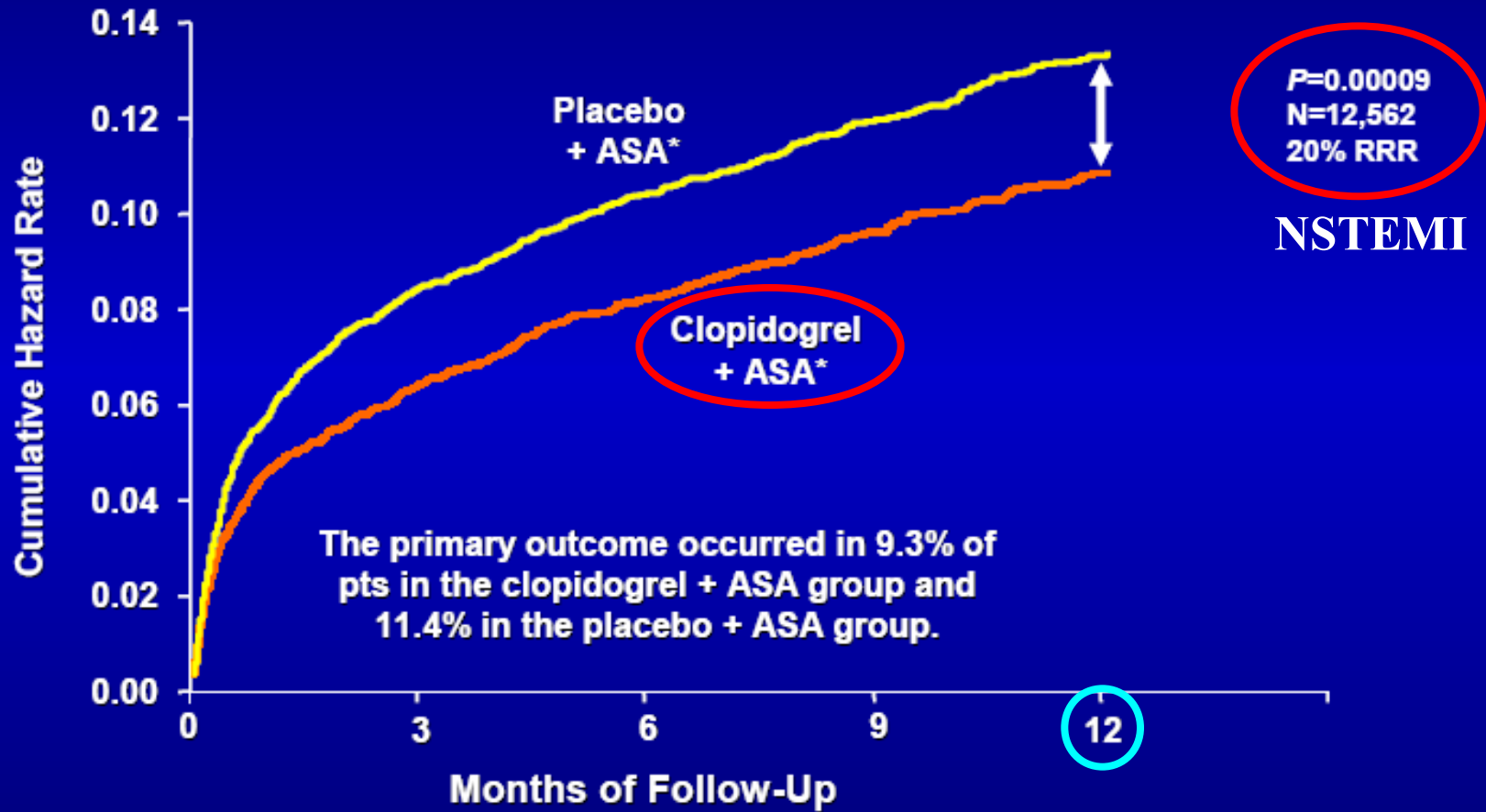


# Продължителност на DAPT след ОКС

What are we treating?

The **patient** or the stent?

## Primary Endpoint—MI/Stroke/CV Death



\*Other standard therapies were used as appropriate.  
Yusuf S et al. *N Engl J Med.* 2001;345:494-502.

# Безопасност на продължителния прием на DAPT след ОКС

CURE

## Bleeding Results

### NSTEMI

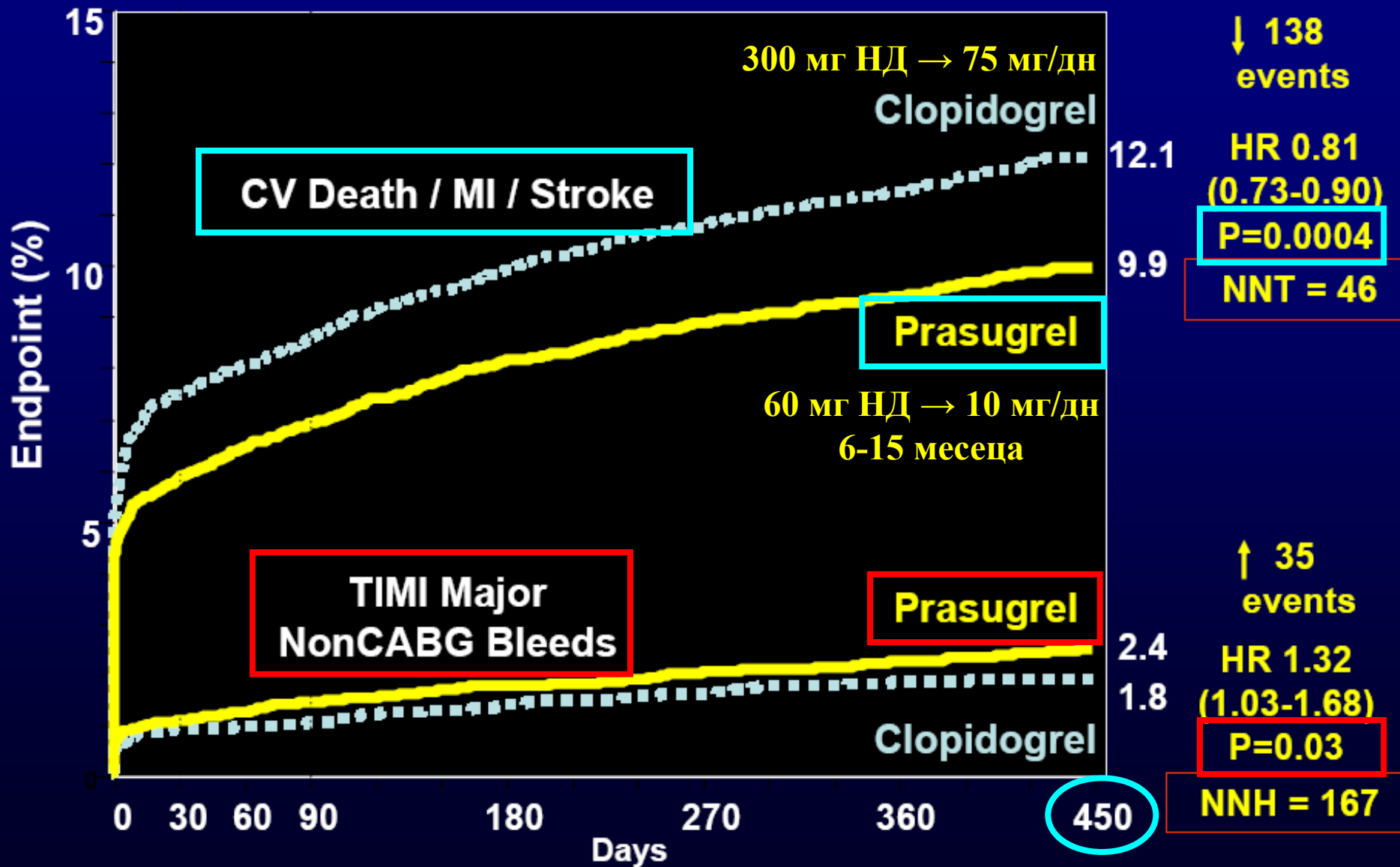
End Point	Placebo + ASA* N = 6303	Clopidogrel + ASA* N = 6259
Major bleeding	2.7%	3.7%**
Life-threatening bleeding ICH	1.8%	2.2% † NS
Non-life-threatening bleeding	0.9%	1.5% ‡
Minor bleeding	2.4%	5.1% §

\* In combination with standard therapy

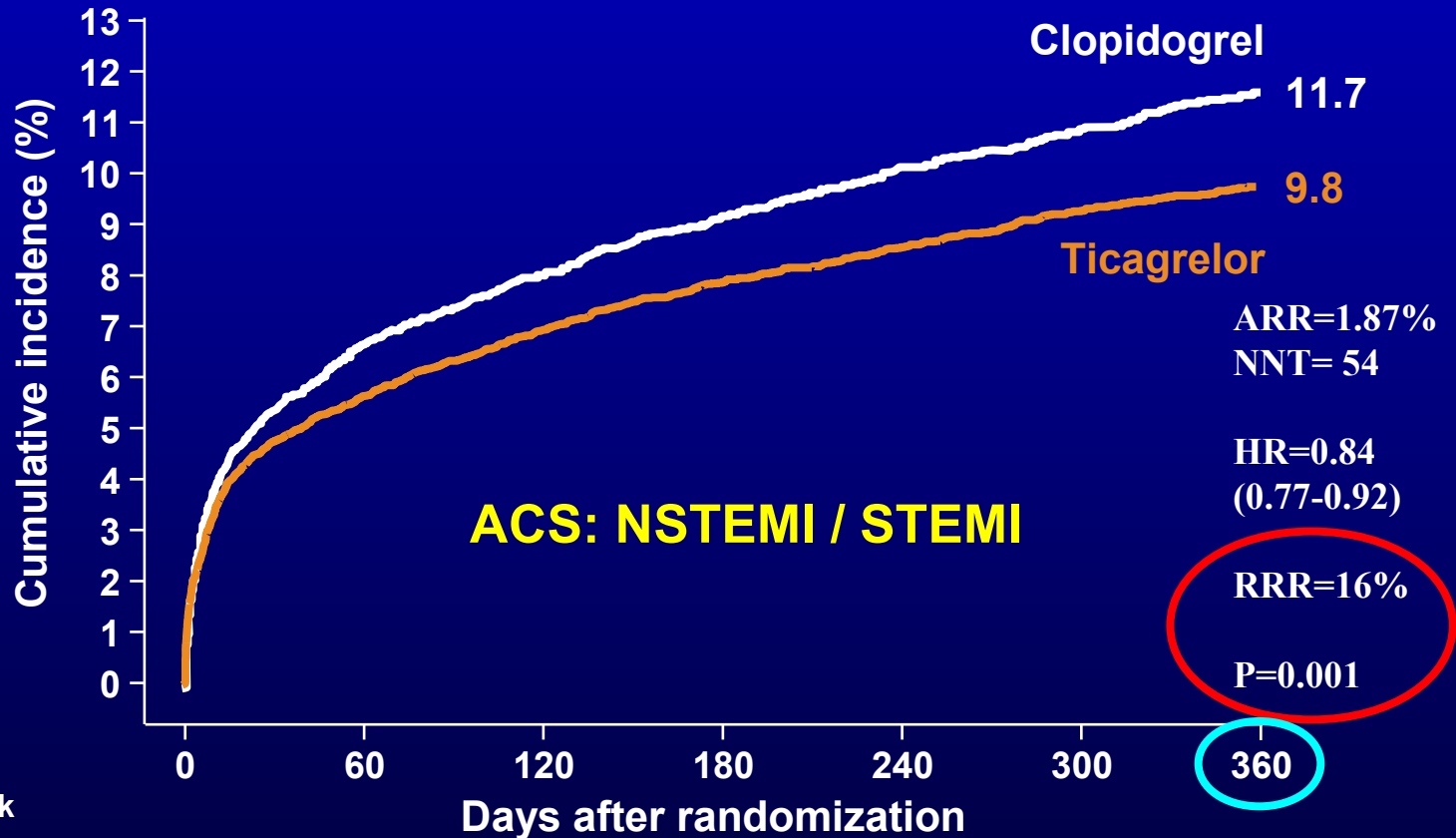
\*\*  $P = 0.001$ ; †  $P = NS$ ; ‡  $P = 0.002$ ; §  $P < 0.001$

The CURE Trial Investigators. *N Engl J Med.* 2001;345:494-502.

Пациенти с ОКС → ПКИ  
Баланс между ефикасност  
и безопасност



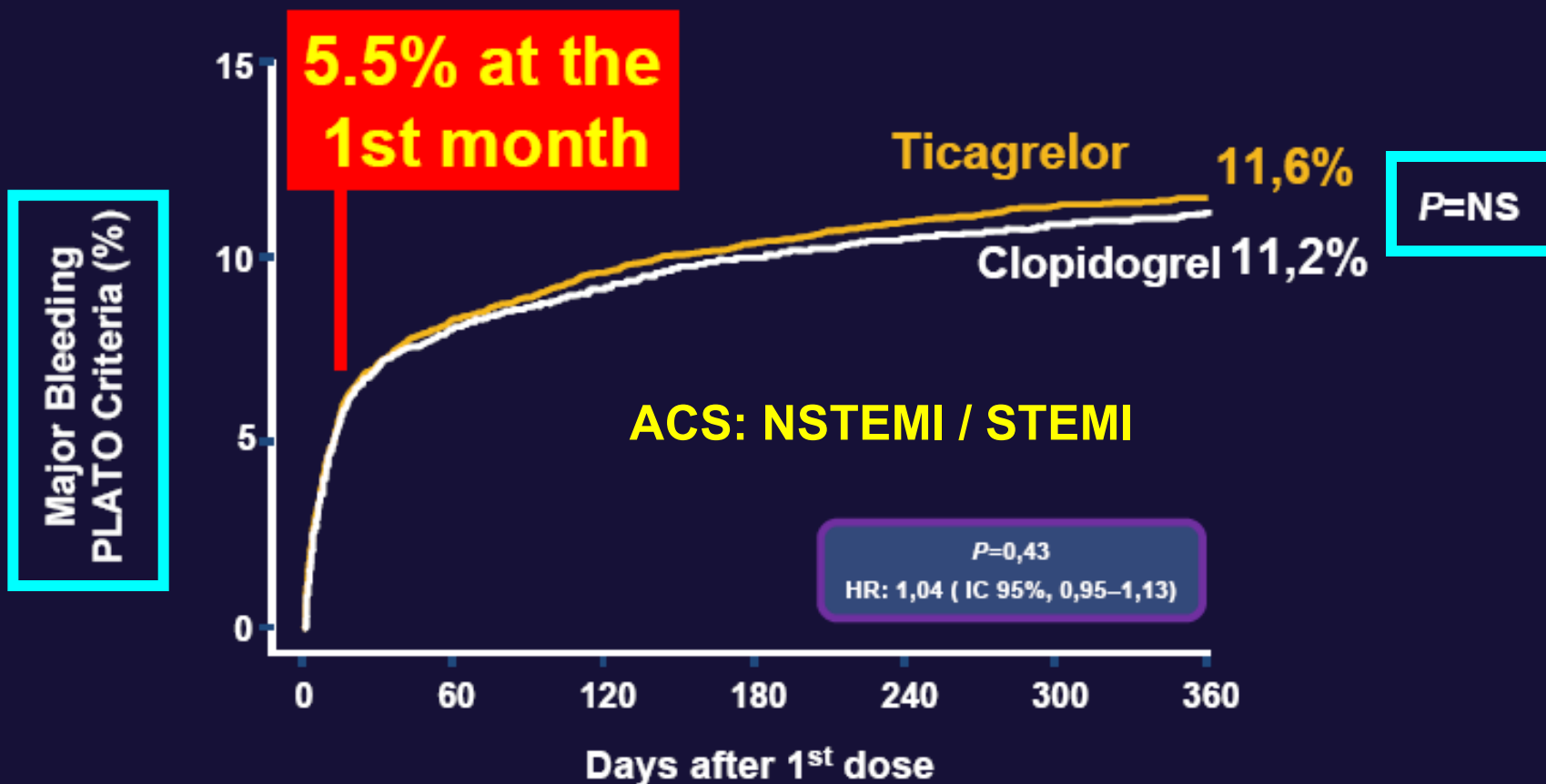
# PLATO – Първична крайна цел: (СС смърт, МИ или инсулт)



No. at risk

<b>Ticagrelor</b>	<b>9333</b>	<b>8628</b>	<b>8460</b>	<b>8219</b>	<b>6743</b>	<b>5161</b>	<b>4147</b>
<b>Clopidogrel</b>	<b>9291</b>	<b>8521</b>	<b>8362</b>	<b>8124</b>	<b>6743</b>	<b>5096</b>	<b>4047</b>

# PLATO: Safety of Long -Term DAPT

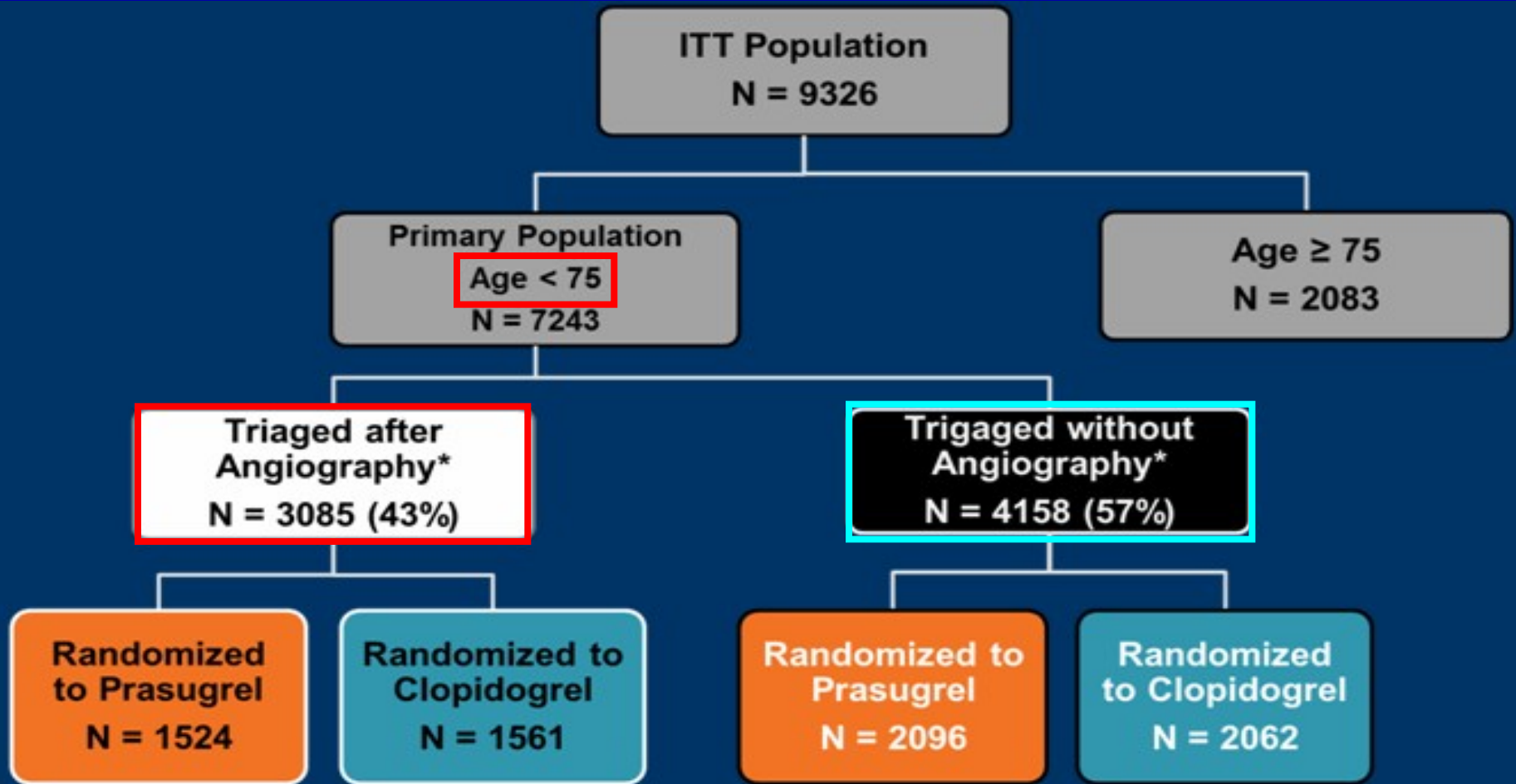


No	0	60	120	180	240	300	360
<b>Ticagrelor</b>	<b>9.235</b>	<b>7.246</b>	<b>6.826</b>	<b>6.545</b>	<b>5.129</b>	<b>3.783</b>	<b>3.433</b>
<b>Clopidogrel</b>	<b>9.186</b>	<b>7.305</b>	<b>6.930</b>	<b>6.670</b>	<b>5.209</b>	<b>3.841</b>	<b>3.479</b>

Ambos os grupos incluíram AAS

Wallentin L, et al. *N Engl J Med.* 2009;361:1045–1057.

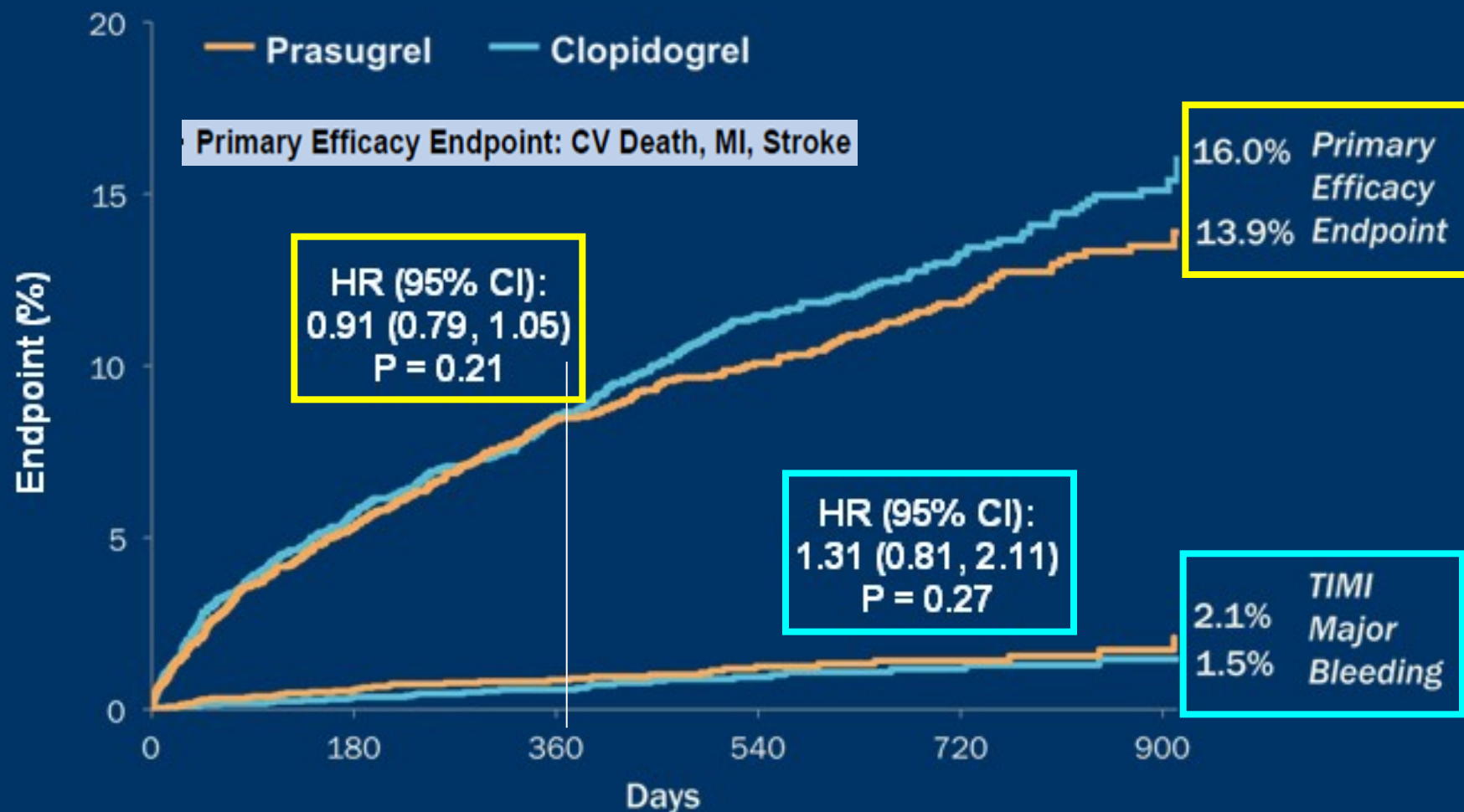
## Medically Managed UA/NSTEMI Patients



Primary Efficacy Endpoint: CV Death, MI, Stroke



# Primary Efficacy Endpoint and TIMI Major Bleeding Through 30 Months (Age < 75 years, N = 7243)

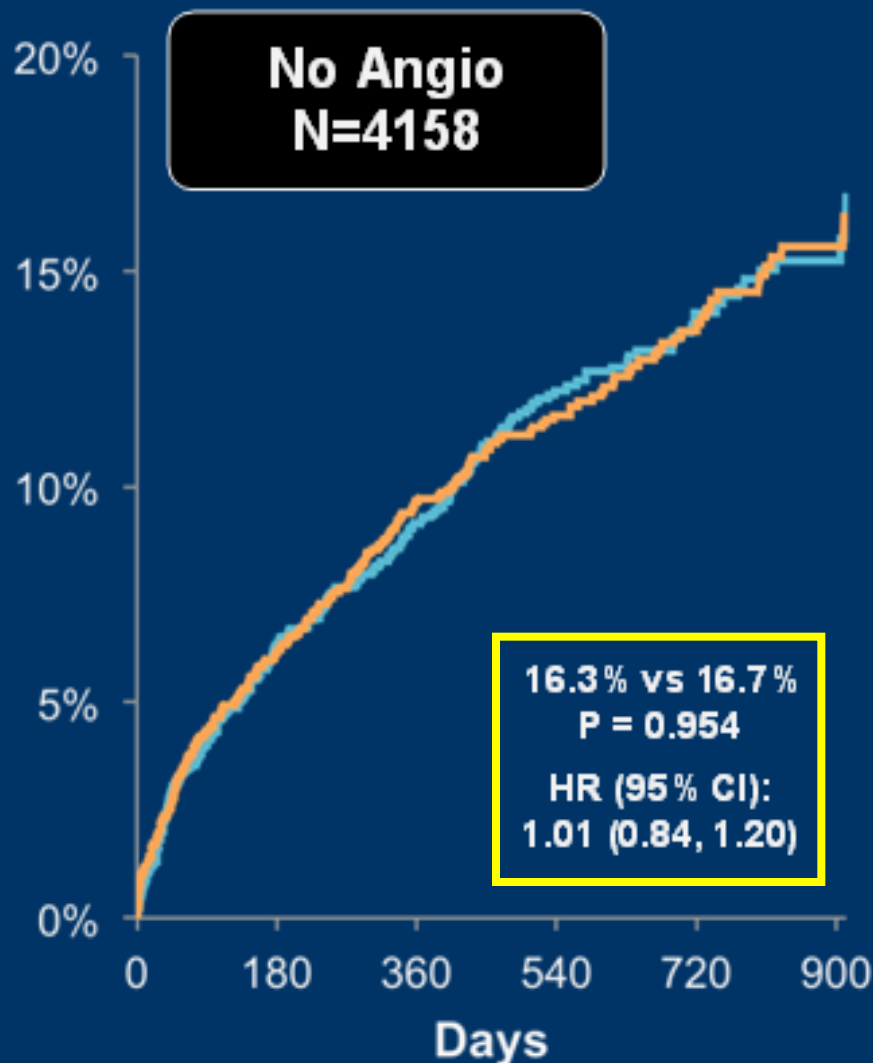
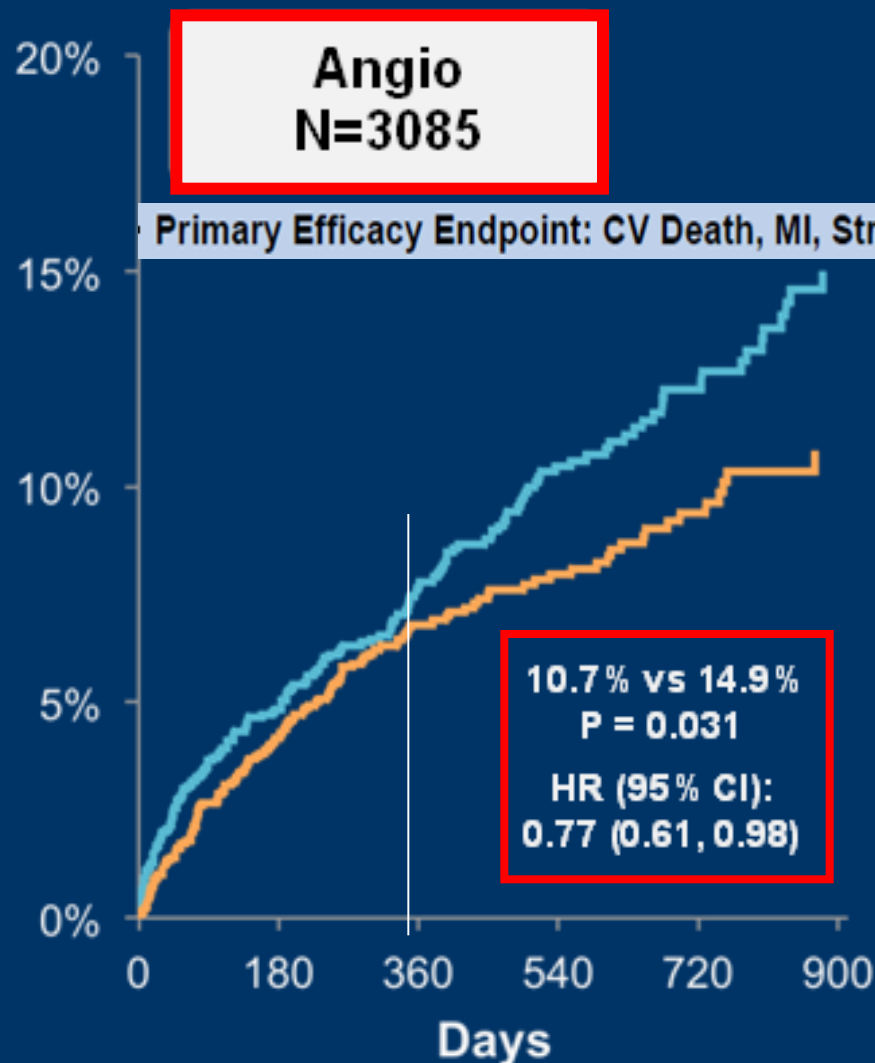


# Primary Efficacy Endpoint to 30 Months

(Age < 75 years)

— Prasugrel

— Clopidogrel



**P interaction = 0.08**

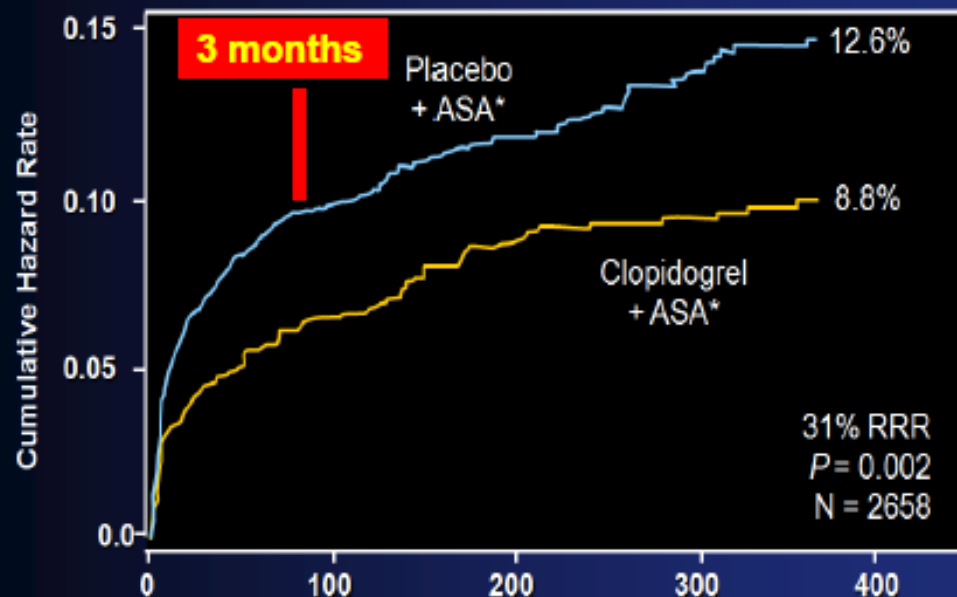
# Продължителност на DAPT след ОКС

What are we treating?

The patient or the stent?

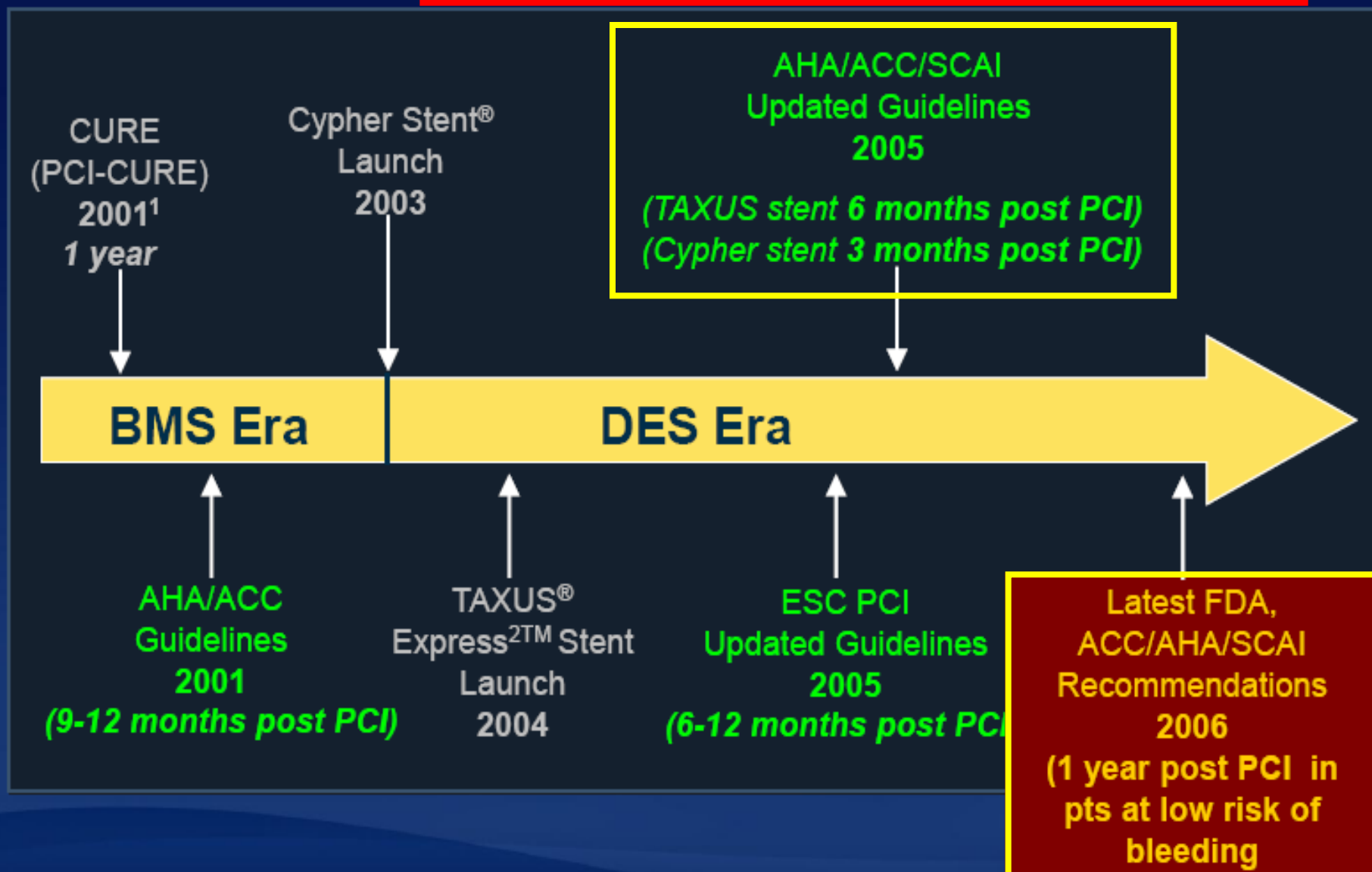
## Overall Long-Term Results

Composite of cardiovascular death or MI from randomization to end of follow-up

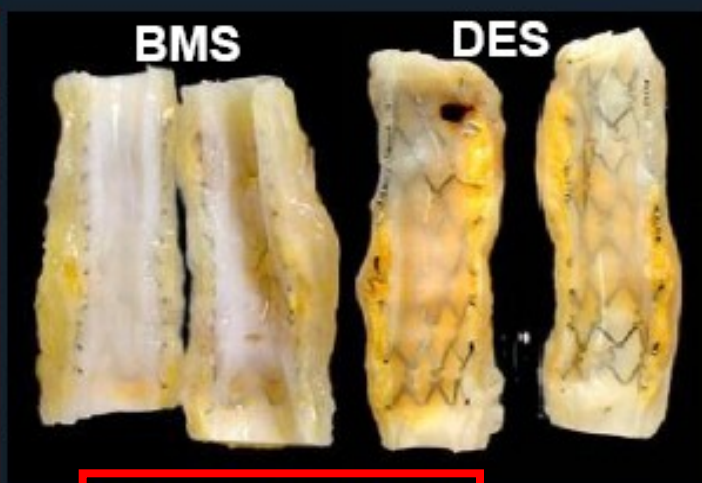
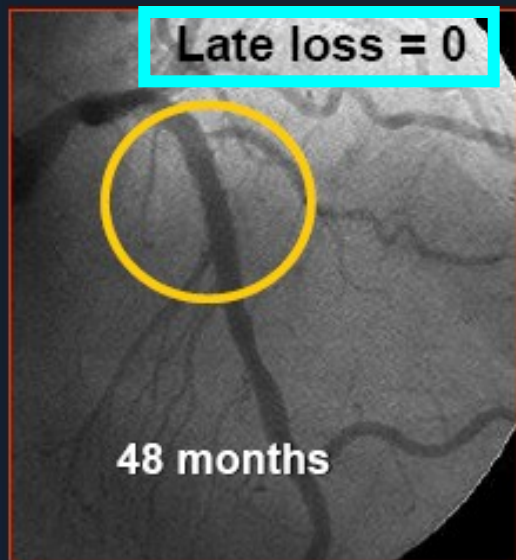


- *DAPT prevented 22CV events/1000 Pts during the 12 months*
- 50% (11CV events/1000) in the first 30 days
- 50% of the benefit occurred from 1 month to 12 months
- 9 of the 11 prevented CV events occurred between 1 & 3 months
- *Only 2 CV events/1000 pts were prevented between 3 & 12 months*
- That works out to a NNT of 500 for the time period 3-12 months

# Optimal Duration of Anti-platelet Therapy **Post DES Still Unclear**



# Drug-Eluting Stents.... the good, the bad, and the ugly!



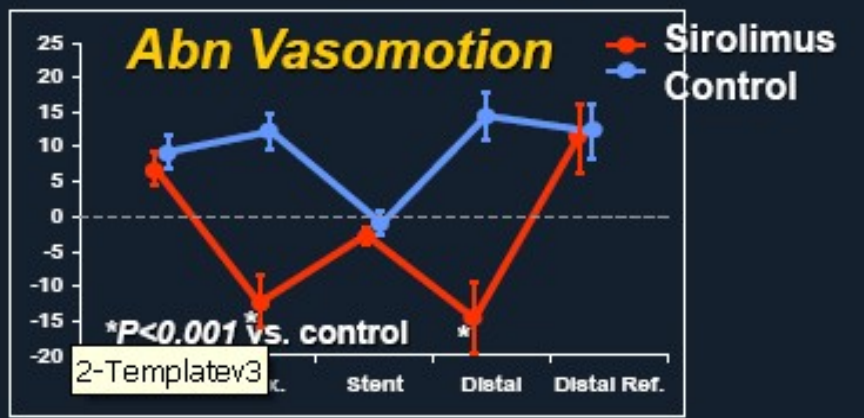
**Delayed Healing!**



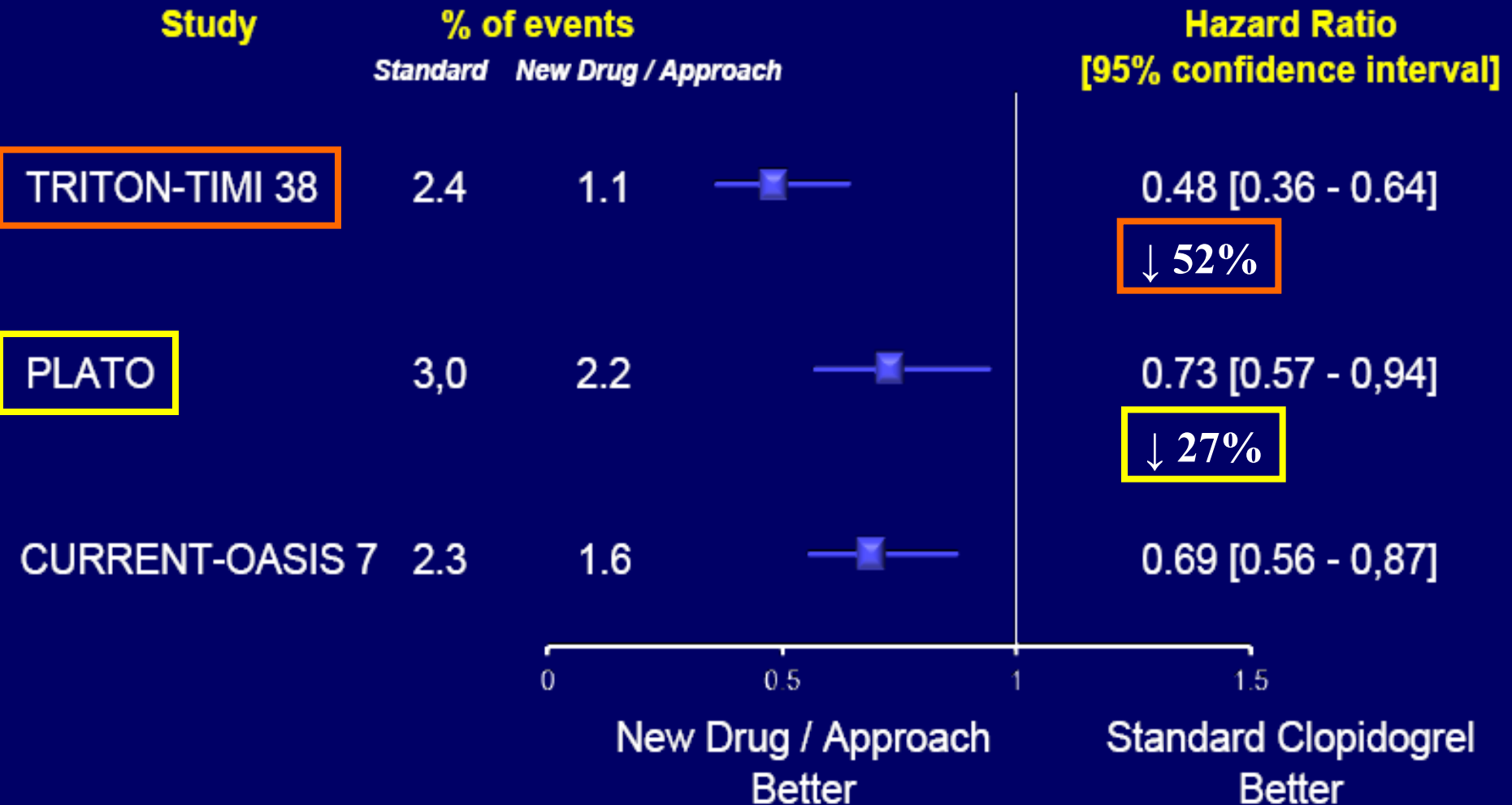
Angioscopy



Inflammation



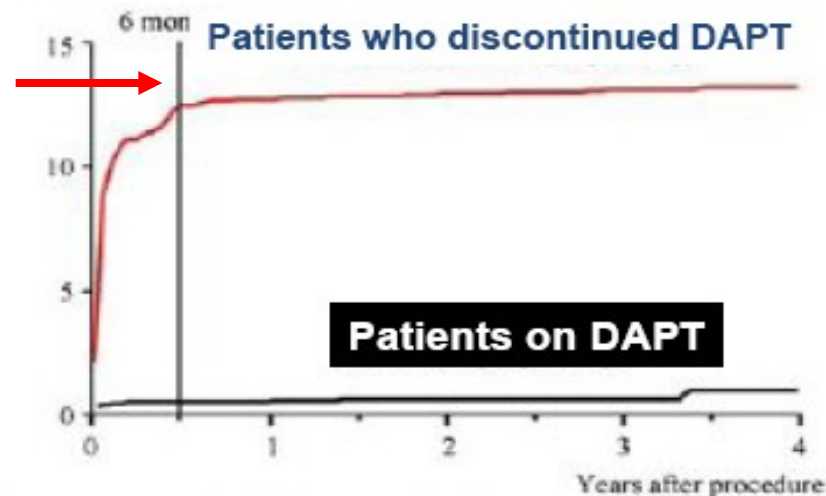
# NEW APPROACHES: STENT THROMBOSIS



# Стент–тромбоза и прекъсване на DAPT

Cumulative incidence of stent thrombosis (%)

1<sup>st</sup> Generation DES



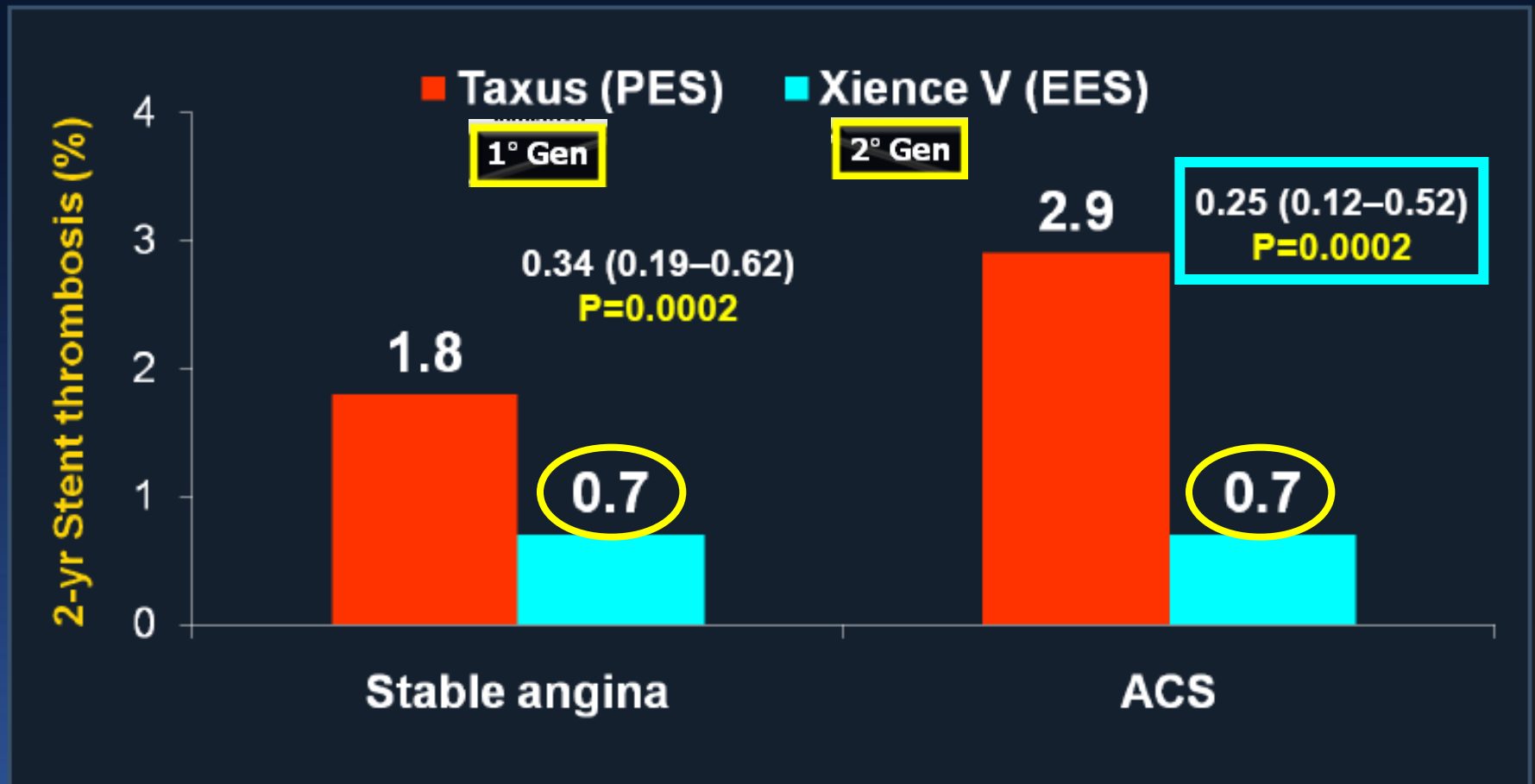
No. of patients	0	1	2	3	4
Off clopidogrel	0	1,277	3,934	2,539	1,373
On clopidogrel	6,816	5,181	1,074	398	116

**Figure 4** Cumulative incidence of stent thrombosis in patients who continued (black) and those who discontinued clopidogrel therapy (red). Patients switched from one group to the other as soon as they stopped taking clopidogrel.



# SPIRIT II, III, IV and COMPARE trials Pooled database analysis (n=6,789)

## Stent thrombosis (ARC def/prob) at 2 years



# DAPT Duration and Clinical Outcomes at **3 years** Following **Endeavor Stent**

1414 event-free pts on DAPT at 6 months

<b>Zotarolimus-Eluting Stents</b>	<b>6 months on DAPT</b>	<b>12 months on DAPT</b>	<b>p Value</b>
Death	2.7%	2.2%	0.48
MI	0.3%	1.1%	0.24
Stroke	1.0%	0.8%	0.42
Stent Thrombosis	0.3%	0	0.19
Death/MI/ Stroke	3.9%	3.9%	0.75

# EXCELLENT Trial

**1443 Patients Matching Enrollment Criteria**

Stable angina, UA, post MI, silent ischemia

DAT 6 months  
N=722

DAT 12 months  
N=721

2x2  
factorial design

EES  
N=540

SES  
N=182

EES  
N=539

SES  
N=182

Percutaneous Coronary Intervention

Primary clinical  
endpoint evaluation

Clinical

1mo

3mo

9mo

12mo

2yr

3yr

4yr

5yr

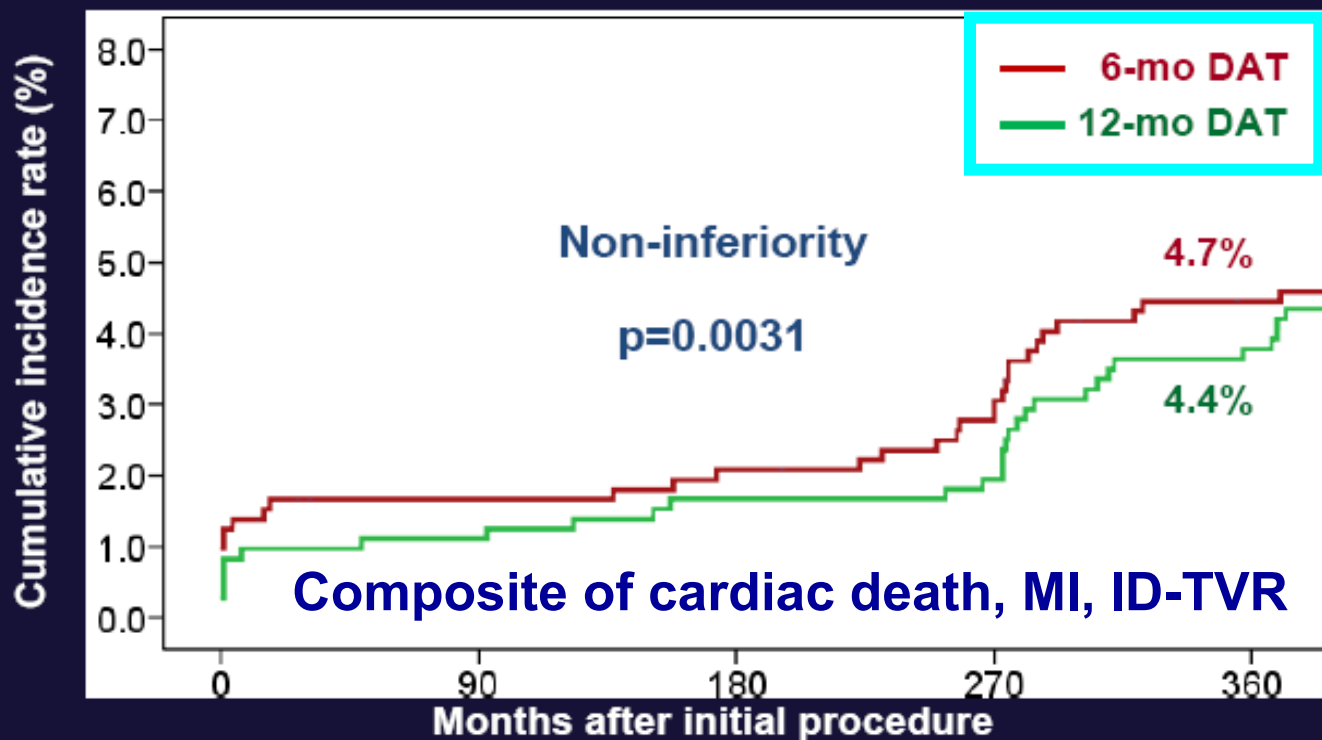
Angiographic

Co-primary angiographic  
endpoint evaluation

*Am Heart J* 2009 May;157:811-817.e1  
Gwon HC et al ACC 2011

# EXCELLENT Trial

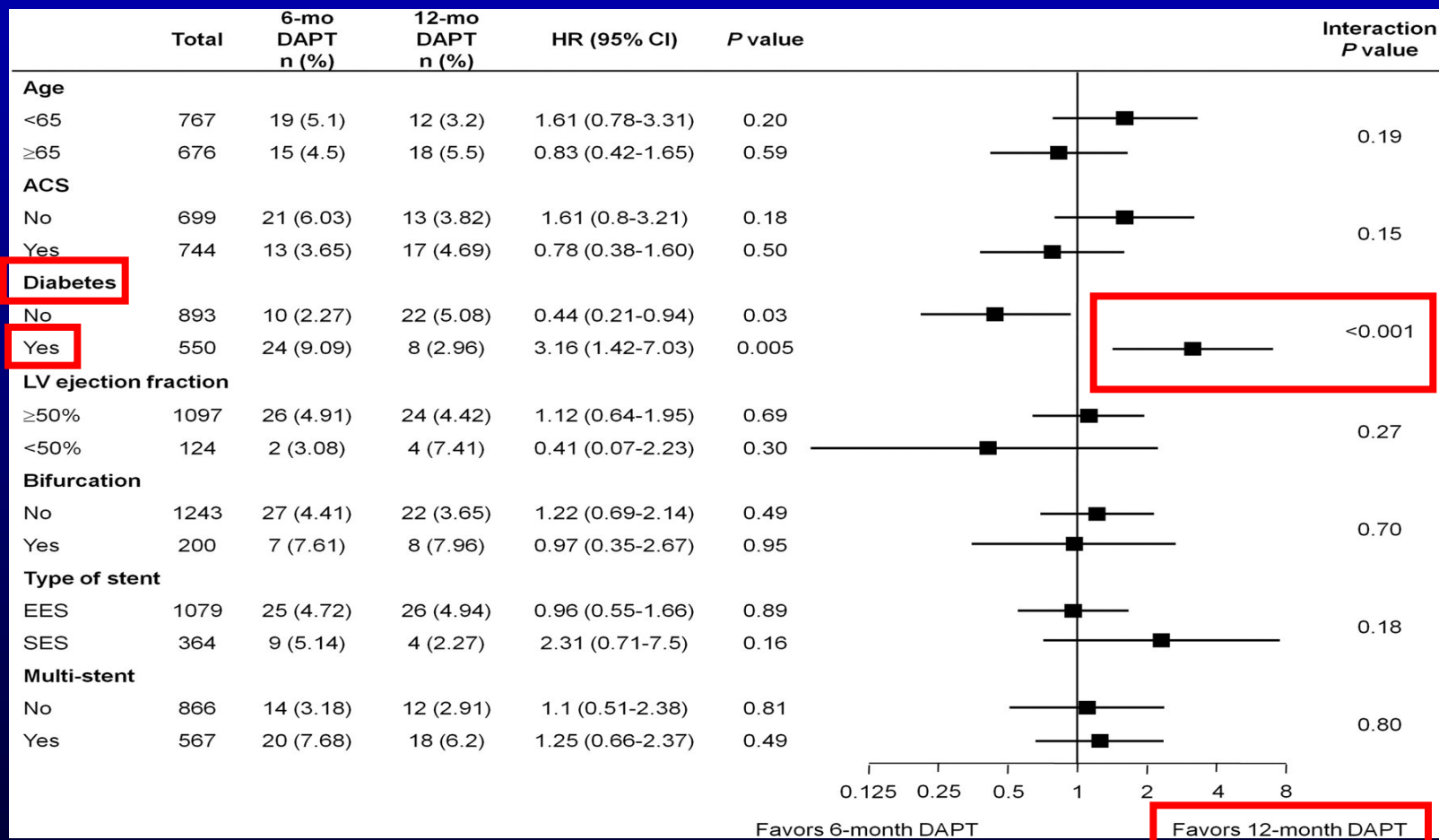
## Target Vessel Failure



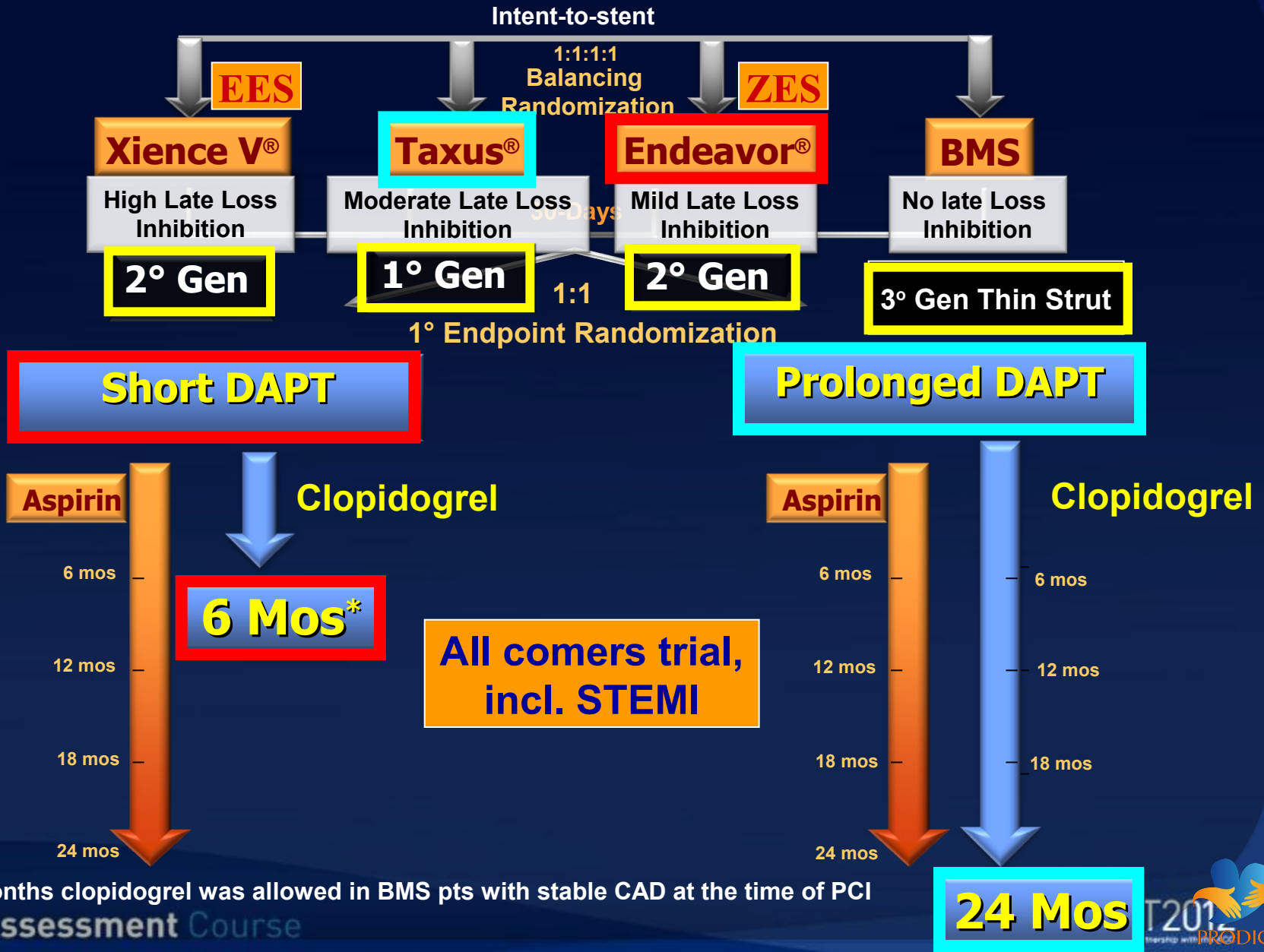
<i>Patient Number at Risks</i>					
6-month	722	707	701	697	681
12-month	721	710	699	698	680

# EXCELLENT trial:

## Подгрупов анализ на първичната крайна цел



# PRODIGY Study Flow Chart



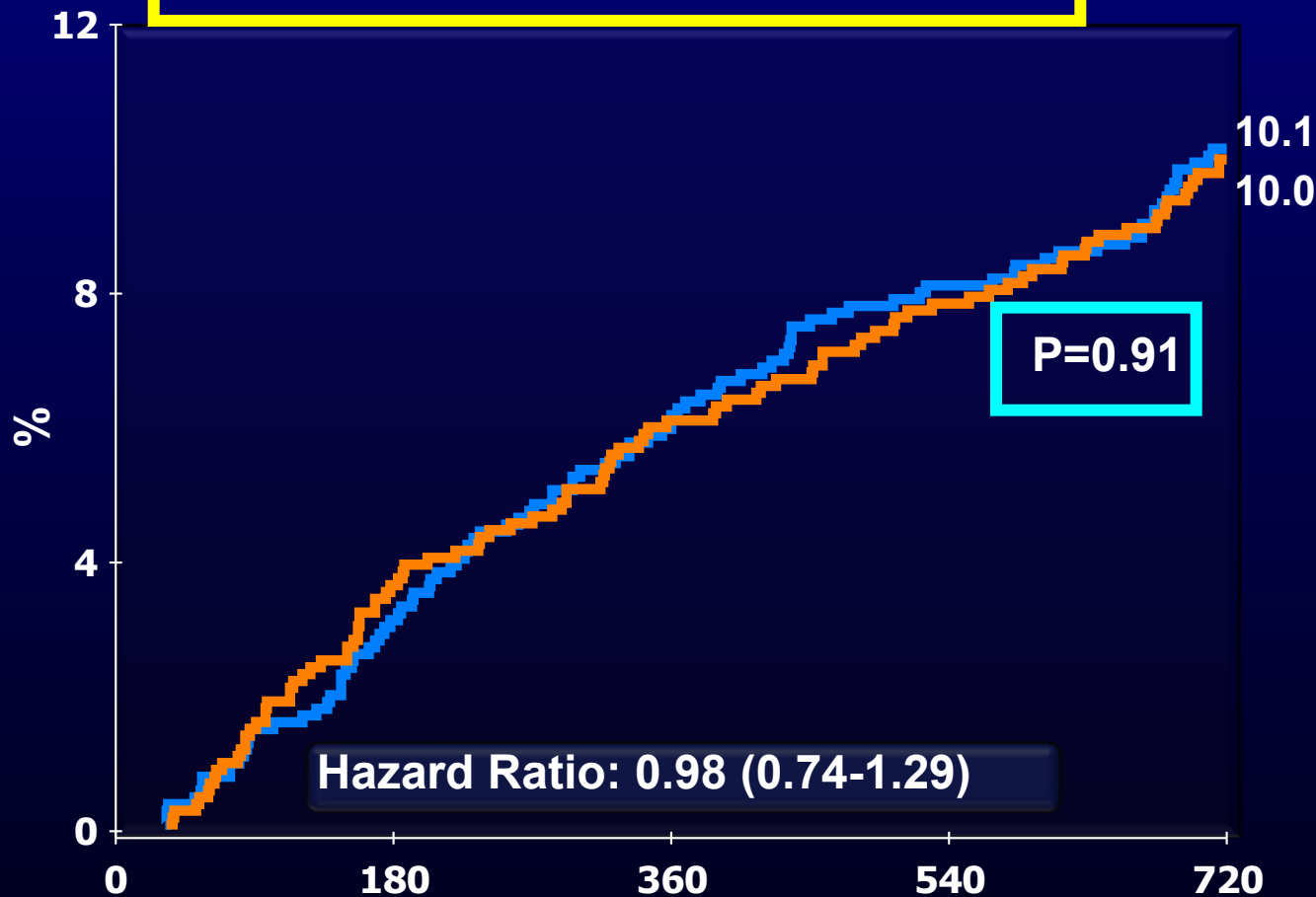
# Primary Endpoint

## Overall Death, MI or CVA

CEC adjudicated

24 mo DAPT

6 mo DAPT



### No. at Risk

24-Month Clopidogrel 987  
6-Month Clopidogrel 983

925

919

884

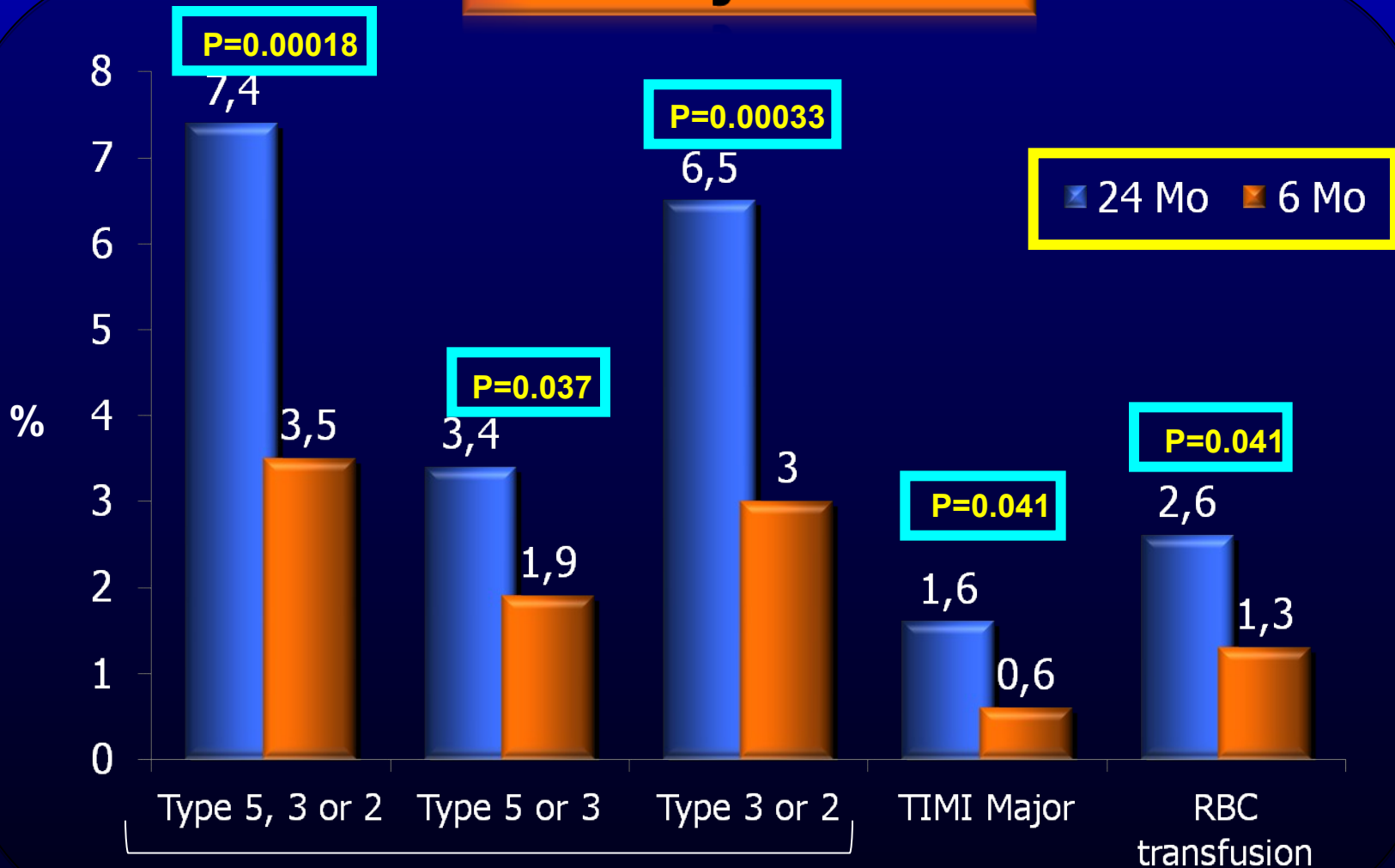
881



PRODIGY

# Bleeding Events and RBC Transfusion

CEC adjudicated

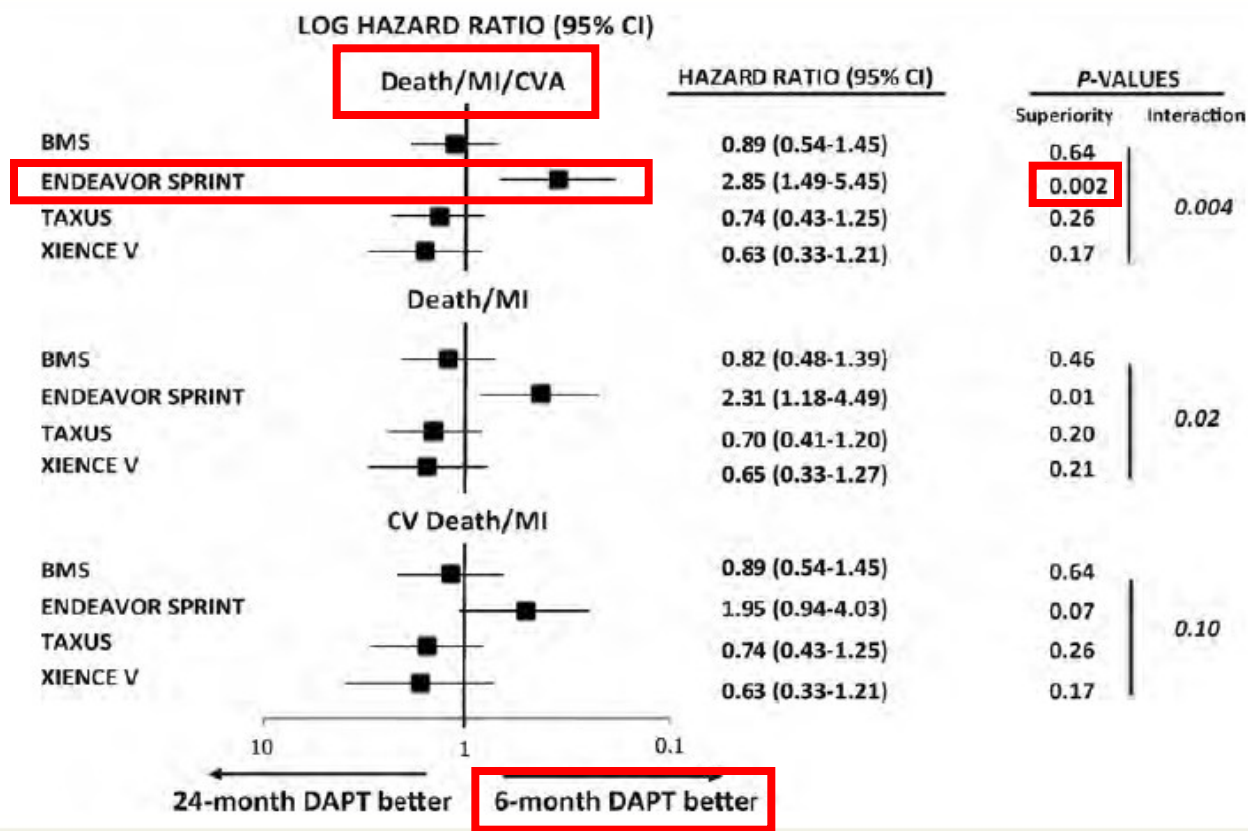


Bleeding Academic Research Consortium



## Should duration of dual antiplatelet therapy depend on the type and/or potency of implanted stent? A pre-specified analysis from the PROlonging Dual antiplatelet treatment after Grading stent-induced Intimal hyperplasia studY (PRODIGY)

Marco Valgimigli<sup>1,2\*</sup>, Marco Borghesi<sup>1</sup>, Matteo Tebaldi<sup>1</sup>, Pascal Vranckx<sup>3</sup>, Giovanni Parrinello<sup>4</sup>, and Roberto Ferrari<sup>1,2</sup>, for the PROlonging Dual antiplatelet treatment after Grading stent-induced Intimal hyperplasia studY (PRODIGY) Investigators



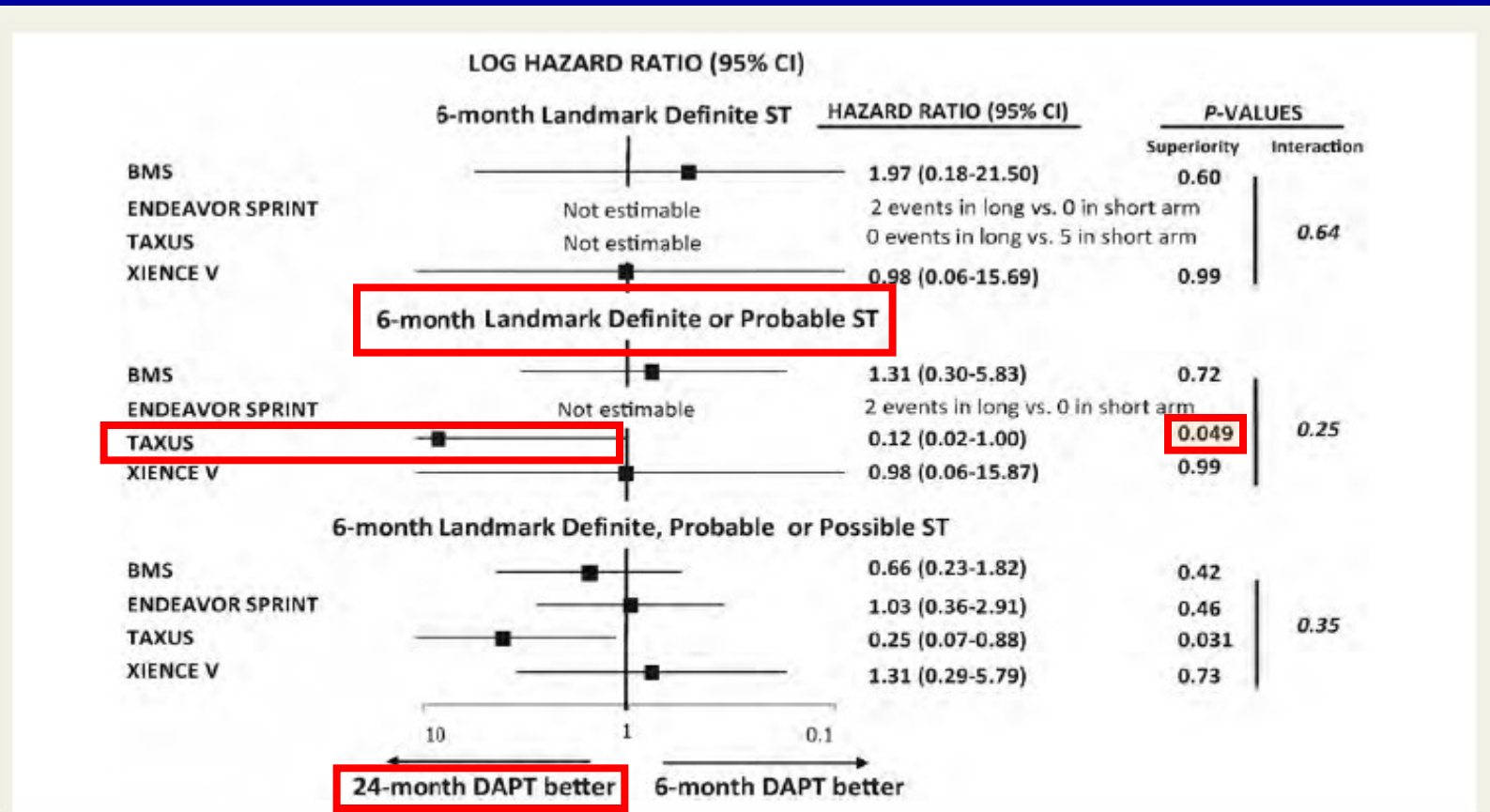
**Figure 1** Stent analyses are shown, with hazard ratios and 95% confidence intervals for cerebrovascular accident (CVA), death or MI, and 24-month vs 6-month dual antiplatelet therapy. The P-value for interaction represents the likelihood of interaction between the variable and the relative treatment effect.

**Implications:** Optimal duration of dual antiplatelet therapy may be stent specific.

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**Figure 4** Stent and confidence interval among patients rare of interaction between the variable and the relative treatment effect.

**Implications:** Optimal duration of dual antiplatelet therapy may be stent specific.

hazard ratios and 95% the stent thrombosis (ST) represents the likelihood

# JAMA<sup>®</sup>

The Journal of the American Medical Association

F Feres and coauthors for the OPTIMIZE  
Trial Investigators

Three vs Twelve Months of Dual Antiplatelet  
Therapy After Zotarolimus-Eluting Stents:  
The OPTIMIZE Randomized Trial

Published online **October 31, 2013**

## **OPTIMIZE:** **A Prospective, Randomized Trial** **of 3 Months Versus 12 Months** **of Dual Antiplatelet Therapy with the** **Endeavor Zotarolimus-Eluting Stent**

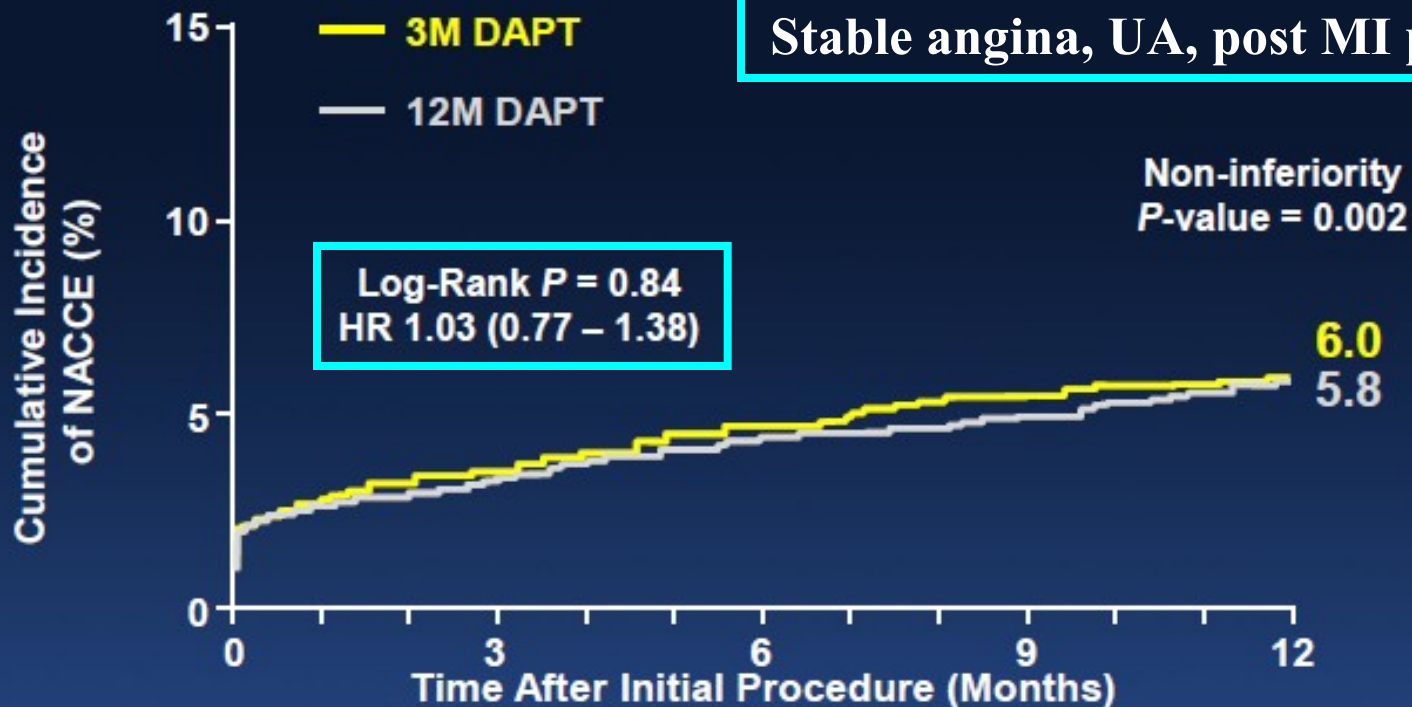
*Fausto Feres, MD, PhD*

On behalf of the OPTIMIZE Trial Investigators

Instituto Dante Pazzanese de Cardiologia

São Paulo, Brazil

# Primary Endpoint: NACCE at 1 Year (All-Cause Death, MI, Stroke, Major Bleeding)

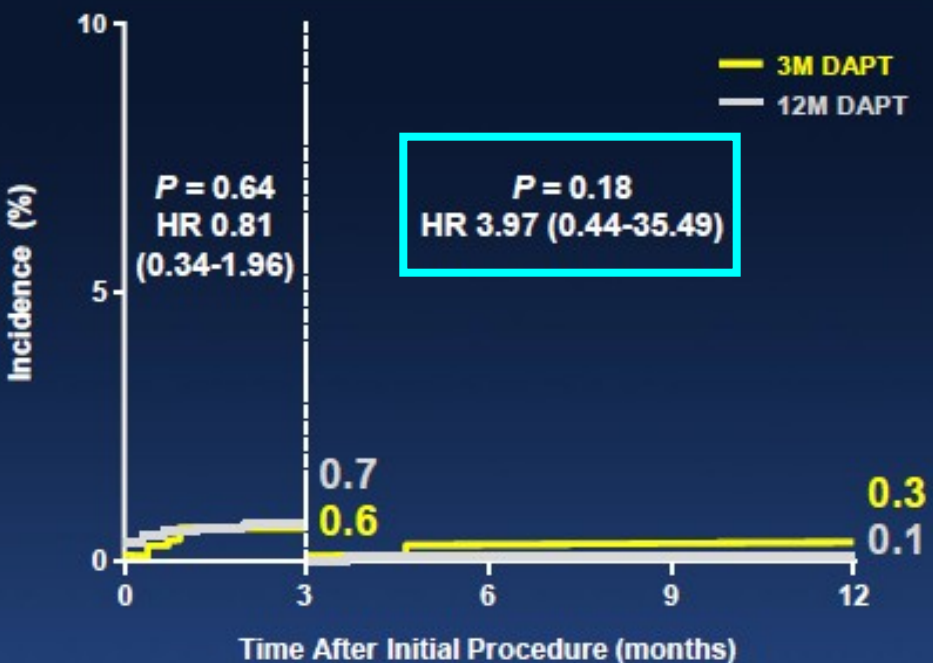


Month	0	1	3	6	12
No. at risk	1563	1520	1504	1468	1384
No. events	18	25	11	18	21
No. at risk	1556	1514	1497	1466	1381
No. events	16	25	11	16	22

# Stent Thrombosis vs. Bleeding

## ARC Def./Prob. Stent Thrombosis

## Any Bleeding\*

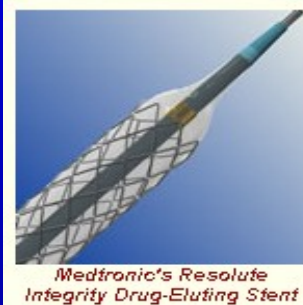


Month	0	1	3	6	12
No at risk	1563	1555	1540	1506	1505
No events	0	6	3	4	0
No at risk	1556	1541	1525	1501	1500
No events	5	3	3	1	0

Month	0	1	3	6	12
No at risk	1563	1538	1516	1482	1439
No events	4	15	10	4	2
No at risk	1556	1528	1501	1472	1387
No events	11	8	12	6	8

# With Resolute Stent, Interrupting DAPT After One Month Showed No Increased Risk

ACC.13 presentation features unprecedented data on nearly 5,000 patients, including "all comers," from global RESOLUTE clinical program



## Resolute™ zotarolimus-eluting stent

March 4, 2013 5:06 PM ET

*Interruption or Discontinuation After One Month Following Implant Procedure Posed 'Low and No Increased Risk' of Stent Thrombosis at One Year in Clinical Studies*

**MINNEAPOLIS — March 4, 2013** — Of relevance to the clinical practice of interventional cardiology, Medtronic, Inc. (NYSE: MDT) announced today that it has received regulatory approval to update the CE (Conformité Européenne) mark labeling for the Resolute Integrity drug-eluting stent with new information on one month of dual antiplatelet therapy (DAPT), the shortest minimum duration referenced on the label for any device of its kind.

The updated labeling states: "One year data from the RESOLUTE Clinical Program indicates low stent thrombosis rates for those who interrupted or discontinued DAPT any time after one month. While physicians should continue to adhere to current ESC or ACC/AHA/SCAI guidelines for PCI, patients who interrupt or discontinue DAPT medication one month or more after stent implantation are considered at low risk and showed no increased risk for stent thrombosis."

# Тройна анти тромботична терапия

European Heart Journal Advance Access published May 6, 2010



European Heart Journal  
doi:10.1093/eurheartj/ehq117

REVIEW

*Novel therapeutic concepts*

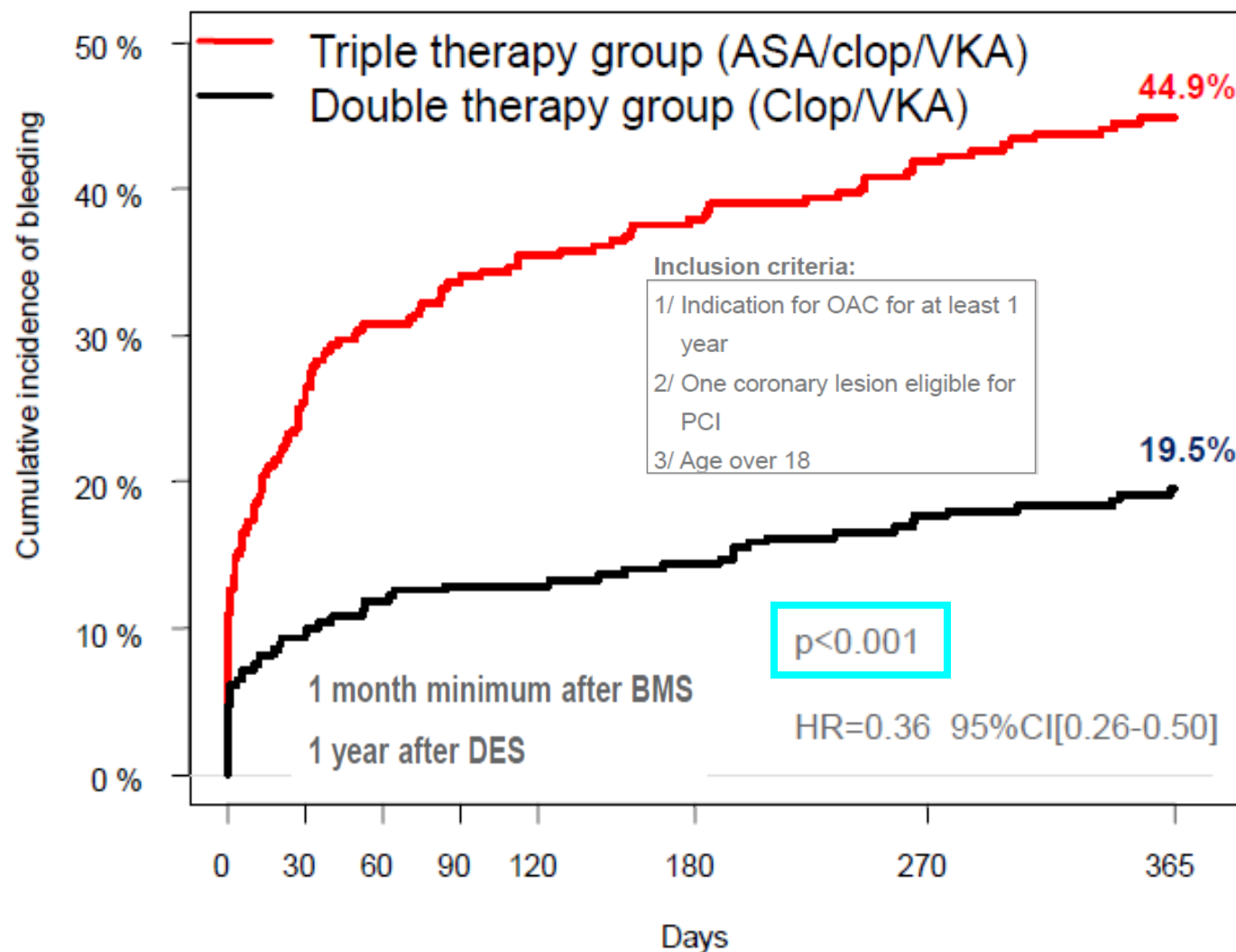
## Antithrombotic management of atrial fibrillation patients presenting with acute coronary syndrome and/or undergoing coronary stenting: executive summary—a **Consensus Document** of the **European Society of Cardiology Working Group on Thrombosis**, endorsed by the European Heart Rhythm Association (EHRA) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

Gregory Y.H. Lip<sup>1\*</sup>, Kurt Huber<sup>2</sup>, Felicita Andreotti<sup>3</sup>, Harald Arnesen<sup>4</sup>, Juhani K. Airaksinen<sup>5</sup>, Thomas Cuisset<sup>6</sup>, Paulus Kirchhof<sup>7</sup>, and Francisco Marín<sup>8</sup>

Клиника	Стент	Препоръки (Experts, level C)
1. Планова PCI	BMS	<ul style="list-style-type: none"> <li>• 2–4 седм: TAT – OAK (INR 2.0–2.5) + ASA 100 mg + clopidogrel 75 mg</li> <li>• за цял живот: OAK (INR 2.0–3.0) самостоятелно</li> </ul>
2. OKC	BMS	<ul style="list-style-type: none"> <li>• 4 седм.: TAT - OAK (INR 2.0 –2.5) + ASA 100 mg + clopidogrel 75 mg</li> <li>• До 12 мес: DAT - OAK (INR 2.0–2.5) + clopidogrel 75 mg (или ASA 100 mg)</li> <li>• за цял живот: OAK (INR 2.0–3.0) самостоятелно</li> </ul>

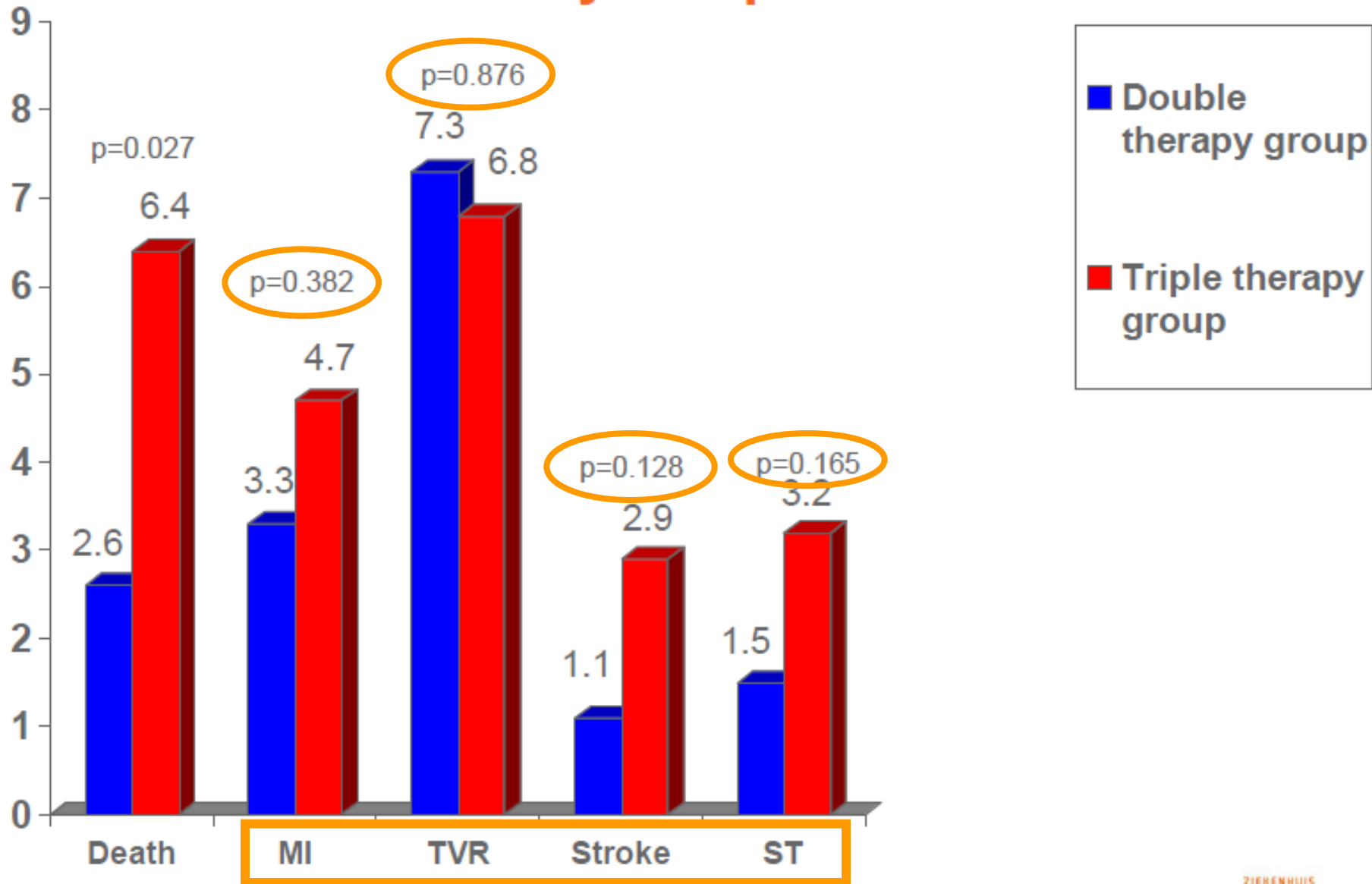


Primary Endpoint: Total number of TIMI bleeding events



n at risk:	284	210	194	186	181	173	159	140
	279	253	244	241	241	236	226	208

## Secondary Endpoint



MI=any myocardial infarction; TVR= target vessel revascularisation (PCI + CABG); ST= stent thrombosis

# ПОСЛАНИЯ

1. Продължителността на **ДАТ след ПКИ при стабилна стенокардия** се определя **основно от вида на стента:**

(1) **BMS: поне 1 месец (I A)**

(2) **DES 2-ра ген.: 6-12 месеца (I B)**

**Endeavor (ZES) - 3 мес. ДАТ ?**

**Resolute™ (ZES) - 1 мес. ДАТ ?**

2. Цел на продължителната ДАТ след **планова ПКИ с имплантиране на DES: предотвратяване на късна стент-тромбоза**

# ПОСЛАНИЯ

3. При всички пациенти с:

(1) NSTEMI / STEMI + DES / BMS

(2) ОКС без стент (IIa C)



**1 година ДАТ: Лекувай пациента !**

4. Цел на продължителната ДАТ след ОКС:

- профилактика на СС събития

- предотвратяване на късна стент-тромбоза





# Trial Schema

N ~ 21,000

Stable pts with history of MI 1-3 yrs prior  
+  $\geq 1$  additional atherothrombosis risk factor\*

\* Age >65 yrs, diabetes, 2<sup>nd</sup> prior MI, multivessel CAD,  
or chronic non-end stage renal dysfunction

RANDOMIZE  
DOUBLE BLIND

Planned treatment with ASA 75 – 150 mg &  
Standard background care

Ticagrelor  
90 mg bid

Ticagrelor  
60 mg bid

Placebo

Follow-up Visits  
Q4 mos for 1<sup>st</sup> yr, then Q6 mos

Min 12 mos and median 26 mos follow-up  
Event-driven trial

Primary Efficacy Endpoint: CV Death, MI, or Stroke  
Primary Safety Endpoint: TIMI Major Bleeding

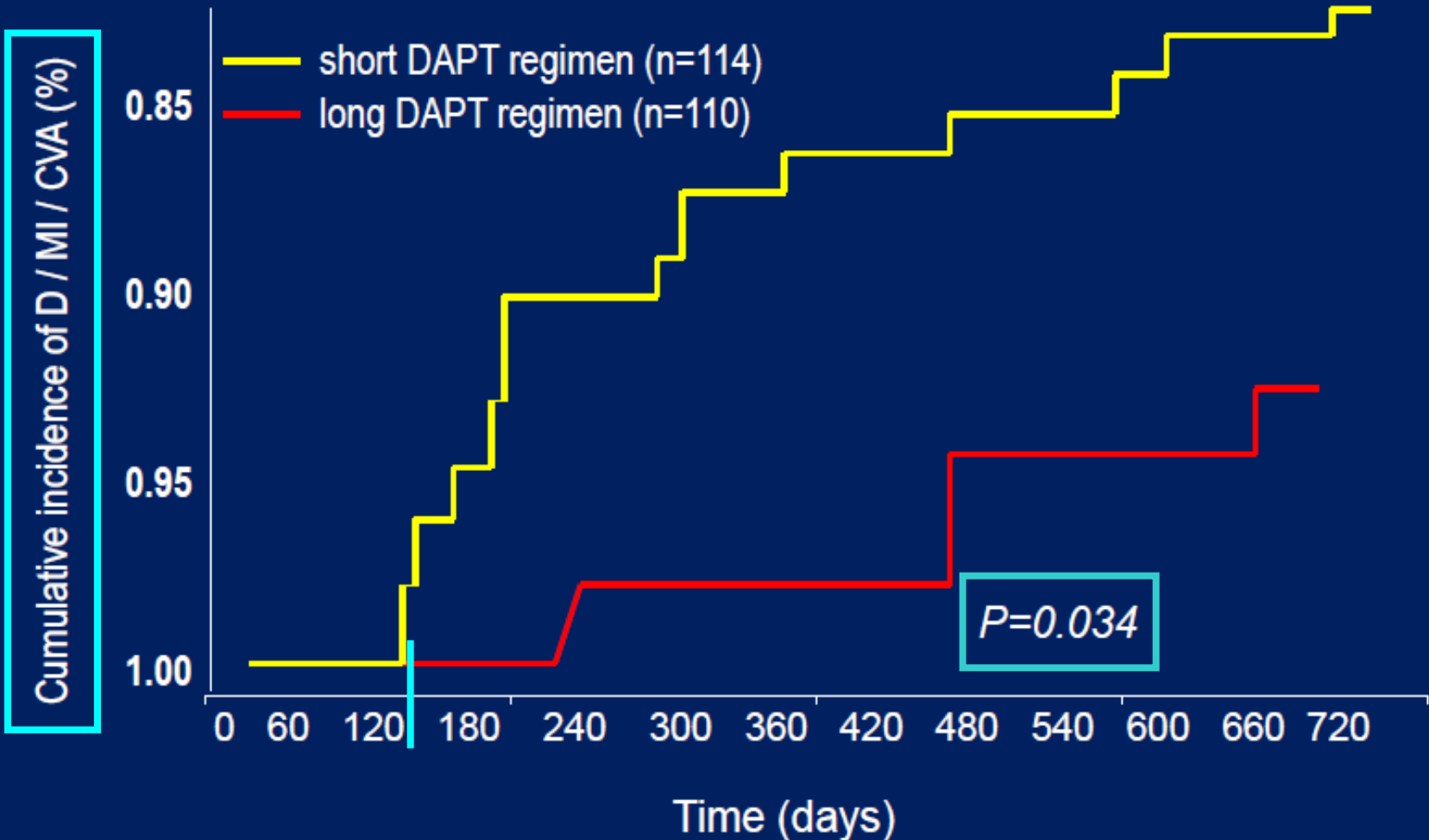
Клиника	Стент	Препоръки (Experts, level C)
1. Планова PCI	BMS	<ul style="list-style-type: none"> <li>• 1 мес.: TAT - OAK (INR 2.0–2.5) + ASA 100 mg + clopidogrel 75 mg</li> <li>• за цял живот: OAK (INR 2.0–3.0) самостоятелно</li> </ul>
	DES	<ul style="list-style-type: none"> <li>• 3 (sirolimus) и 6 (paclitaxel) месеца: TAT - OAK (INR 2.0–2.5) + ASA 100 mg + clopidogrel 75 mg</li> <li>• До 12 мес: DAT - OAK (INR 2.0–2.5) + clopidogrel 75 mg (или ASA 100 mg)</li> <li>• за цял живот: OAK (INR 2.0–3.0) самостоятелно</li> </ul>
2. OKC	BMS / DES	<ul style="list-style-type: none"> <li>• 6 мес.: TAT - OAK (INR 2.0–2.5) + ASA 100 mg + clopidogrel 75 mg</li> <li>• До 12 мес: DAT - OAK (INR 2.0–2.5) + clopidogrel 75 mg (или ASA 100 mg)</li> <li>• за цял живот: OAK (INR 2.0–3.0) самостоятелно</li> </ul>



## North American Consensus Statement Regarding Antithrombotic Therapy in Atrial Fibrillation Requiring a Stent

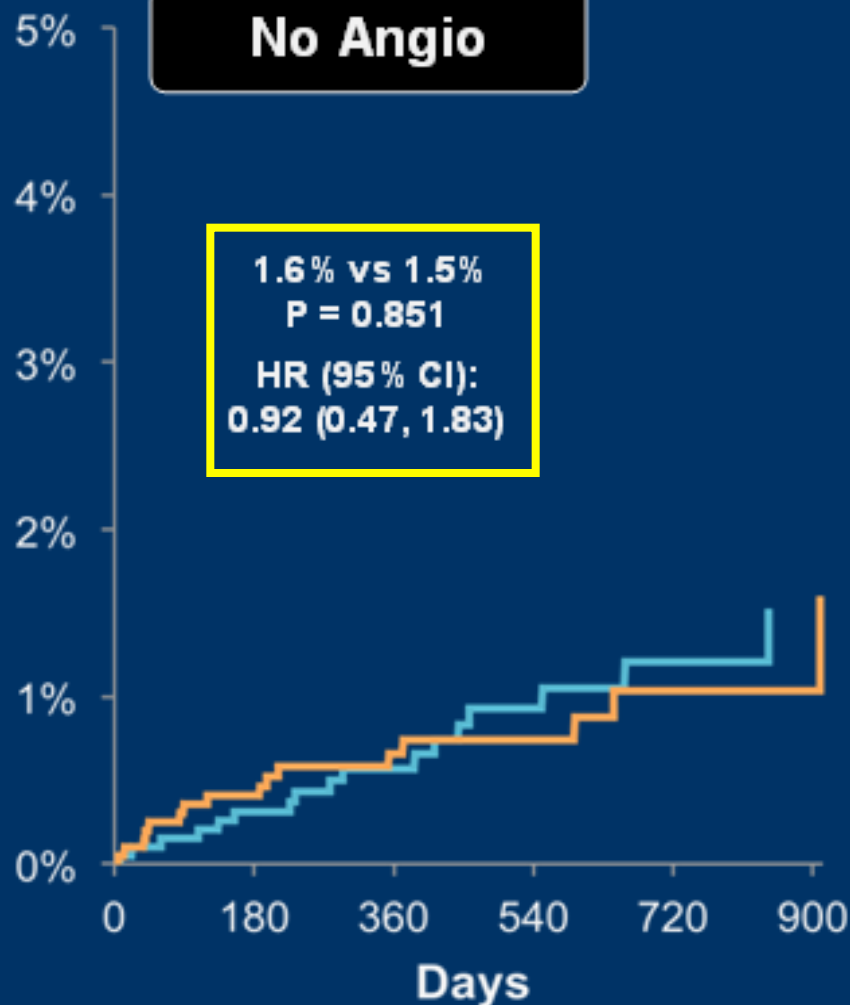
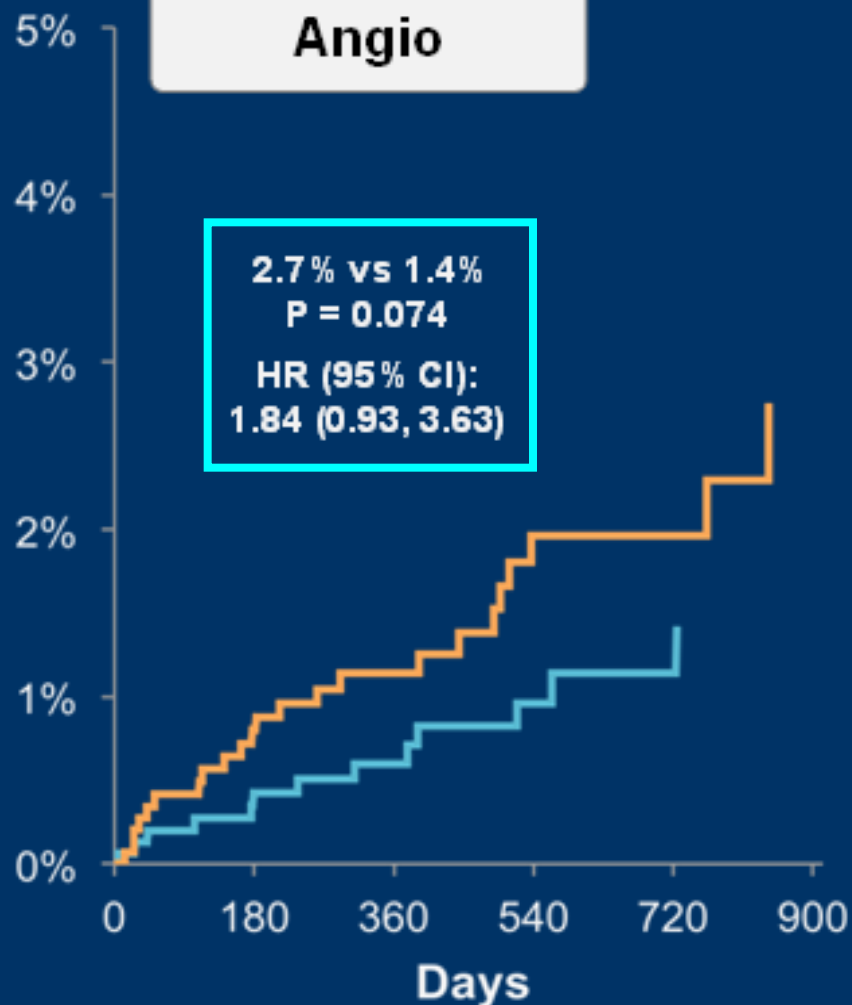
- Low dose aspirin (<100 mg per day)
- Clopidogrel is preferred in combination with aspirin and warfarin.
- **Prasugrel and ticagrelor cannot be recommended**
- Warfarin dose adjusted INR between 2 and 2.5.
- Not unreasonable to use dabigatran in place of warfarin based on the PETRO trial (dabigatran 50, 150, 300 mg BID with or without aspirin vs warfarin)

# Stenting for ISR: PRODIGY Substudy



# TIMI Major Bleeding

— Prasugrel — Clopidogrel



**P interaction = 0.16**

# Meta-analysis: Clinical Impact of Extended DAPT After PCI in the DES Era

4 RCTs (8,231 patients) comparing extended (50.2%; median 16.8 months) or control (49.8%; median 6.2 months) durations of DAPT.

## Clinical Outcomes: Extended vs. Control DAPT

All-cause Death

OR (95% CI)

1.15 (0.85-1.54)

P Value

0.36

Stent Thrombosis

0.88 (0.43-1.81)

0.73

TIMI Major Bleeding

2.64 (1.31-5.30)

0.006

**Conclusion:** Extending the duration of dual antiplatelet therapy after PCI may increase the risk of bleeding without reducing ischemic events.

Cassese S, et al. *Eur Heart J.*  
2012;Epub ahead of print.