# Long-Term DAPT after AMI: Which Drug and How Long?

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# Disclosures

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- Cardinal Health

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- Rationale for long-term DAPT
- What are the data?
- How should we individualize care?

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# Rationale for Long-Term DAPT

- Single antiplatelet therapy is highly beneficial both early and late after AMI
- Despite contemporary medical therapy, late ischemic events are frequent after AMI
  - *AMI is a "biomarker" of a vulnerable patient population*
  - *PROVE-IT Trial→ 30 month ischemic event rate 22.4% with high dose atorvastatin*
- Most late events after AMI are not stent-related→ systemic prevention is critical
  - PROSPECT trial→ nearly 50% of events at 3 years after NSTEMI are attributable to the non-target lesion

# Long-Term DAPT after AMI

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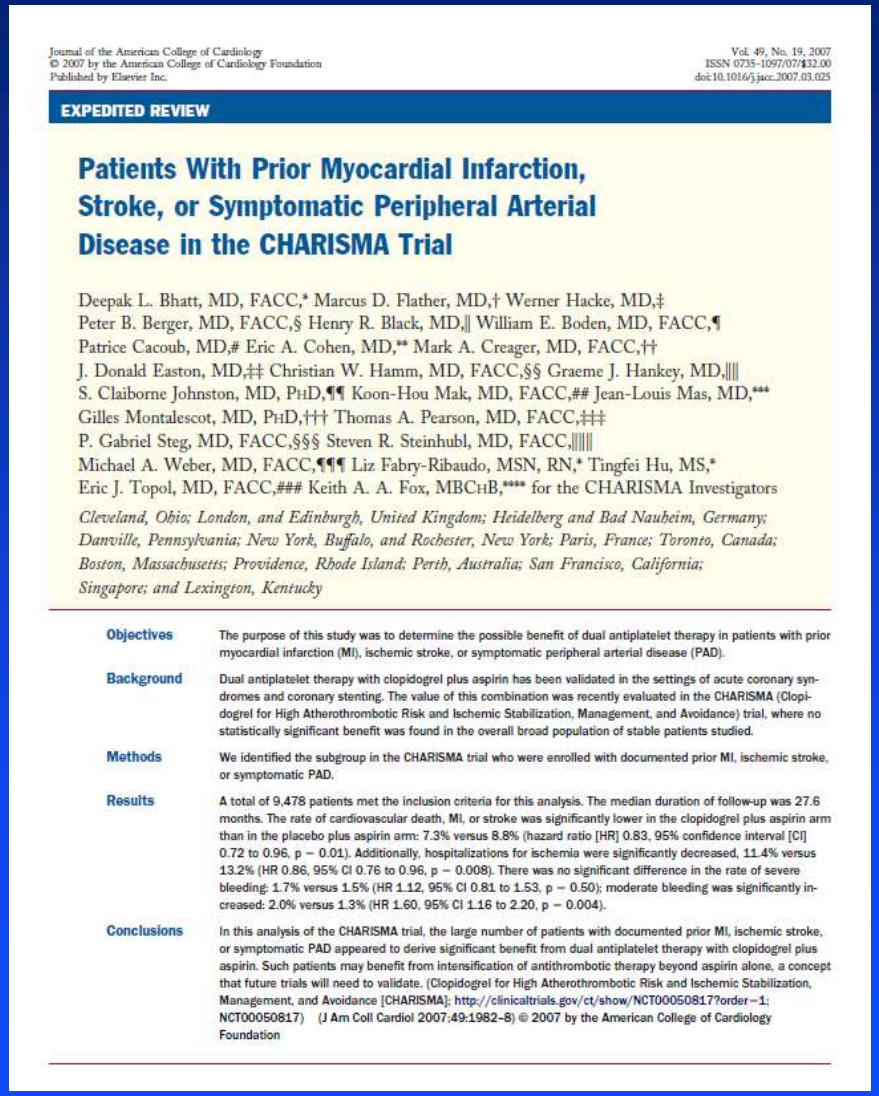
- What are the data?
- How should we individualize care?

# CHARISMA : Established Disease Subgroup



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EXPEDITED REVIEW

## Patients With Prior Myocardial Infarction, Stroke, or Symptomatic Peripheral Arterial Disease in the CHARISMA Trial

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*Cleveland, Ohio; London, and Edinburgh, United Kingdom; Heidelberg and Bad Nauheim, Germany; Danville, Pennsylvania; New York, Buffalo, and Rochester, New York; Paris, France; Toronto, Canada; Boston, Massachusetts; Providence, Rhode Island; Perth, Australia; San Francisco, California; Singapore; and Lexington, Kentucky*

**Objectives** The purpose of this study was to determine the possible benefit of dual antiplatelet therapy in patients with prior myocardial infarction (MI), ischemic stroke, or symptomatic peripheral arterial disease (PAD).

**Background** Dual antiplatelet therapy with clopidogrel plus aspirin has been validated in the settings of acute coronary syndromes and coronary stenting. The value of this combination was recently evaluated in the CHARISMA (Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance) trial, where no statistically significant benefit was found in the overall broad population of stable patients studied.

**Methods** We identified the subgroup in the CHARISMA trial who were enrolled with documented prior MI, ischemic stroke, or symptomatic PAD.

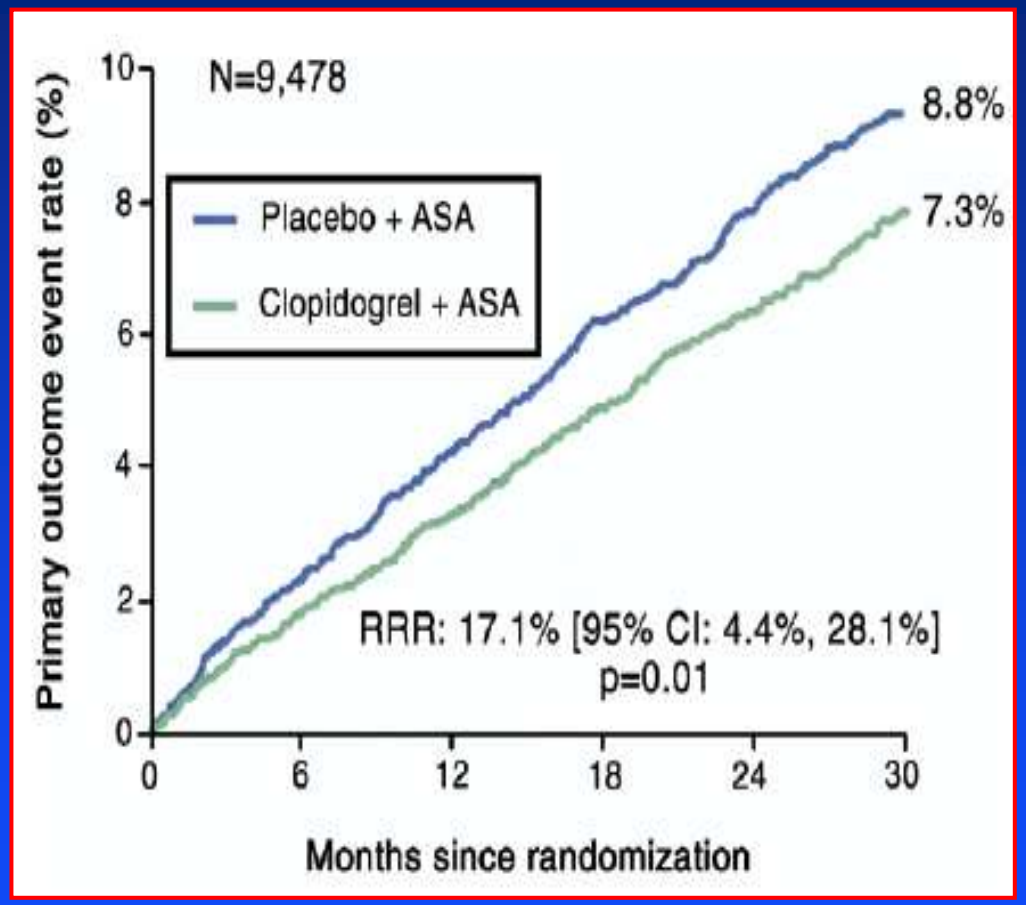
**Results** A total of 9,478 patients met the inclusion criteria for this analysis. The median duration of follow-up was 27.6 months. The rate of cardiovascular death, MI, or stroke was significantly lower in the clopidogrel plus aspirin arm than in the placebo plus aspirin arm: 7.3% versus 8.8% (hazard ratio [HR] 0.83, 95% confidence interval [CI] 0.72 to 0.96, p = 0.01). Additionally, hospitalizations for ischemia were significantly decreased, 11.4% versus 13.2% (HR 0.86, 95% CI 0.76 to 0.96, p = 0.008). There was no significant difference in the rate of severe bleeding: 1.7% versus 1.5% (HR 1.12, 95% CI 0.81 to 1.53, p = 0.50); moderate bleeding was significantly increased: 2.0% versus 1.3% (HR 1.60, 95% CI 1.16 to 2.20, p = 0.004).

**Conclusions** In this analysis of the CHARISMA trial, the large number of patients with documented prior MI, ischemic stroke, or symptomatic PAD appeared to derive significant benefit from dual antiplatelet therapy with clopidogrel plus aspirin. Such patients may benefit from intensification of antithrombotic therapy beyond aspirin alone, a concept that future trials will need to validate. (Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance [CHARISMA]; http://clinicaltrials.gov/ct/show/NCT00050817?order=1; NCT00050817) (J Am Coll Cardiol 2007;49:1982–8) © 2007 by the American College of Cardiology Foundation

- Subgroup analysis of patients with prior MI, ischemic stroke, or PAD (n=9478)
- All received ASA
- Randomized to clopidogrel vs. placebo (median 27 months)
- Primary endpoint = composite of CV death, MI, or stroke

Bhatt DL, et al. JACC 2007;49:1982-2

# CHARISMA : Established Disease Subgroup

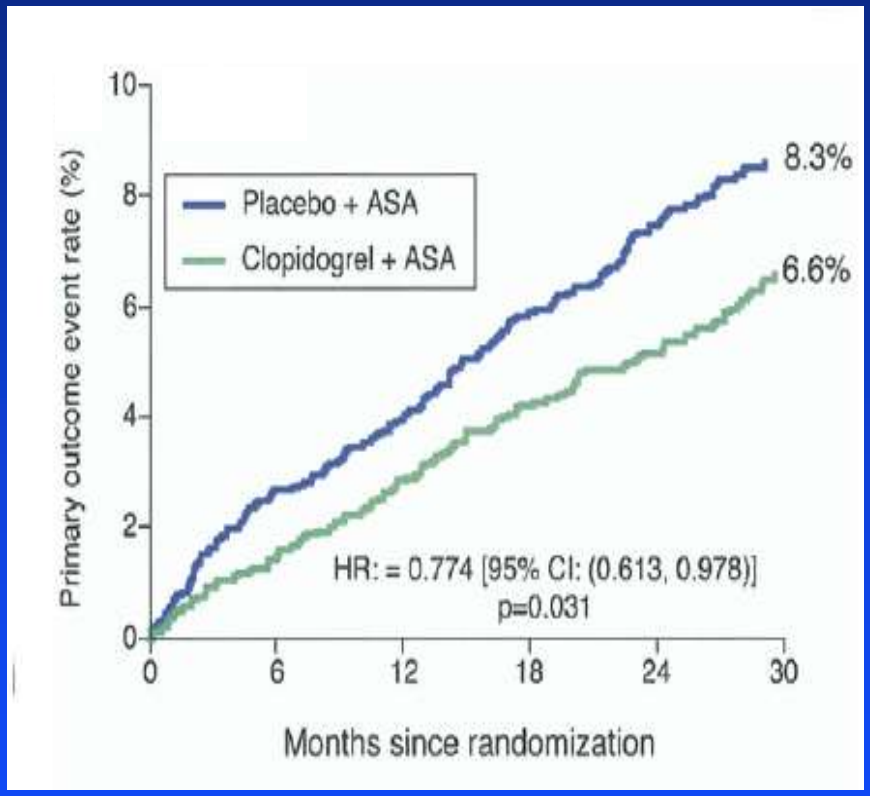



- Relative and absolute benefit similar across all 3 patient subsets
- No difference in GUSTO severe bleeding or fatal bleeding, but GUSTO moderate bleeding was increased (2.0% vs. 1.3%, p=0.004)

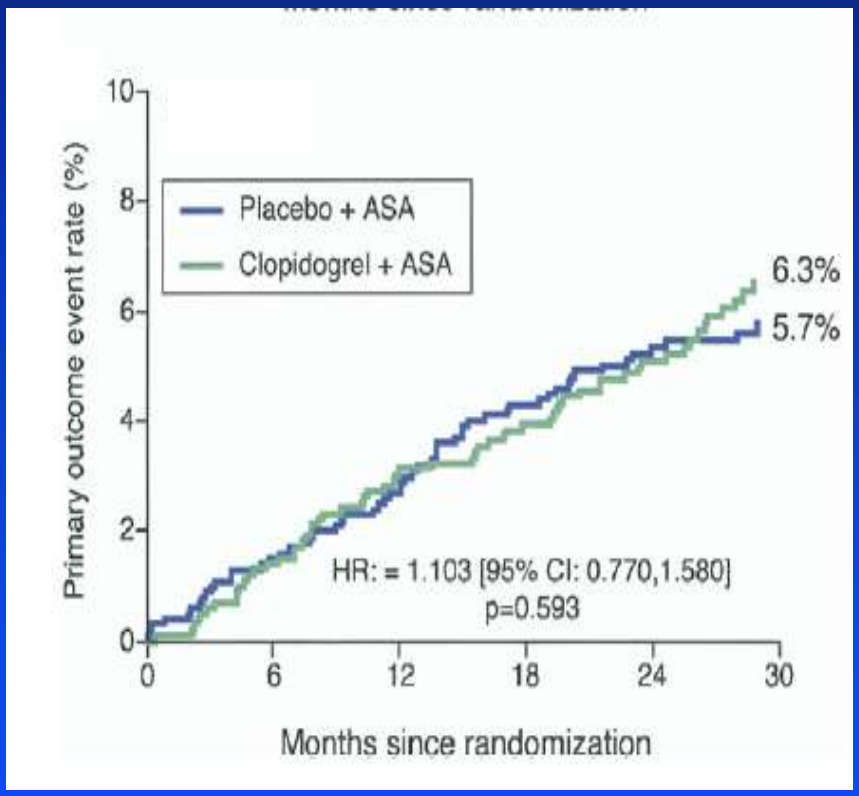
Bhatt DL, et al. JACC 2007;49:1982-2

# CHARISMA : Prior MI vs. CAD (without MI)

Prior MI (n=3846)

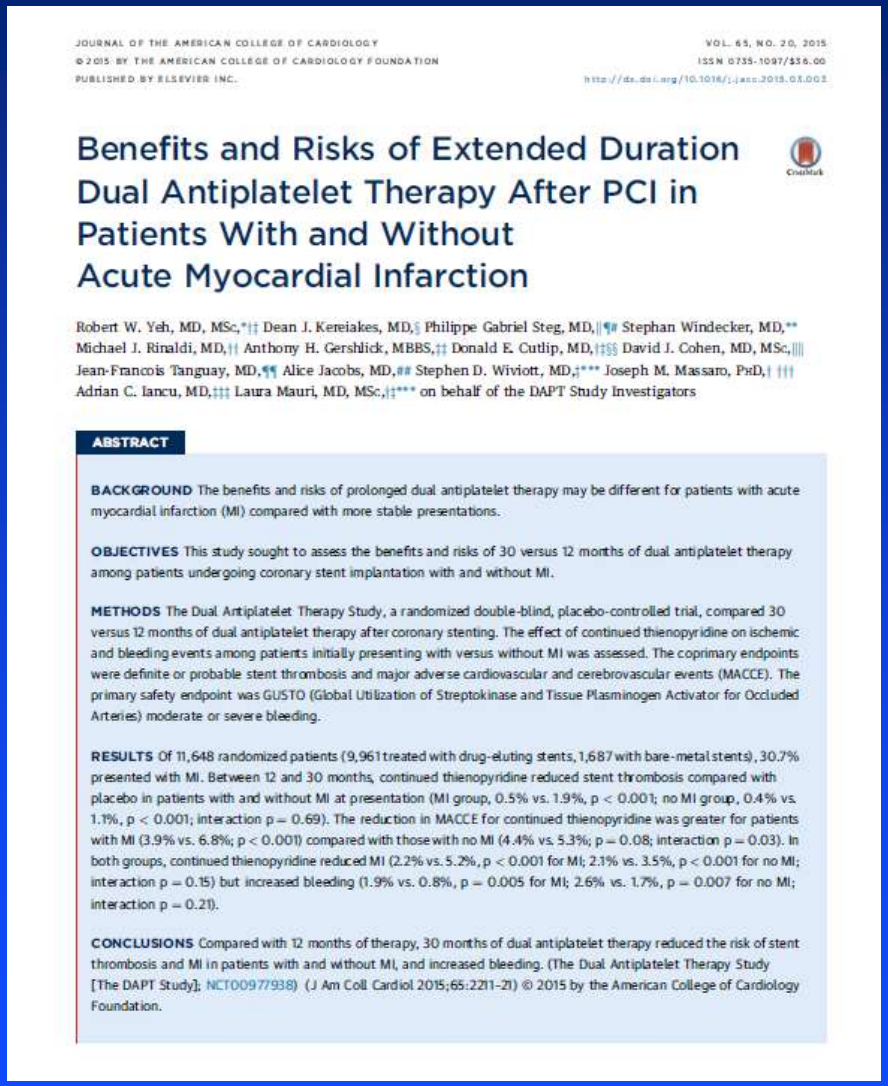



CAD without MI (n=1989)




Bhatt DL, et al. JACC 2007;49:1982-2

# DAPT Trial: ACS Subset



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## Benefits and Risks of Extended Duration Dual Antiplatelet Therapy After PCI in Patients With and Without Acute Myocardial Infarction

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**ABSTRACT**

**BACKGROUND** The benefits and risks of prolonged dual antiplatelet therapy may be different for patients with acute myocardial infarction (MI) compared with more stable presentations.

**OBJECTIVES** This study sought to assess the benefits and risks of 30 versus 12 months of dual antiplatelet therapy among patients undergoing coronary stent implantation with and without MI.

**METHODS** The Dual Antiplatelet Therapy Study, a randomized double-blind, placebo-controlled trial, compared 30 versus 12 months of dual antiplatelet therapy after coronary stenting. The effect of continued thienopyridine on ischemic and bleeding events among patients initially presenting with versus without MI was assessed. The coprimary endpoints were definite or probable stent thrombosis and major adverse cardiovascular and cerebrovascular events (MACCE). The primary safety endpoint was GUSTO (Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Arteries) moderate or severe bleeding.

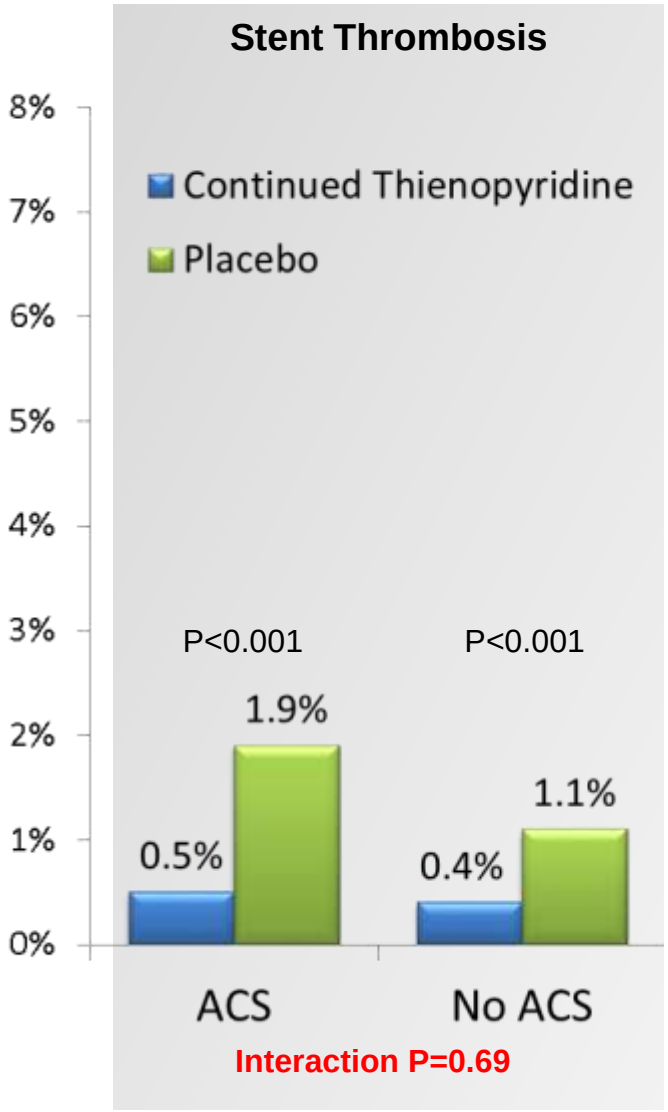
**RESULTS** Of 11,648 randomized patients (9,961 treated with drug-eluting stents, 1,687 with bare-metal stents), 30.7% presented with MI. Between 12 and 30 months, continued thienopyridine reduced stent thrombosis compared with placebo in patients with and without MI at presentation (MI group, 0.5% vs. 1.9%, $p < 0.001$; no MI group, 0.4% vs. 1.1%, $p < 0.001$; interaction $p = 0.69$). The reduction in MACCE for continued thienopyridine was greater for patients with MI (3.9% vs. 6.8%; $p < 0.001$) compared with those with no MI (4.4% vs. 5.3%; $p = 0.08$; interaction $p = 0.03$). In both groups, continued thienopyridine reduced MI (2.2% vs. 5.2%, $p < 0.001$ for MI; 2.1% vs. 3.5%, $p < 0.001$ for no MI; interaction $p = 0.15$) but increased bleeding (1.9% vs. 0.8%, $p = 0.005$ for MI; 2.6% vs. 1.7%, $p = 0.007$ for no MI; interaction $p = 0.21$).

**CONCLUSIONS** Compared with 12 months of therapy, 30 months of dual antiplatelet therapy reduced the risk of stent thrombosis and MI in patients with and without MI, and increased bleeding. (The Dual Antiplatelet Therapy Study [The DAPT Study]; NCT00977938) (J Am Coll Cardiol 2015;65:2211–21) © 2015 by the American College of Cardiology Foundation.

- Subgroup analysis of DAPT trial patients who presented with AMI (n=3576; 47% STEMI)
- All patients were event free at 12 months
- Randomized to continued DAPT vs. ASA alone from month 12-30

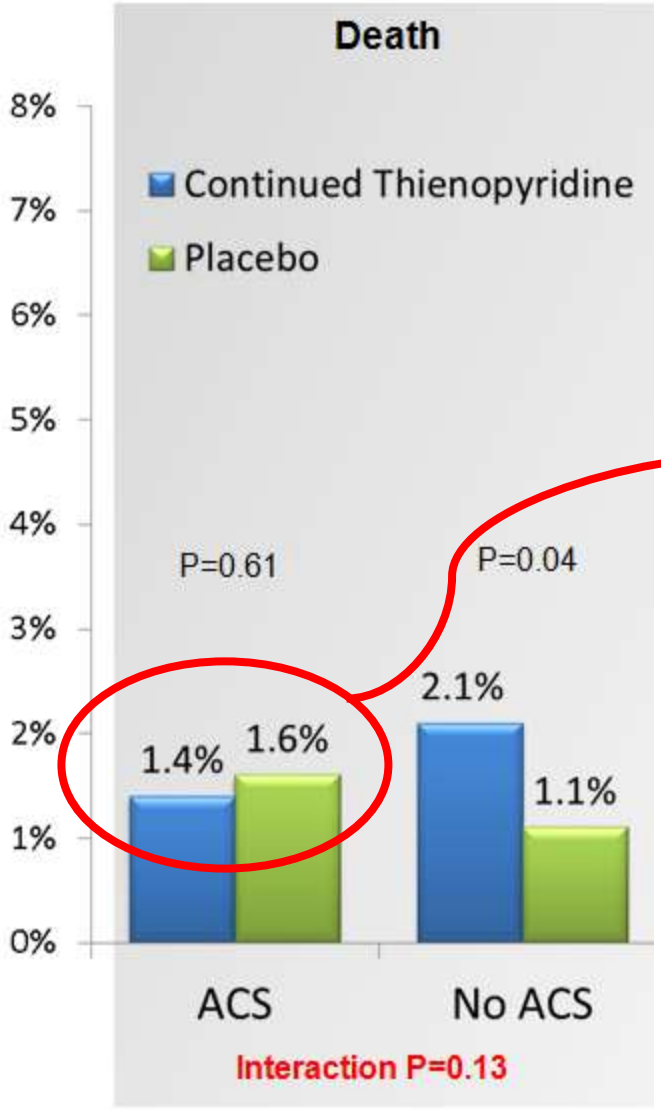
Yeh RW, et al. JACC 2015;65:2211-21

# Treatment Effect According to ACS Status




Yeh et al., *J Am Coll Cardiol.* 2015 May 26.

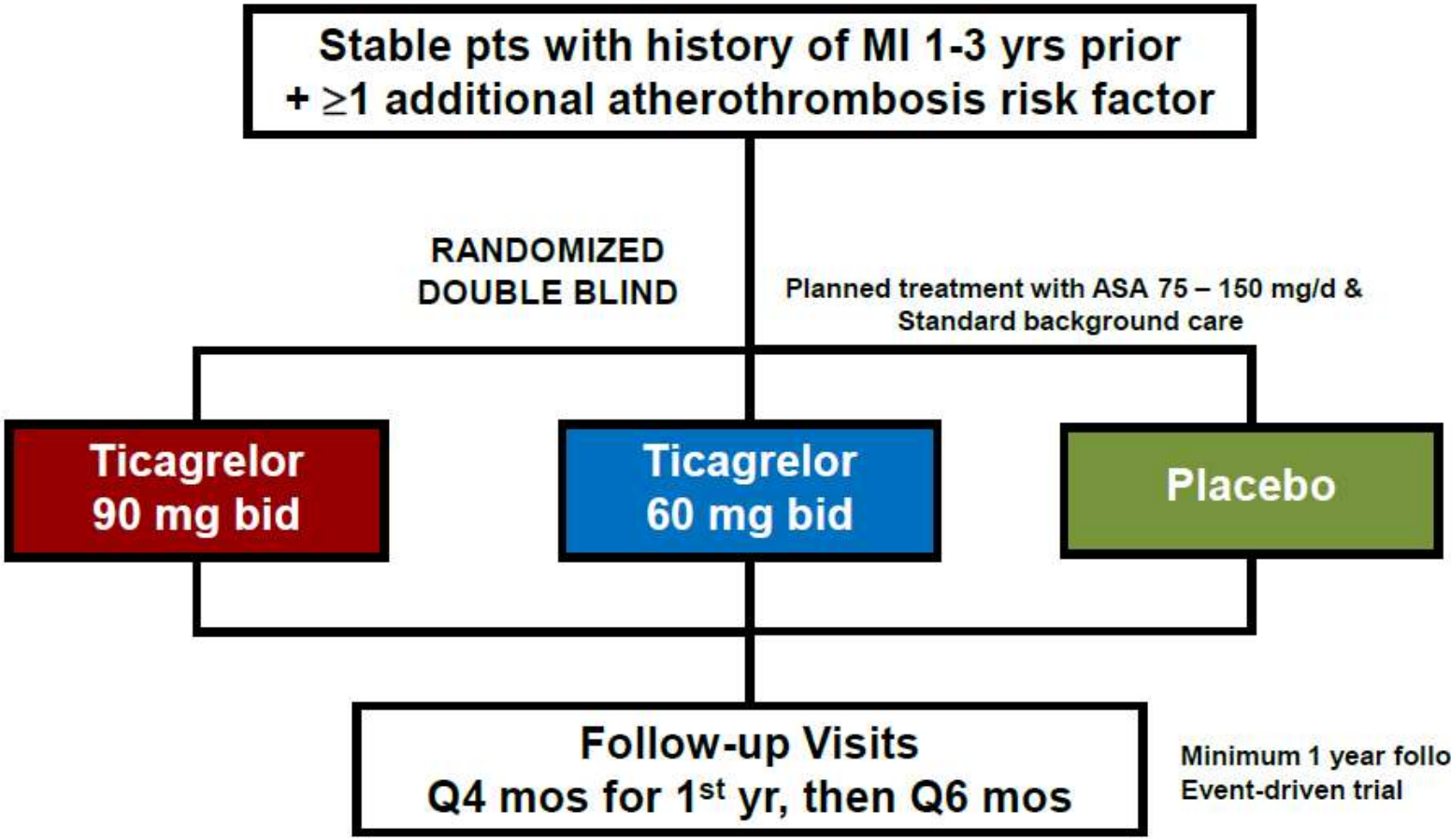
# Treatment Effect According to ACS Status: Mortality




**No evidence of excess mortality in ACS cohort**

Yeh et al., *J Am Coll Cardiol.* 2015 May 26.

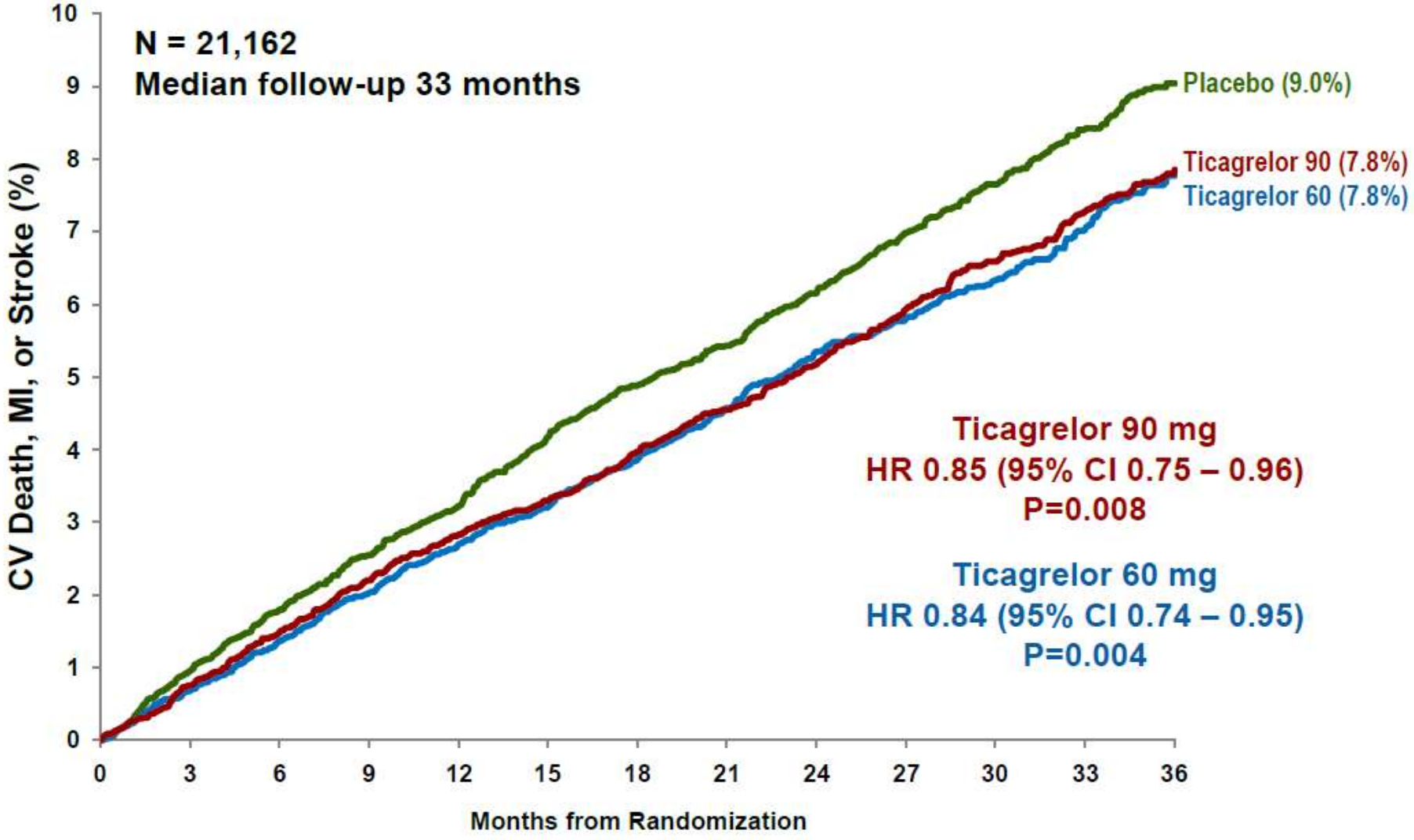
# Trial Design



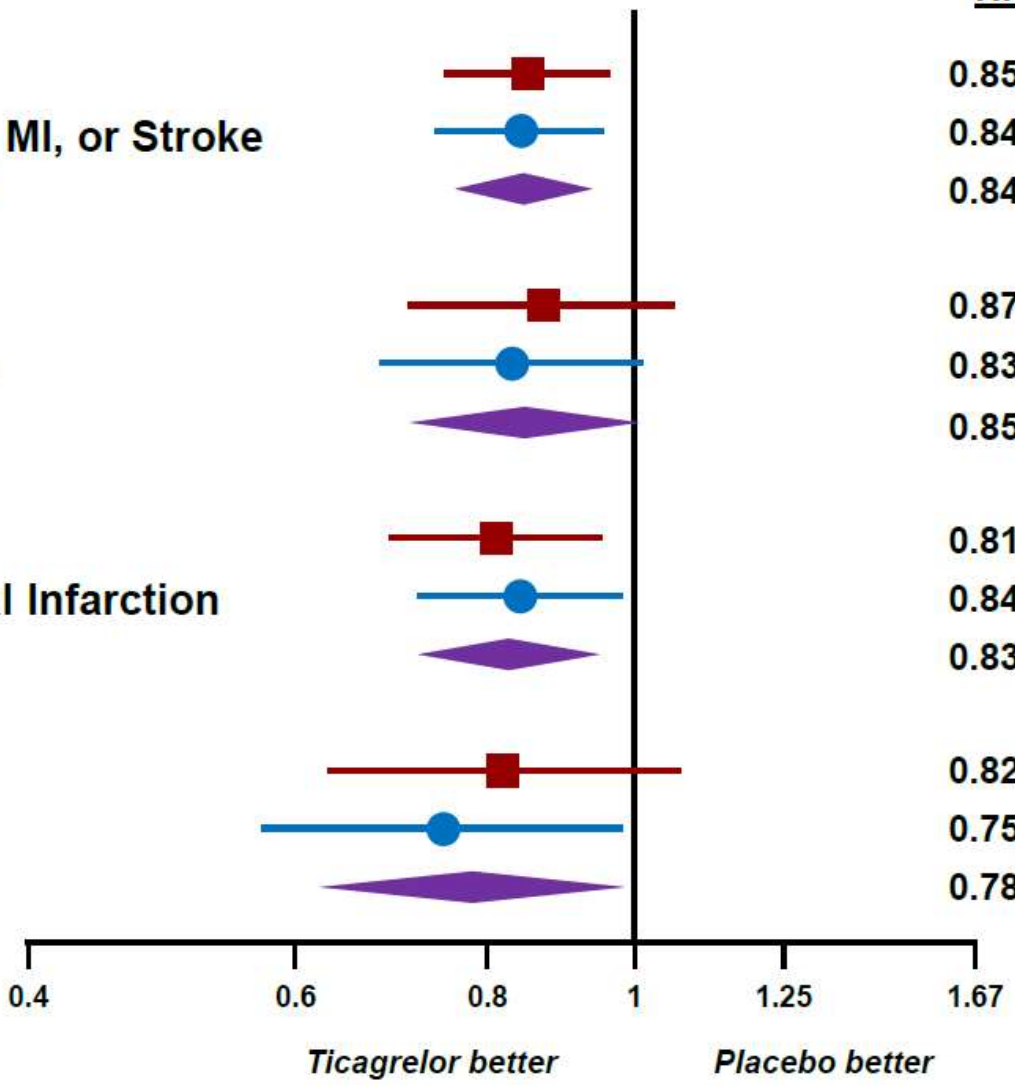



Bonaca MP et al. *Am Heart J* 2014;167:437-44

# Primary Endpoint



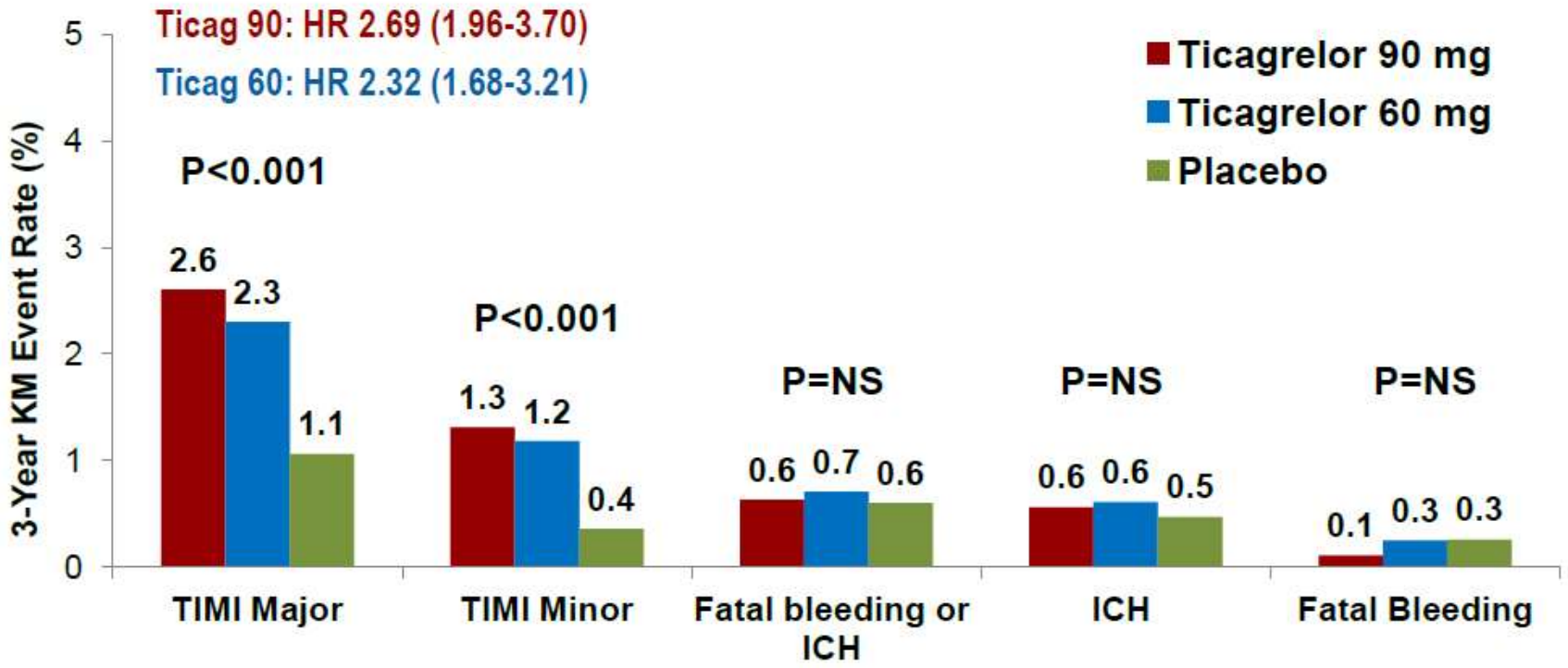
# Components of Primary Endpoint




| Endpoint | HR (95% CI) | P value |
|---|---|---|
| CV Death, MI, or Stroke (1558 events) | 0.85 (0.75-0.96) | 0.008 |
| | 0.84 (0.74-0.95) | 0.004 |
| | 0.84 (0.76-0.94) | 0.001 |
| CV Death (566 events) | 0.87 (0.71-1.06) | 0.15 |
| | 0.83 (0.68-1.01) | 0.07 |
| | 0.85 (0.71-1.00) | 0.06 |
| Myocardial Infarction (898 events) | 0.81 (0.69-0.95) | 0.01 |
| | 0.84 (0.72-0.98) | 0.03 |
| | 0.83 (0.72-0.95) | 0.005 |
| Stroke (313 events) | 0.82 (0.63-1.07) | 0.14 |
| | 0.75 (0.57-0.98) | 0.03 |
| | 0.78 (0.62-0.98) | 0.03 |

Ticagrelor 90 mg
Ticagrelor 60 mg
Pooled

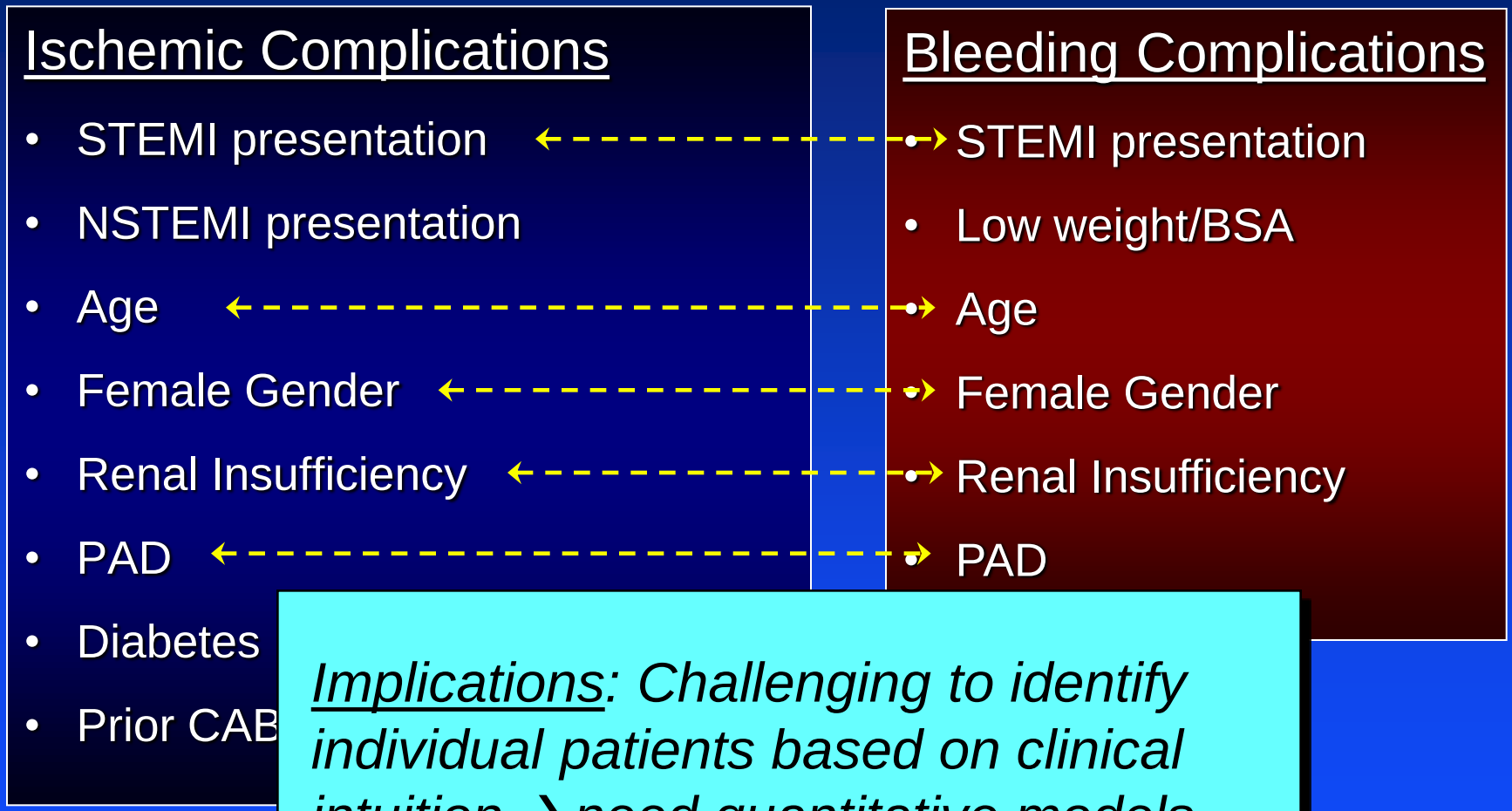
# Bleeding


Ticag 90: HR 2.69 (1.96-3.70)
Ticag 60: HR 2.32 (1.68-3.21)
Ticagrelor 90 mg
Ticagrelor 60 mg
Placebo
3-Year KM Event Rate (%)
0
1
2
3
4
5
P<0.001
2.6
2.3
1.1
P<0.001
1.3
1.2
0.4
P=NS
0.6
0.7
0.6
P=NS
0.6
0.6
0.5
P=NS
0.1
0.3
0.3
TIMI Major
TIMI Minor
Fatal bleeding or ICH
ICH
Fatal Bleeding

# Long-Term DAPT after AMI

- Rationale for long-term DAPT
- What are the data?
- How should we individualize care?

# Key challenge in risk stratification: Concordance of risk factors for benefit and harm




*Implications: Challenging to identify individual patients based on clinical intuition → need quantitative models*

Salisbury A, et al. ACC 2010

# Identifying Patients for Long-Term DAPT after PCI:

# The DAPT Score

Research

Original Investigation

## Development and Validation of a Prediction Rule for Benefit and Harm of Dual Antiplatelet Therapy Beyond 1 Year After Percutaneous Coronary Intervention

Robert W. Yeh, MD, MSc; Eric A. Secemsky, MD, MSc; Dean J. Kereiakes, MD; Sharon-Lise T. Normand, PhD; Anthony H. Gershlick, MBBS; David J. Cohen, MD, MSc; John A. Spertus, MD, MPH; Philippe Gabriel Steg, MD; Donald E. Cutlip, MD; Michael J. Rinaldi, MD; Edoardo Camenzind, MD; William Wijns, MD, PhD; Patricia K. Apruzzese, MA; Yang Song, MS; Joseph M. Massaro, PhD; Laura Mauri, MD, MSc; for the DAPT Study Investigators

**IMPORTANCE** Dual antiplatelet therapy after percutaneous coronary intervention (PCI) reduces ischemia but increases bleeding.

**OBJECTIVE** To develop a clinical decision tool to identify patients expected to derive benefit vs harm from continuing thienopyridine beyond 1 year after PCI.

**DESIGN, SETTING, AND PARTICIPANTS** Among 11 648 randomized DAPT Study patients from 11 countries (August 2009-May 2014), a prediction rule was derived stratifying patients into groups to distinguish ischemic and bleeding risk 12 to 30 months after PCI. Validation was internal via bootstrap resampling and external among 8136 patients from 36 countries randomized in the PROTECT trial (June 2007-July 2014).

**EXPOSURES** Twelve months of open-label thienopyridine plus aspirin, then randomized to 18 months of continued thienopyridine plus aspirin vs placebo plus aspirin.

**MAIN OUTCOMES AND MEASURES** Ischemia (myocardial infarction or stent thrombosis) and bleeding (moderate or severe) 12 to 30 months after PCI.

**RESULTS** Among DAPT Study patients (derivation cohort; mean age, 61.3 years; women, 25.1%), ischemia occurred in 348 patients (3.0%) and bleeding in 215 (1.8%). Derivation cohort models predicting ischemia and bleeding had *c* statistics of 0.70 and 0.68, respectively. The prediction rule assigned 1 point each for myocardial infarction at presentation, prior myocardial infarction or PCI, diabetes, stent diameter less than 3 mm, smoking, and paclitaxel-eluting stent; 2 points each for history of congestive heart failure/low ejection fraction and vein graft intervention; −1 point for age 65 to younger than 75 years; and −2 points for age 75 years or older. Among the high score group (score ≥2, n = 5917), continued thienopyridine vs placebo was associated with reduced ischemic events (2.7% vs 5.7%; risk difference [RD], −3.0% [95% CI, −4.1% to −2.0%], $P < .001$) compared with the low score group (score <2, n = 5731; 1.7% vs 2.3%; RD, −0.7% [95% CI, −1.4% to 0.09%], $P = .07$; interaction $P < .001$). Conversely, continued thienopyridine was associated with smaller increases in bleeding among the high score group (1.8% vs 1.4%; RD, 0.4% [95% CI, −0.3% to 1.0%], $P = .26$) compared with the low score group (3.0% vs 1.4%; RD, 1.5% [95% CI, 0.8% to 2.3%], $P < .001$; interaction $P = .02$). Among PROTECT patients (validation cohort; mean age, 62 years; women, 23.7%), ischemia occurred in 79 patients (1.0%) and bleeding in 37 (0.5%), with a *c* statistic of 0.64 for ischemia and 0.64 for bleeding. In this cohort, the high-score patients (n = 2848) had increased ischemic events compared with the low-score patients and no significant difference in bleeding.

**CONCLUSION AND RELEVANCE** Among patients not sustaining major bleeding or ischemic events 1 year after PCI, a prediction rule assessing late ischemic and bleeding risks to inform dual antiplatelet therapy duration showed modest accuracy in derivation and validation cohorts. This rule requires further prospective evaluation to assess potential effects on patient care, as well as validation in other cohorts.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT00977938.

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Supplemental content at jama.com

**Author Affiliations:** Author affiliations are listed at the end of this article.

**Group Information:** DAPT Study Investigators are listed at the end of this article.

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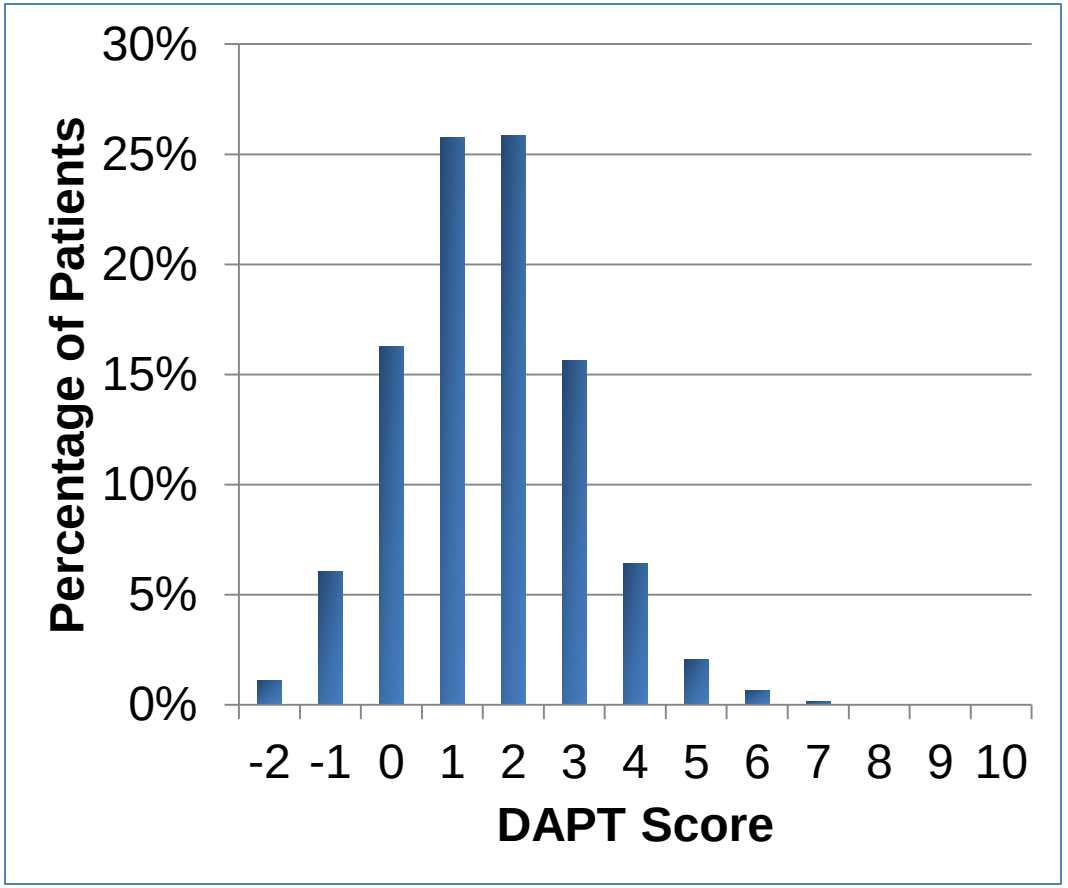
# The DAPT Score

| Variable | Points |
|---|---|
| **Patient Characteristic** | |
| Age | |
| ≥ 75 | -2 |
| 65 - <75 | -1 |
| < 65 | 0 |
| Diabetes Mellitus | 1 |
| Current Cigarette Smoker | 1 |
| Prior PCI or Prior MI | 1 |
| CHF or LVEF < 30% | 2 |
| **Index Procedure Characteristic** | |
| MI at Presentation | 1 |
| Vein Graft PCI | 2 |
| Stent Diameter < 3mm | 1 |

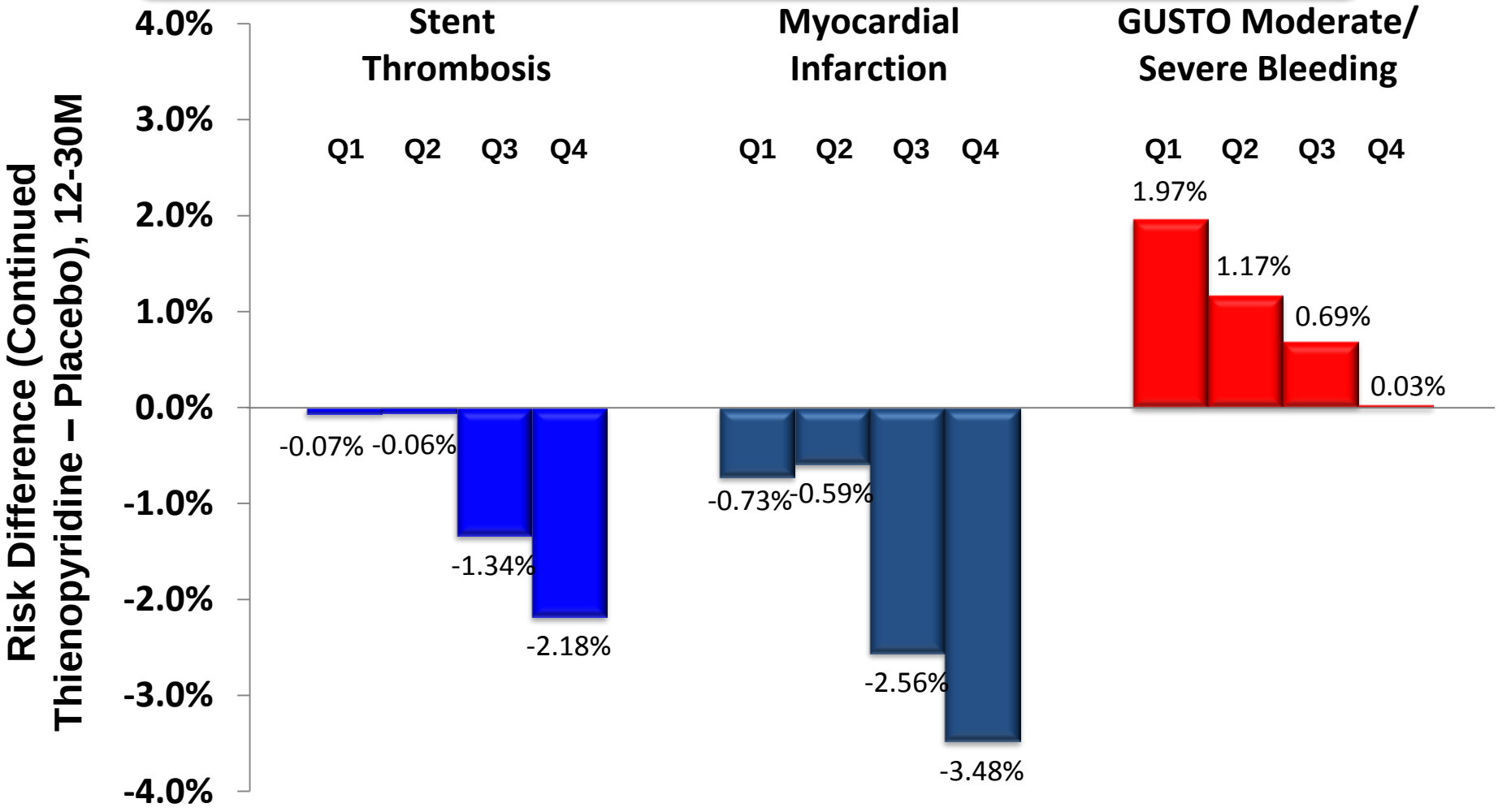
**Distribution of DAPT Scores among all randomized subjects in the DAPT Study**



# Continued Thienopyridine vs. PlaceboTreatment Effect by DAPT Score Quartile (N = 11,648)

DAPT STUDY

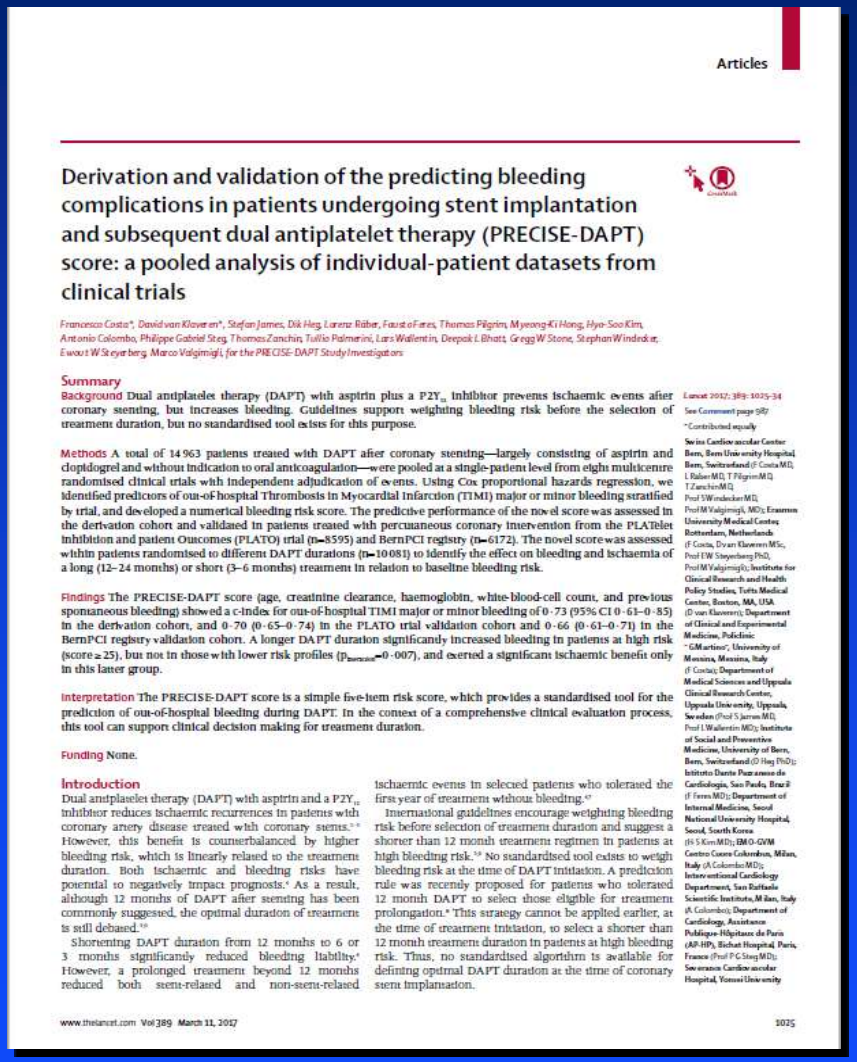
Q1 = DAPT Score -2 to 0
Q2 = DAPT Score 1
Q3 = DAPT Score 2
Q4 = DAPT Score > 2



# Limitations of the DAPT Score

- Predicts “net clinical benefit”– assumes that ischemic and bleeding complications have similar prognostic impact
- Excludes certain patient types for whom risk prediction may be desirable
  - *Patients on oral anticoagulation or with prior h/o bleeding*
- Only predicts benefit of extending DAPT from 12 to 30 months → does not provide insight about shortening DAPT

# PRECISE Risk Score



Articles

Derivation and validation of the predicting bleeding complications in patients undergoing stent implantation and subsequent dual antiplatelet therapy (PRECISE-DAPT) score: a pooled analysis of individual-patient datasets from clinical trials

Francesco Costa*, David van Klaveren*, Stefan James, Dik Heg, Lorenz Räber, Faisal Feres, Thomas Pilgrim, Myeong-Ki Hong, Hyo-Soo Kim, Antonio Colombo, Philippe Gabriel Steg, Thomas Zanchin, Tullio Palmerini, Lars Wallentin, Deepak L Bhatt, Gregg W Stone, Stephan Windecker, Ewout W Steyerberg, Marco Valgimigli, for the PRECISE-DAPT Study Investigators

**Summary**

**Background** Dual antiplatelet therapy (DAPT) with aspirin plus a $P2Y_{12}$ inhibitor prevents ischaemic events after coronary stenting, but increases bleeding. Guidelines support weighing bleeding risk before the selection of treatment duration, but no standardised tool exists for this purpose.

**Methods** A total of 14 963 patients treated with DAPT after coronary stenting—largely consisting of aspirin and clopidogrel and without indication to oral anticoagulation—were pooled at a single-patient level from eight multicentre randomised clinical trials with independent adjudication of events. Using Cox proportional hazards regression, we identified predictors of out-of-hospital Thrombosis in Myocardial Infarction (TIMI) major or minor bleeding stratified by trial, and developed a numerical bleeding risk score. The predictive performance of the novel score was assessed in the derivation cohort and validated in patients treated with percutaneous coronary intervention from the PLATelet Inhibition and patient Outcomes (PLATO) trial (n=8595) and BernPCI registry (n=6172). The novel score was assessed within patients randomised to different DAPT durations (n=10 081) to identify the effect on bleeding and ischaemia of a long (12–24 months) or short (3–6 months) treatment in relation to baseline bleeding risk.

**Findings** The PRECISE-DAPT score (age, creatinine clearance, haemoglobin, white-blood-cell count, and previous spontaneous bleeding) showed a c-index for out-of-hospital TIMI major or minor bleeding of 0·73 (95% CI 0·61–0·85) in the derivation cohort, and 0·70 (0·65–0·74) in the PLATO trial validation cohort and 0·66 (0·61–0·71) in the BernPCI registry validation cohort. A longer DAPT duration significantly increased bleeding in patients at high risk (score ≥ 25), but not in those with lower risk profiles ($p_{interaction}$=0·007), and exerted a significant ischaemic benefit only in this latter group.

**Interpretation** The PRECISE-DAPT score is a simple five-item risk score, which provides a standardised tool for the prediction of out-of-hospital bleeding during DAPT. In the context of a comprehensive clinical evaluation process, this tool can support clinical decision making for treatment duration.

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Lancet 2017; 389: 1025–34
See Comment page 987

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**Introduction**

Dual antiplatelet therapy (DAPT) with aspirin and a $P2Y_{12}$ inhibitor reduces ischaemic recurrences in patients with coronary artery disease treated with coronary stents.[1–3] However, this benefit is counterbalanced by higher bleeding risk, which is linearly related to the treatment duration. Both ischaemic and bleeding risks have potential to negatively impact prognosis.[4] As a result, although 12 months of DAPT after stenting has been commonly suggested, the optimal duration of treatment is still debated.[5,6]

Shortening DAPT duration from 12 months to 6 or 3 months significantly reduced bleeding liability.[4] However, a prolonged treatment beyond 12 months reduced both stent-related and non-stent-related ischaemic events in selected patients who tolerated the first year of treatment without bleeding.[4,7]

International guidelines encourage weighting bleeding risk before selection of treatment duration and suggest a shorter than 12 month treatment regimen in patients at high bleeding risk.[5,8] No standardised tool exists to weigh bleeding risk at the time of DAPT initiation. A prediction rule was recently proposed for patients who tolerated 12 month DAPT to select those eligible for treatment prolongation.[4] This strategy cannot be applied earlier, at the time of treatment initiation, to select a shorter than 12 month treatment duration in patients at high bleeding risk. Thus, no standardised algorithm is available for defining optimal DAPT duration at the time of coronary stent implantation.



- Risk score to predict 1-year major bleeding on DAPT
- Developed using pooled data from 8 multicenter RCTs of varying DAPT duration
- Bleeding endpoint = TIMI major or minor bleeding between 7 days and 1 year after PCI
- Score based on patient characteristics available at time of index PCI procedure

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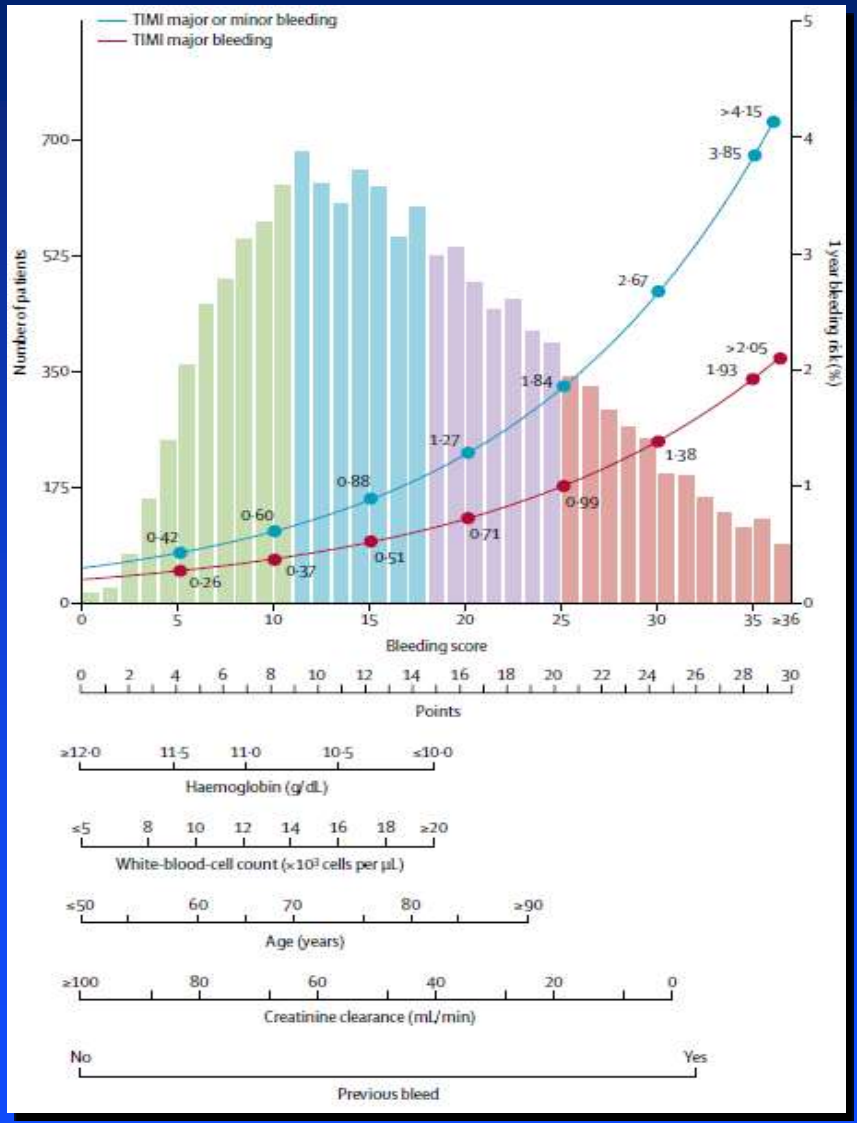
# PRECISE Risk Score




- Score (range 0-100) includes 5 independent risk factors
  - *Hemoglobin* -- *WBC*
  - *Age* -- *CrCl*
  - *Prior bleeding*
- Top quartile (score >25) correlates with high risk of bleeding (2-4%/year)
- Available as web-based calculator (http://www.precisedaptscore.com/predapt/webcalculator.html) and phone app

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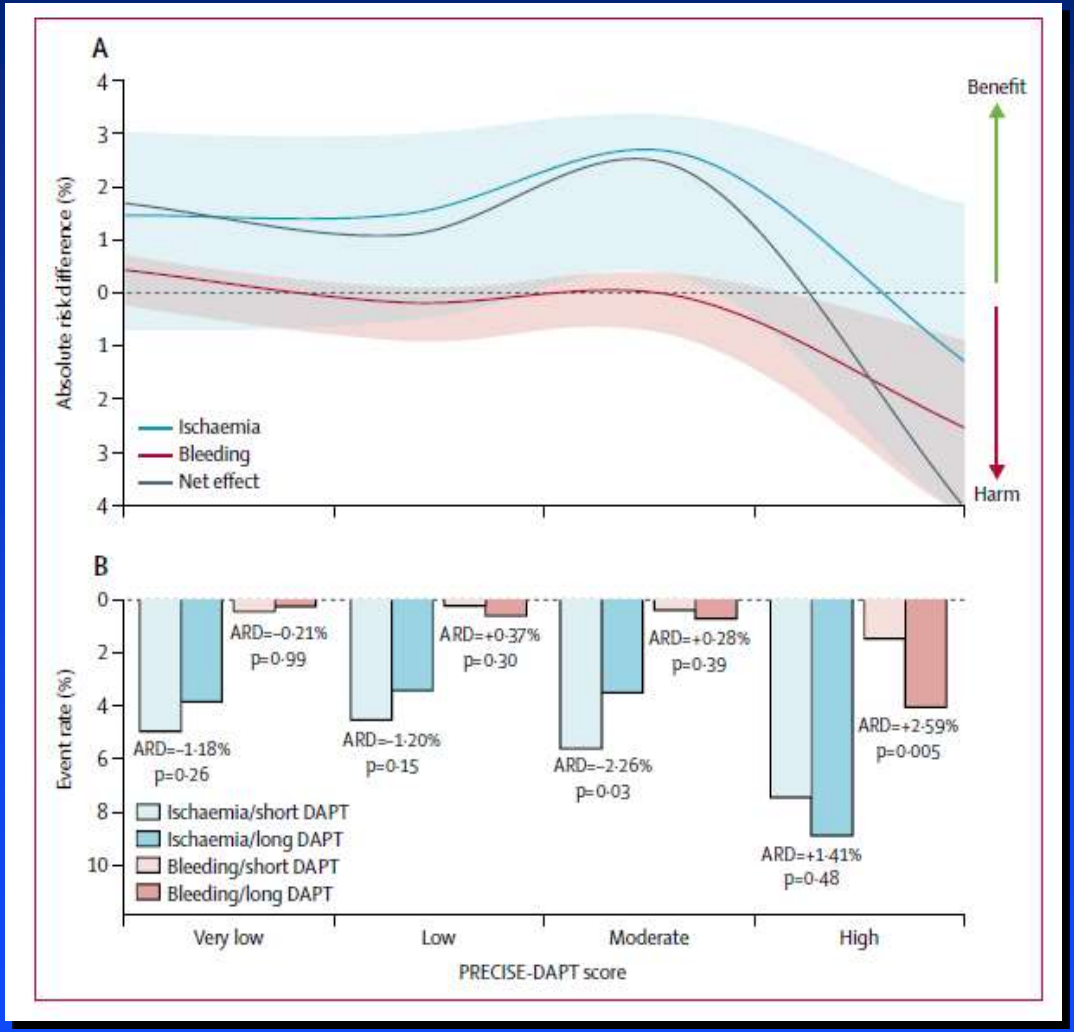
# PRECISE Risk Score: Net Clinical Benefit




- Net benefit of long DAPT positive in first 3 quartiles and only harmful in top quartile

| Risk Quartile | Net Clinical Benefit |
|---|---|
| 1 | + 1.4% |
| 2 | + 0.8% |
| 3 | + 2.0% |
| 4 | - 1.2% |

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# Summary/Conclusions

- There is strong evidence that prolonged DAPT (esp. with ticagrelor and clopidogrel) can provide meaningful reductions in ischemic events in patients with prior AMI
- These benefits come at a price of increased bleeding
- Optimizing the risk:benefit ratio of extended DAPT after AMI requires the ability to predict the risk of both ischemic and bleeding complications with reasonable accuracy
- Although not developed specifically for this purpose, at the present time, both the DAPT score and the PRECISE score may provide reasonable guidance until more specific post-MI risk scores can be developed