Antiagregants et diabete

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Disclosures

- Amgen
- Astra-Zeneca
- Bayer
- Boehringer
- Daichi Sankyo
- Lilly
- Novartis
- Novo Nordisk
- Sanofi

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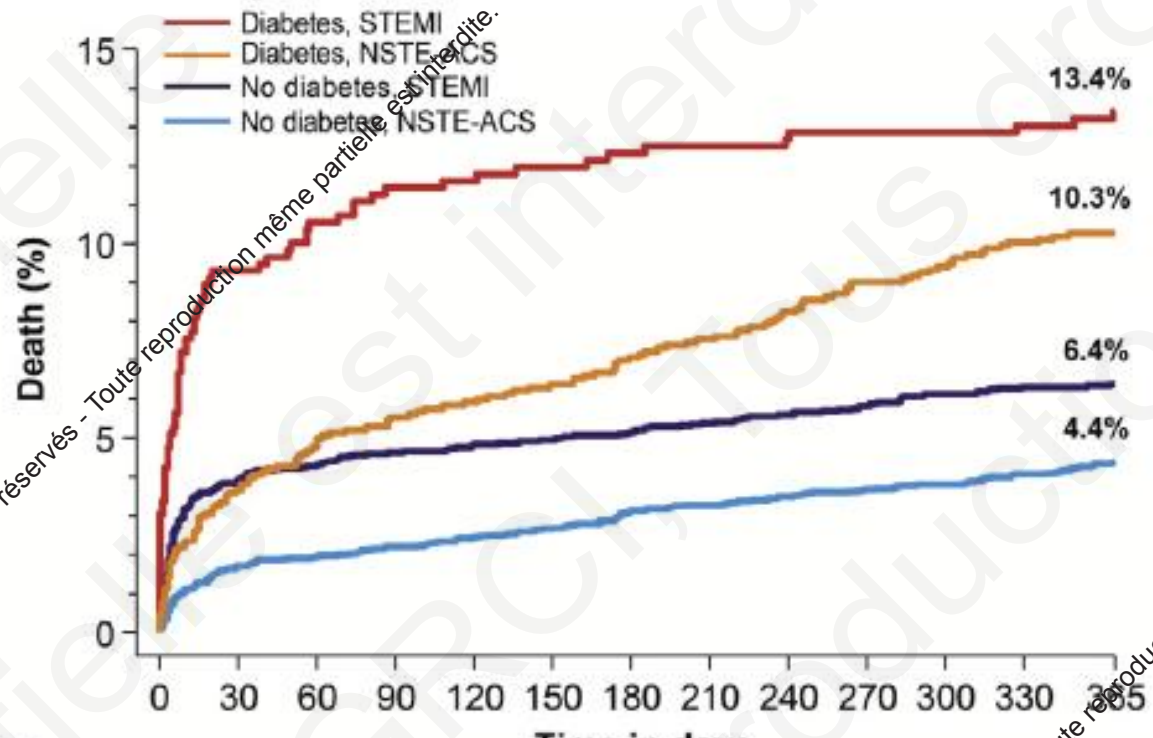
16 600 patients
poolés de 6 études

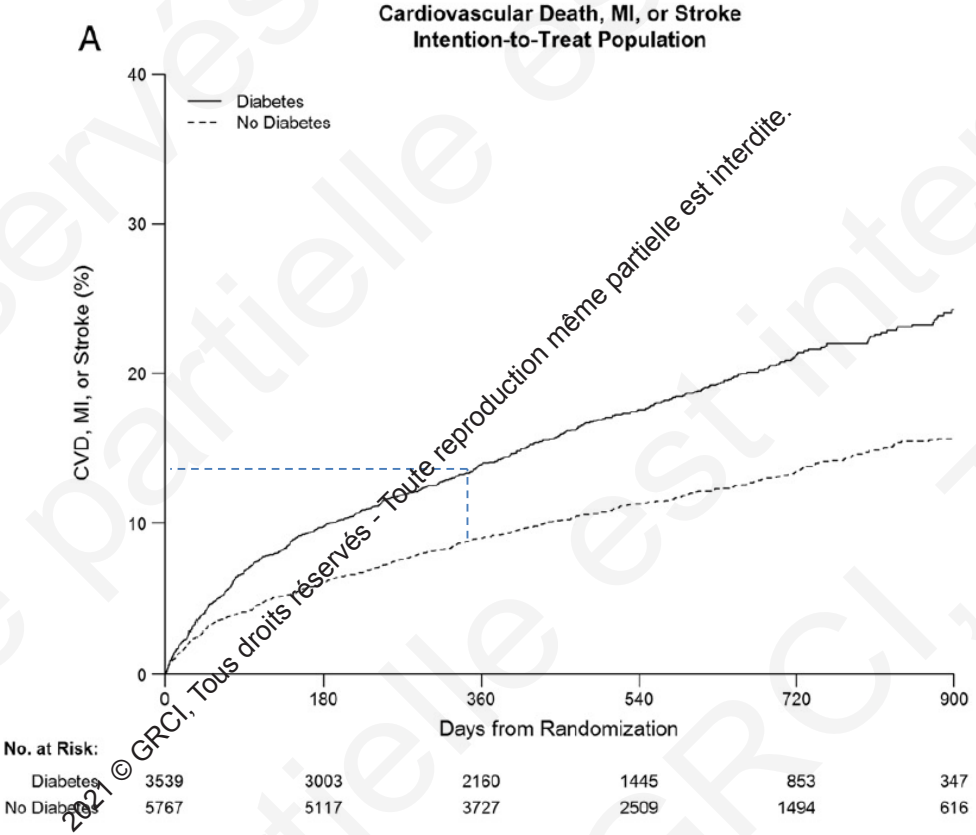


Number at risk

No diabetes, STEMI	3339	3092	3068	3054	3046	3041	3034	3022	3013	3006	2996	2987	2843
No diabetes, NSTE-ACS	4226	4027	4007	3996	3986	3976	3955	3941	3929	3922	3916	3901	3747
Diabetes, STEMI	591	514	504	498	497	495	491	490	489	488	488	486	462
Diabetes, NSTE-ACS	1336	1247	1229	1219	1213	1207	1197	1190	1181	1168	1163	1153	1100

Figure 1. Kaplan–Meier time-to-event curves showing all-cause mortality at 1 year across the 4 study groups.

Piccolo et al, Am J Cardiol 2016;118:345-52



TRILOGY ACS
Diabetic patients

Spontaneous MI After Non–ST-Segment Elevation Acute Coronary Syndrome Managed Without Revascularization

The TRILOGY ACS Trial

ABSTRACT

BACKGROUND Patients with acute coronary syndrome (ACS), especially those receiving medical management without revascularization, are at high risk for spontaneous myocardial infarction (MI), but its frequency and predictors are unknown.

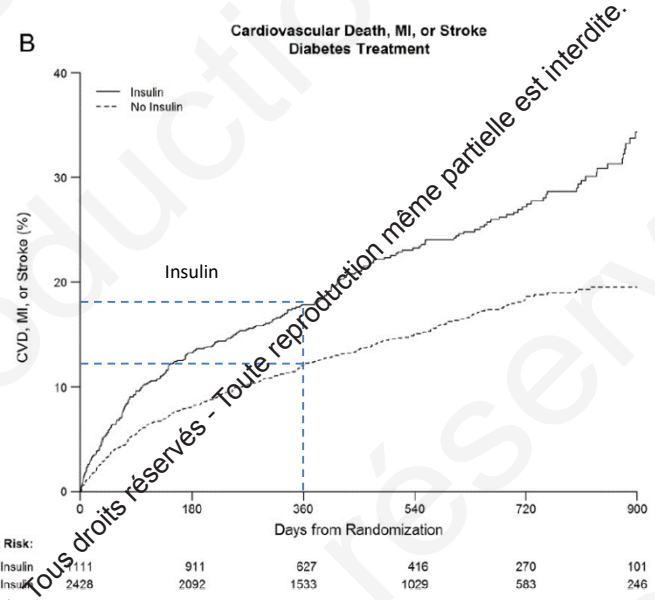
OBJECTIVES This study sought to characterize spontaneous MI events in a randomized population during 30 months of follow-up and develop a prediction model for spontaneous MI to assign risk of spontaneous MI events in ACS populations.

METHODS We analyzed data from the randomized TRILOGY ACS (TaRgeted platelet Inhibition to clarify the Optimal strateGy to medically manage Acute Coronary Syndromes) trial of aspirin plus prasugrel or clopidogrel following ACS. The trial included 9,326 patients with non–ST-segment elevation myocardial infarction (NSTEMI)/unstable angina (UA) who were managed medically without planned revascularization. Our study population included 9,294 patients. A multivariable Cox proportional hazards model was developed to determine predictors of time to first spontaneous MI event through 30 months. After model validation, we developed a calculator for model implementation.

RESULTS Among 9,294 patients, 695 spontaneous MI events occurred over a median of 17 months, representing 94% of adjudicated MI events (n = 739). The Kaplan-Meier event rate of spontaneous MI through 30 months was 10.7%. The strongest predictors of spontaneous MI were older age, NSTEMI versus UA as index event, diabetes mellitus, no pre-randomization angiography, and higher baseline creatinine values. The model exhibited good predictive capabilities (c-index = 0.732) and had good calibration, especially for patients with low-to-moderate risk of spontaneous MI.

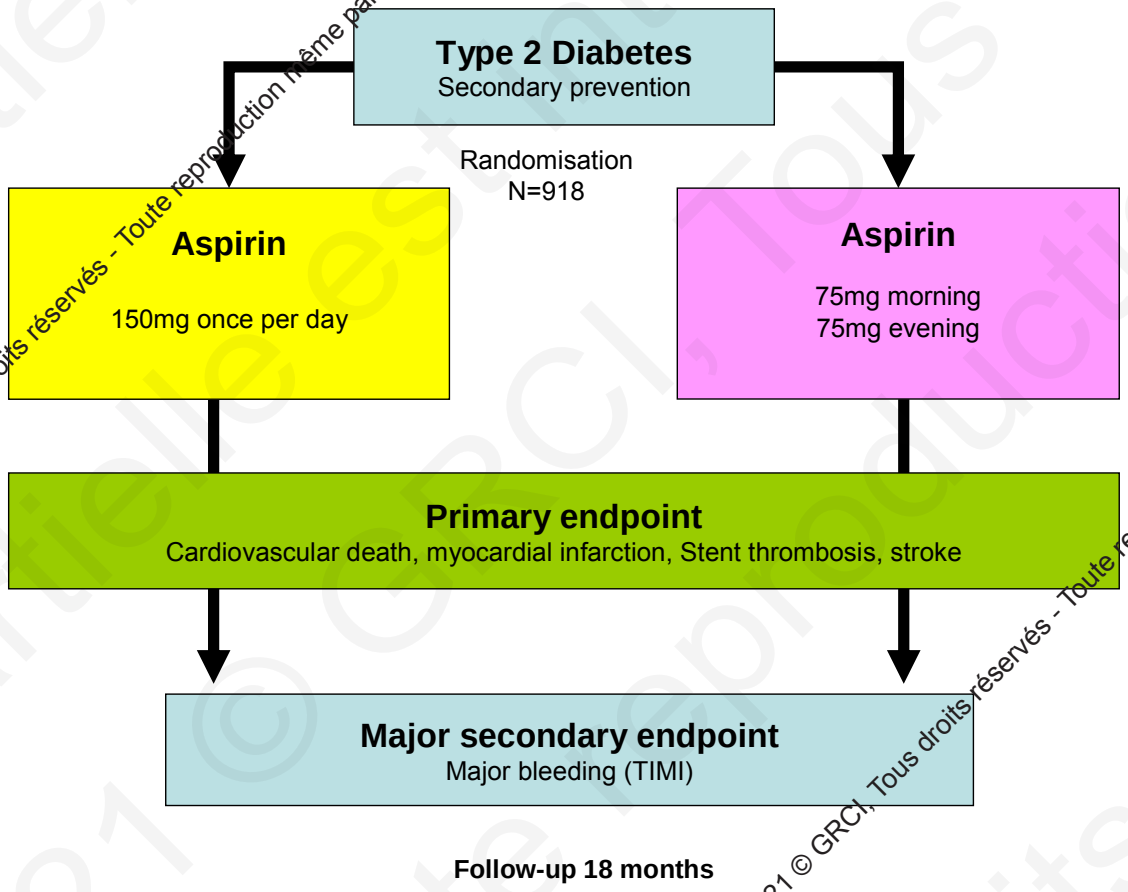
CONCLUSIONS Spontaneous MI following a medically managed UA/NSTEMI event is common. Baseline characteristics can be used to predict subsequent risk of spontaneous MI in this population. These findings provide insight into the long-term natural history of medically managed UA/NSTEMI patients and could be used to optimize risk stratification and treatment of these patients. (A Comparison of Prasugrel and Clopidogrel in Acute Coronary Syndrome Subjects [TRILOGY ACS]; NCT00699998) (J Am Coll Cardiol 2016;67:1289–97) © 2016 by the American College of Cardiology Foundation.

Insulin or not



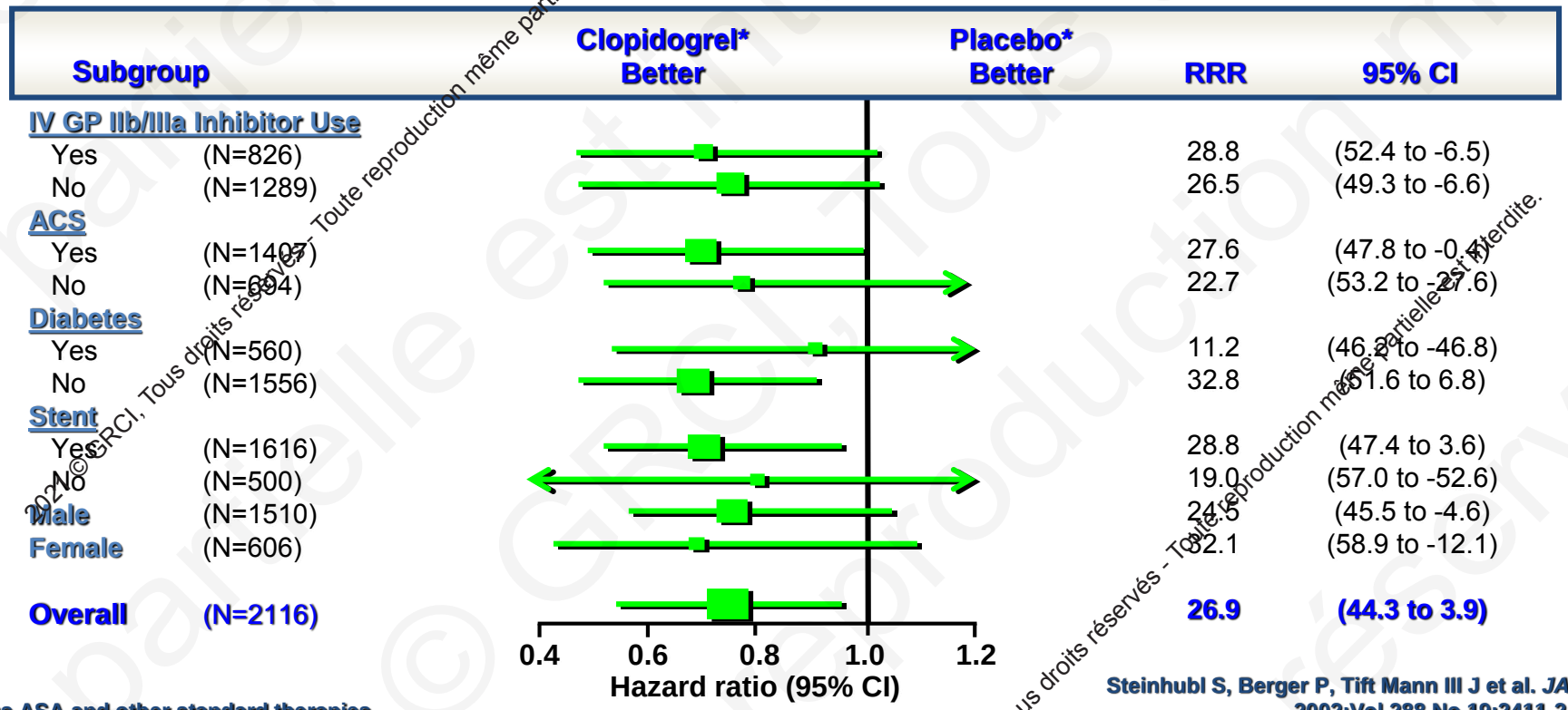
Dalby et al, Am Heart J 2017; 188: 156-66

Aspirine



2023

CREDO : Long-Term Benefit of Clopidogrel: MI, Stroke, or Death at 1 Year

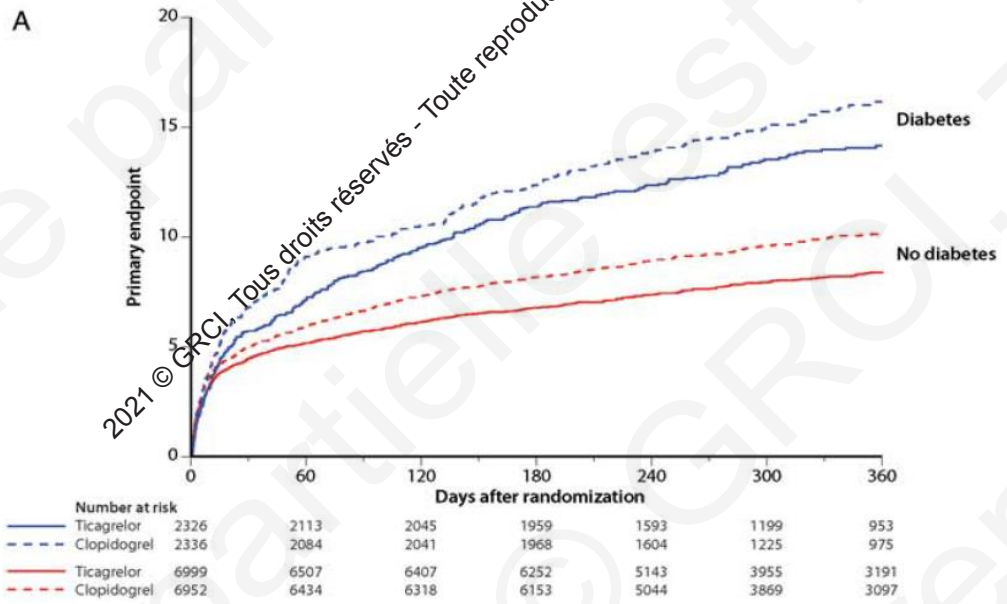


* Plus ASA and other standard therapies

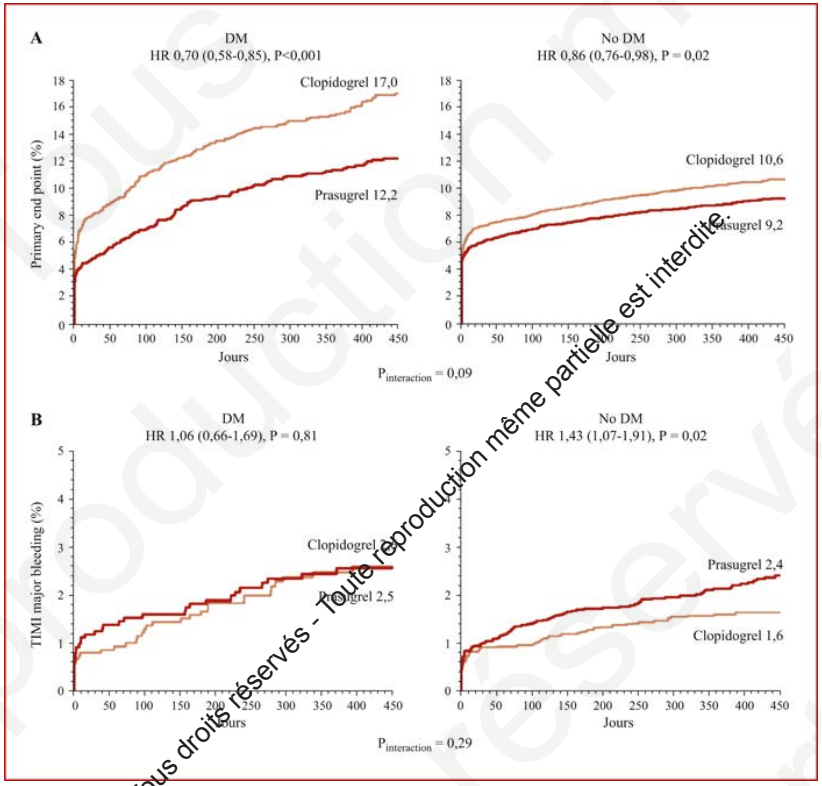
Steinhubl S, Berger P, Tift Mann III J et al. *JAMA*. 2002;Vol 288,No 19:2411-2420.

PLATO Diabetes

MACE



TRITON Diabetes



James et al, EHJ 2010

Wiviott et al, NEJM 2007

Ticagrelor or Prasugrel in Patients With Acute Coronary Syndromes and Diabetes Mellitus

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ABSTRACT

OBJECTIVES The aim of this study was to assess the efficacy and safety of ticagrelor versus prasugrel in patients with diabetes mellitus (DM) presenting with acute coronary syndromes (ACS) in whom invasive therapy was planned.

BACKGROUND The efficacy and safety of ticagrelor versus prasugrel in patients with ACS with DM undergoing invasive treatment remain unknown.

METHODS This pre-specified analysis of the ISAR-REACT (Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment) 5 trial included 892 patients with ACS with DM and 3,124 patients with ACS without DM randomized to prasugrel or ticagrelor. The primary endpoint was a composite of death, myocardial infarction, or stroke; the safety endpoint was Bleeding Academic Research Consortium types 3 to 5 bleeding (BARC 3-5) assessed 12 months after randomization).

RESULTS The primary endpoint occurred in 51 patients (11.2%) in the ticagrelor group and 55 patients (13.0%) in the prasugrel group in the DM cohort (hazard ratio: 0.84; 95% confidence interval: 0.58 to 1.24; p = 0.383) and in 132 patients (8.6%) in the ticagrelor group and 81 patients (5.2%) in the prasugrel group in the non-DM cohort (hazard ratio: 1.70; 95% confidence interval: 1.29 to 2.24; p < 0.001). There was a significant treatment arm-by-diabetic status interaction (p_{int} = 0.0035). Bleeding Academic Research Consortium BARC 3 to 5 bleeding occurred in 27 patients (6.9%) in the ticagrelor group and 19 patients (5.5%) in the prasugrel group (p = 0.425) in the DM cohort and in 68 patients (5.2%) in the ticagrelor group and 60 patients (4.6%) in the prasugrel group in the non-DM cohort (p = 0.500).

CONCLUSIONS DM seems to affect the efficacy of ticagrelor and prasugrel in patients with ACS. In patients with DM, the efficacy of ticagrelor was comparable with that of prasugrel. (Prospective, Randomized Trial of Ticagrelor Versus Prasugrel in Patients With Acute Coronary Syndromes [ISAR-REACT 5]; NCT01944800)

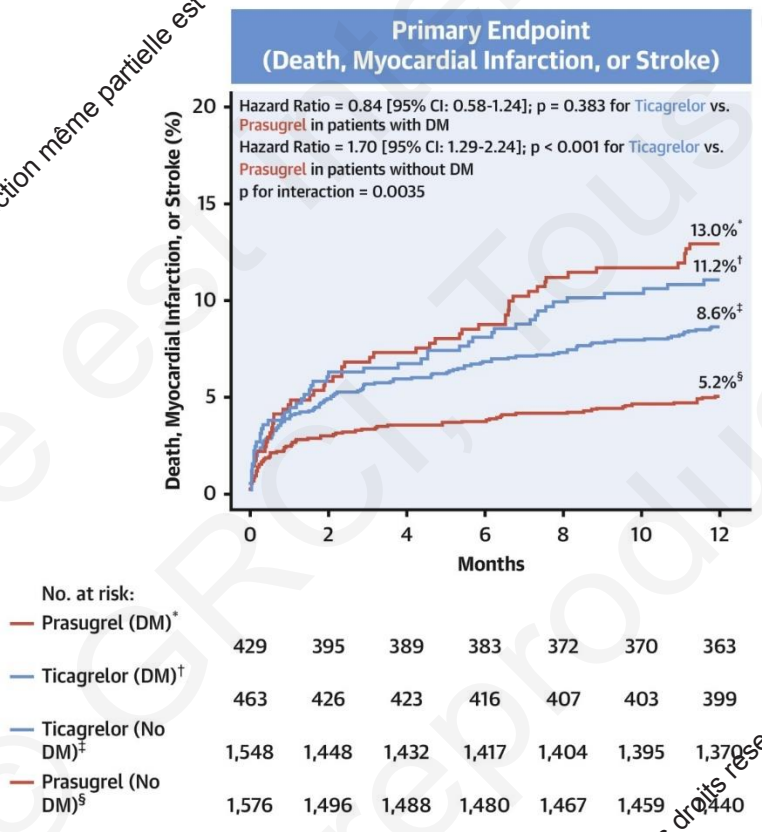
(J Am Coll Cardiol Intv 2020;13:2238–47)

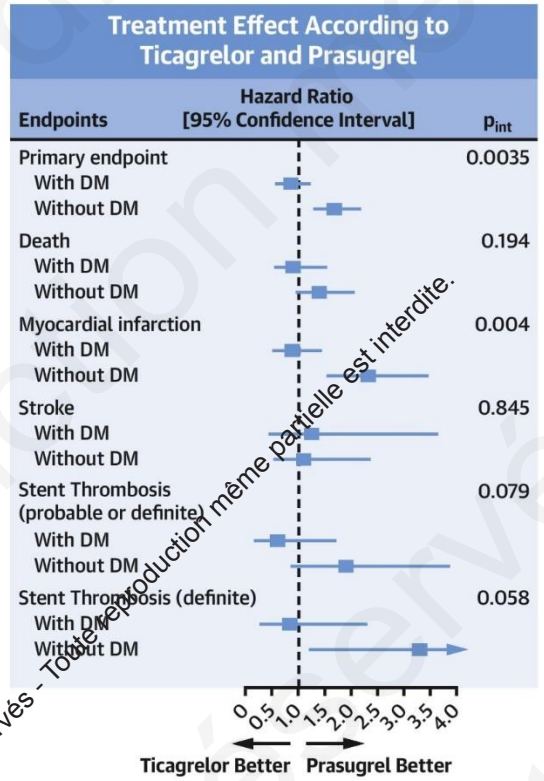
ISAR-REACT 5

892 Dabetics
3124 Non Diabetics

MACE

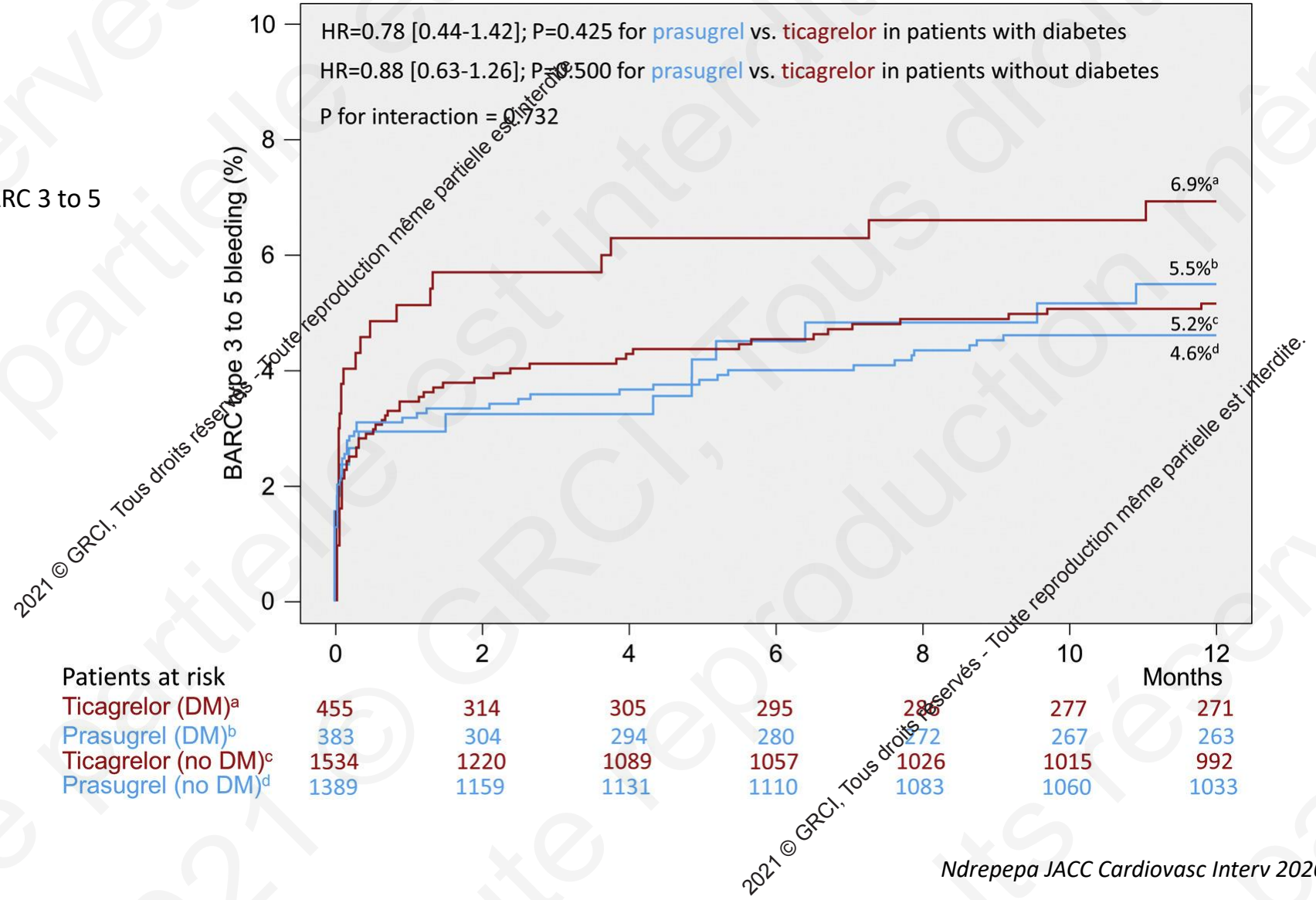
CENTRAL ILLUSTRATION: Efficacy Endpoints With Ticagrelor and Prasugrel in Patients With and Without Diabetes





Ndrepepa, G. et al. J Am Coll Cardiol Intv. 2020;13(19):2238-47.

BARC 3 to 5



Ndrepepa JACC Cardiovasc Interv 2020

PEGASUS

Reduction in Ischemic Events With Ticagrelor in Diabetic Patients With Prior Myocardial Infarction in PEGASUS-TIMI 54

Deepak L. Bhatt, MD, MPH,[a] Marc P. Bonaca, MD, MPH,[a] Sameer Bansilal, MD, MS,[b] Dominick J. Angiolillo, MD, PhD,[c] Marc Cohen, MD,[d] Robert F. Storey, MD,[e] Kyungah Im, PhD,[a] Sabina A. Murphy, MPH,[a] Peter Held, MD, PhD,[f] Eugene Braunwald, MD,[a] Marc S. Sabatine, MD, MPH,[a] Ph. Gabriel Steg, MD[g]

ABSTRACT

BACKGROUND Patients with diabetes appear to be at elevated risk of atherothrombotic events.

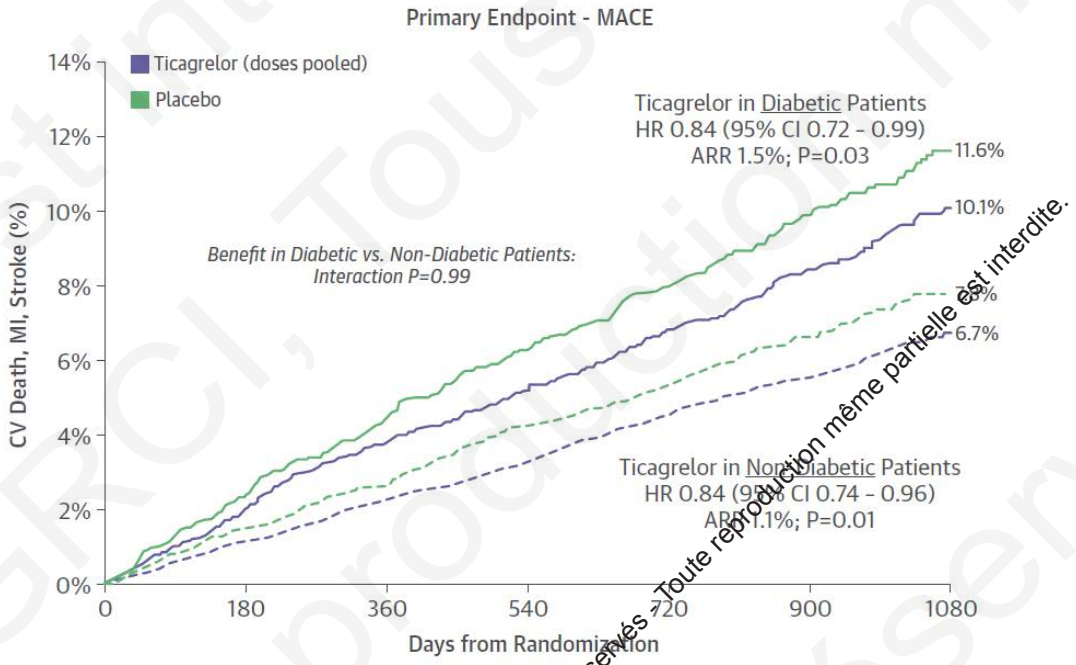
OBJECTIVES The purpose of this study was to determine the effect of antiplatelet therapy with ticagrelor on recurrent ischemic events in patients with diabetes and prior myocardial infarction (MI).

METHODS We examined the subgroups of patients with diabetes (n = 6,806) and without diabetes (n = 14,355) from PEGASUS-TIMI 54 (Prevention of Cardiovascular Events in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin-Thrombolysis in Myocardial Infarction 54), in which 21,162 patients with a history of MI 1 to 3 years prior and with additional risk factors were randomized to ticagrelor (60 or 60 mg twice daily) or placebo. Patients were followed for a median of 33 months. The primary efficacy endpoint was major adverse cardiovascular events (MACE) (cardiovascular death, MI, stroke) and the primary safety endpoint was TIMI (Thrombolysis in Myocardial Infarction) major bleeding.

RESULTS The relative risk reduction in MACE with ticagrelor was consistent for the pooled doses versus placebo in patients with diabetes (hazard ratio [HR]: 0.84; 95% confidence interval [CI]: 0.72 to 0.99; p = 0.035) and without diabetes (HR: 0.84; 95% CI: 0.74 to 0.96; p = 0.01; interaction = 0.99). As patients with diabetes were at higher risk of MACE, the absolute risk reduction tended to be greater in patients with versus without diabetes (1.5% vs. 1.1%, with corresponding 3-year number needed to treat of 67 vs. 91). In patients with diabetes requiring pharmacological therapy (n = 5,960), the absolute risk reduction was 2.1%, with a 3-year number needed to treat of 53. Additionally, in patients with diabetes, ticagrelor reduced cardiovascular death by 22% and coronary heart disease death by 34%. Similar to patients without diabetes, there was increased TIMI major bleeding in patients with diabetes (HR: 2.56; 95% CI: 1.52 to 4.33; p = 0.0004).

CONCLUSIONS In patients with diabetes with prior MI, adding ticagrelor to aspirin significantly reduces the risk of recurrent ischemic events, including cardiovascular and coronary heart disease death. (Prevention of Cardiovascular Events in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin [PEGASUS]; NCT01225562) (J Am Coll Cardiol 2016;67:2732-40) © 2016 by the American College of Cardiology Foundation.

FIGURE 1 Rates of MACE in the Pooled Ticagrelor Versus Placebo Arms For Patients With and Without Diabetes

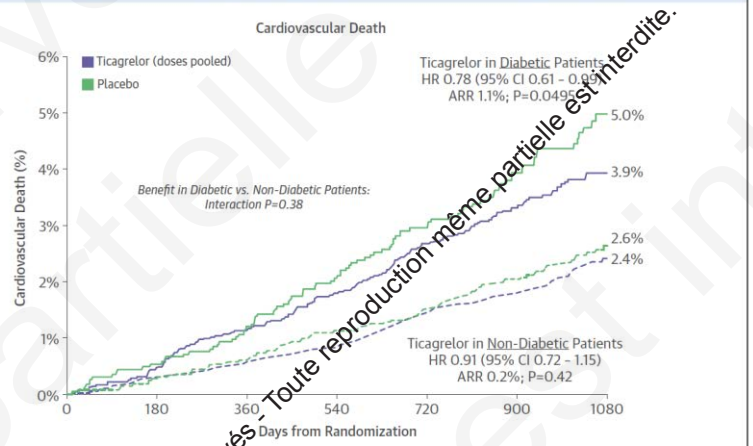


ARR = absolute risk reduction; CI = confidence interval; CV = cardiovascular; HR = hazard ratio; ITT = intention to treat; MACE = major adverse cardiovascular events; MI = myocardial infarction.

Bhatt et al, JACC 2016;67:2732-40

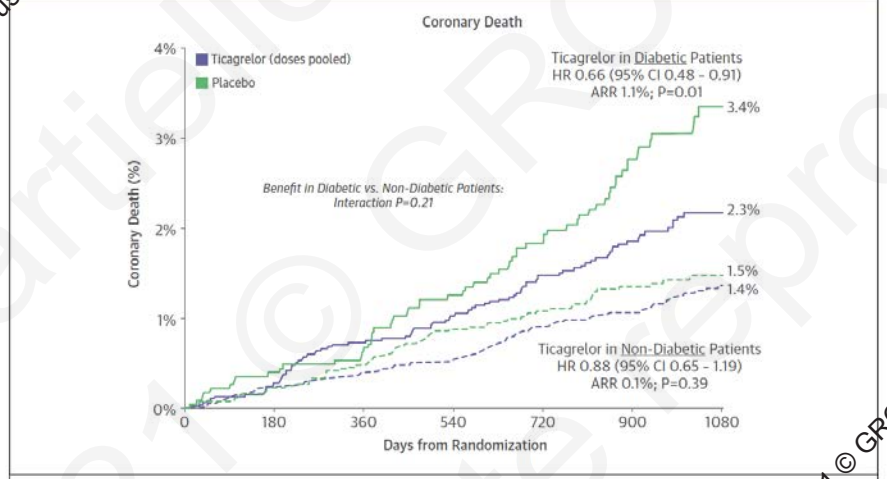
PEGASUS

FIGURE 2 Rates of CV Deaths in the Pooled Ticagrelor Versus Placebo Arms for Patients With and Without Diabetes



Abbreviations as in Figure 1.

FIGURE 3 Rates of Coronary Deaths in the Pooled Ticagrelor Versus Placebo Arms for Patients With and Without Diabetes



Abbreviations as in Figure 1.

TABLE 3 Individual Efficacy and Safety Endpoints Versus Placebo for the Pooled Ticagrelor Doses, 90-mg Dose, and 60-mg Dose in Patients With Diabetes

	Ticagrelor Dose	Placebo	Hazard Ratio (95% CI)	p Value
Pooled Ticagrelor Doses				
Efficacy	(n = 4,549)	(n = 2,257)		
MACE	10.08	11.60	0.84 (0.72-0.99)	0.0348
CV death	3.92	4.97	0.78 (0.61-0.99)	0.0495
MI	5.88	6.51	0.89 (0.72-1.10)	0.28
Stroke	1.79	2.46	0.69 (0.49-0.99)	0.0447
All-cause death	6.23	7.11	0.86 (0.70-1.05)	0.15
CHD death	2.18	3.35	0.66 (0.48-0.91)	0.011
Safety	(n = 4,497)	(n = 2,238)		
TIMI major bleeding	2.56	0.98	2.56 (1.52-4.33)	0.0004
TIMI major or minor bleeding	3.76	1.32	2.91 (1.84-4.59)	<0.0001
Ticagrelor 90-mg Dose				
Efficacy	(n = 2,241)	(n = 2,257)		
MACE	10.14	11.60	0.85 (0.71-1.01)	0.0934
CV death	4.07	4.97	0.82 (0.62-1.10)	0.19
MI	5.79	6.51	0.88 (0.69-1.13)	0.31
Stroke	1.82	2.46	0.74 (0.45-1.06)	0.0914
All-cause death	6.28	7.11	0.88 (0.70-1.12)	0.30
CHD death	2.22	3.35	0.68 (0.47-0.99)	0.0491
Safety	(n = 2,216)	(n = 2,238)		
TIMI major bleeding	2.62	0.98	2.67 (1.52-4.71)	0.0007
TIMI major or minor bleeding	4.34	1.32	3.48 (2.15-5.63)	<0.0001
Ticagrelor 60-mg Dose				
Efficacy	(n = 2,308)	(n = 2,257)		
MACE	10.00	11.60	0.83 (0.69-1.004)	0.0547
CV death	3.79	4.97	0.74 (0.55-0.99)	0.0428
MI	5.97	6.51	0.90 (0.70-1.15)	0.39
Stroke	1.77	2.46	0.69 (0.46-1.06)	0.0906
All-cause death	6.18	7.11	0.84 (0.66-1.06)	0.15
CHD death	2.14	3.35	0.64 (0.43-0.94)	0.0214
Safety	(n = 2,281)	(n = 2,238)		
TIMI major bleeding	2.51	0.98	2.47 (1.40-4.35)	0.0018
TIMI major or minor bleeding	3.22	1.32	2.39 (1.45-3.94)	0.0007

Values are 3-year Kaplan-Meier event rates expressed as % unless otherwise indicated.
CHD = coronary heart disease; CI = confidence interval; CV = cardiovascular; MACE = major adverse cardiovascular events; MI = myocardial infarction; TIMI = Thrombolysis In Myocardial Infarction.

Bhatt et al, JACC 2016;67:2732-40

Extended Duration of Dual-Antiplatelet Therapy After Percutaneous Coronary Intervention: How Long Is Too Long?

Charles E. Howard, MD; Vijay Nambi, MD, PhD; Hani Jneid, MD; Umair Khalid, MD

Table 1. Randomized Controlled Trials Examining Extended Duration of Dual-Antiplatelet Therapy

Trial and Year	Duration Comparison, mo	No. of Participants	Primary Efficacy End Point	Primary Efficacy End Point Result	Bleeding Definition	Bleeding End Point Result	$P2Y_{12}$ Inhibitor	Stent Type	Patients With ACS, %
DAPT 2014[5]	12 vs 30	9961	1. Composite of death, MI, and stroke 2. Stent thrombosis.	Decrease with extended DAPT for both the composite end point (4.3% vs 5.9%) and stent thrombosis (0.4% vs 1.4%)	GUSTO severe or moderate bleeding*	Statistically significant increase in extended DAPT (2.5% vs 1.6%), driven by moderate GUSTO bleeding	Clopidogrel (65%) or prasugrel (35%)	Sirolimus or paclitaxel in ≈40%, zotarolimus or everolimus in ≈60%	≈40
DES-LATE 2014[4]	12 vs 36	5045	Composite of cardiovascular death, MI, and stroke	No difference	TIMI major†	No statistical difference but trend t oward increase in extended DAPT	Clopidogrel	Sirolimus or paclitaxel in ≈65%, zotarolimus or everolimus in ≈30%	≈60
PEGASUS 2015[2]	12 vs 36	21 162	Composite of cardiovascular death, MI, and stroke	Decreased with extended DAPT (7.85% vs 9.04%), primarily driven by MI and stroke.	TIMI major†	Statistically significant increase in extended DAPT (2.6% vs 1.1%)	Ticagrelor	No stenting in 20%, BMS in 41%, DES in 39%	100% with ACS 1–3 y prior
OPTIDUAL 2015[3]	12 vs 33	1385	Composite of death, MI, stroke, and major bleeding	No difference	International Society on Thrombosis and Hemostasis‡	No difference	Clopidogrel	Sirolimus or paclitaxel in ≈35%, zotarolimus or everolimus in ≈60%	≈35

ACS indicates acute coronary syndrome; BMS, bare metal stent; DAPT, Dual Antiplatelet Therapy; DES, drug-eluting stent; DES-LATE, Optimal Duration of Clopidogrel Therapy With DES to Reduce Late Coronary Arterial Thrombotic Event; MI, myocardial infarction; OPTIDUAL, Optimal Dual Antiplatelet Therapy; PEGASUS, Prevention of Cardiovascular Events in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin; TIMI, Thrombolysis in Myocardial Infarction.

*GUSTO (Global Utilization of Streptokinase and Tpa for Occluded Arteries) severe indicates intracerebral hemorrhage or bleed, resulting in substantial hemodynamic compromise requiring treatment. GUSTO moderate indicates requiring blood transfusion but not resulting in hemodynamic compromise.

†TIMI major: any intracranial bleeding (excluding microhemorrhages <10 mm evident only on gradient-echo magnetic resonance imaging) or clinically overt signs of hemorrhage associated with a decrease in hemoglobin of ≥5 g/dL.

‡International Society on Thrombosis and Hemostasis: fatal bleeding and/or symptomatic bleeding in a critical area or organ and/or bleeding causing a decrease in hemoglobin level of ≥20 g/L or leading to transfusion of ≥2 units of whole blood or red cells.

Howard et al, J Am Heart assoc 2019

Extended Duration of Dual-Antiplatelet Therapy After Percutaneous Coronary Intervention: How Long Is Too Long?

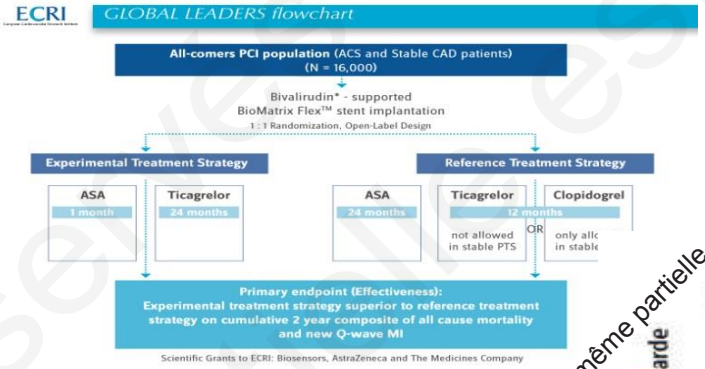
Charles E. Howard, MD; Vijay Nambi, MD, PhD; Hani Jneid, MD; Umair Khalid, MD

Table 2. Clinical Characteristics Benefiting From Extended-Duration DAPT

Clinical Characteristics Benefiting From Extended-Duration DAPT
ACS presentation/prior ACS event
Peripheral arterial disease
Diabetes mellitus
Renal dysfunction
Current cigarette use
Left ventricular ejection fraction <30%
Congestive heart failure
Increased procedure complexity
Stent diameter <3 mm
Vein graft PCI
High CAD burden
Older-generation stents

ACS indicates acute coronary syndrome; CAD, coronary artery disease; DAPT, dual antiplatelet therapy; PCI, percutaneous coronary intervention.

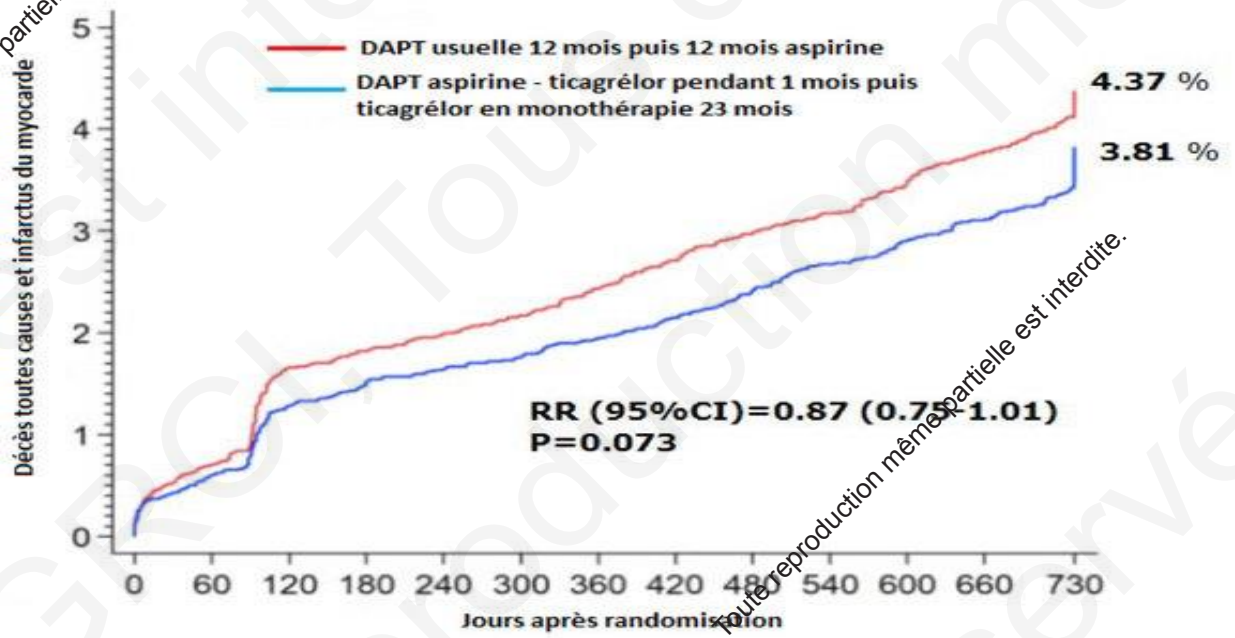
Howard et al, J Am Heart assoc 2019



GLOBAL LEADERS

Patient SCA et stables
Aspirine + ticagrelor / clopidogrel 12 mois
Ou
Aspirine 1 mois et ticagrelor 24 mois
16000 Patients
Endpoint : mortalité et IDM

Décès IDM



Diabetes mellitus					
Yes	102/2049	126/1989	0·78 (0·60–1·01)	0·063	0·33
No	202/5925	222/5994	0·92 (0·76–1·11)	0·38	

Vranks et al, Lancet 2018

THEMIS

- **Introduction**
  - Aucune preuve formelle du bénéfice CV d'une BiAAP pour la prévention des évènements CV chez le DT2 coronarien stable (6 mois) sans ATCD d'IDM ou d'AVC
- **Méthode**
  - Étude randomisée, double aveugle, internationale
    - Ticagrelor 90 mg × 2/j (*pour les premiers patients puis 60 mg × 2/j après les résultats de PEGASUS-TIMI 54)* + aspirine 75-150 mg × 1/j contre aspirine seule 75-150 mg × 1/j

    n = 19 220
    - DT2 ≥ 50 ans : sténose coronaire ≥ 50 % (mono à tritronc.), ATCD ATL ou PAC
  - Âge médian = 66 ans, ♂ = 69 %, IMC = 29 kg/m^2
  - Durée médiane DT2 = 10 ans, HbA1c médiane = 7,1 %, DFG médian = 75 mL/min
  - Revasc. tous types = 79 %
  - Critère principal : mortalité CV, IDM, AVC
    - Suivi médian = 39,9 mois

Steg et al, NEJM 2019

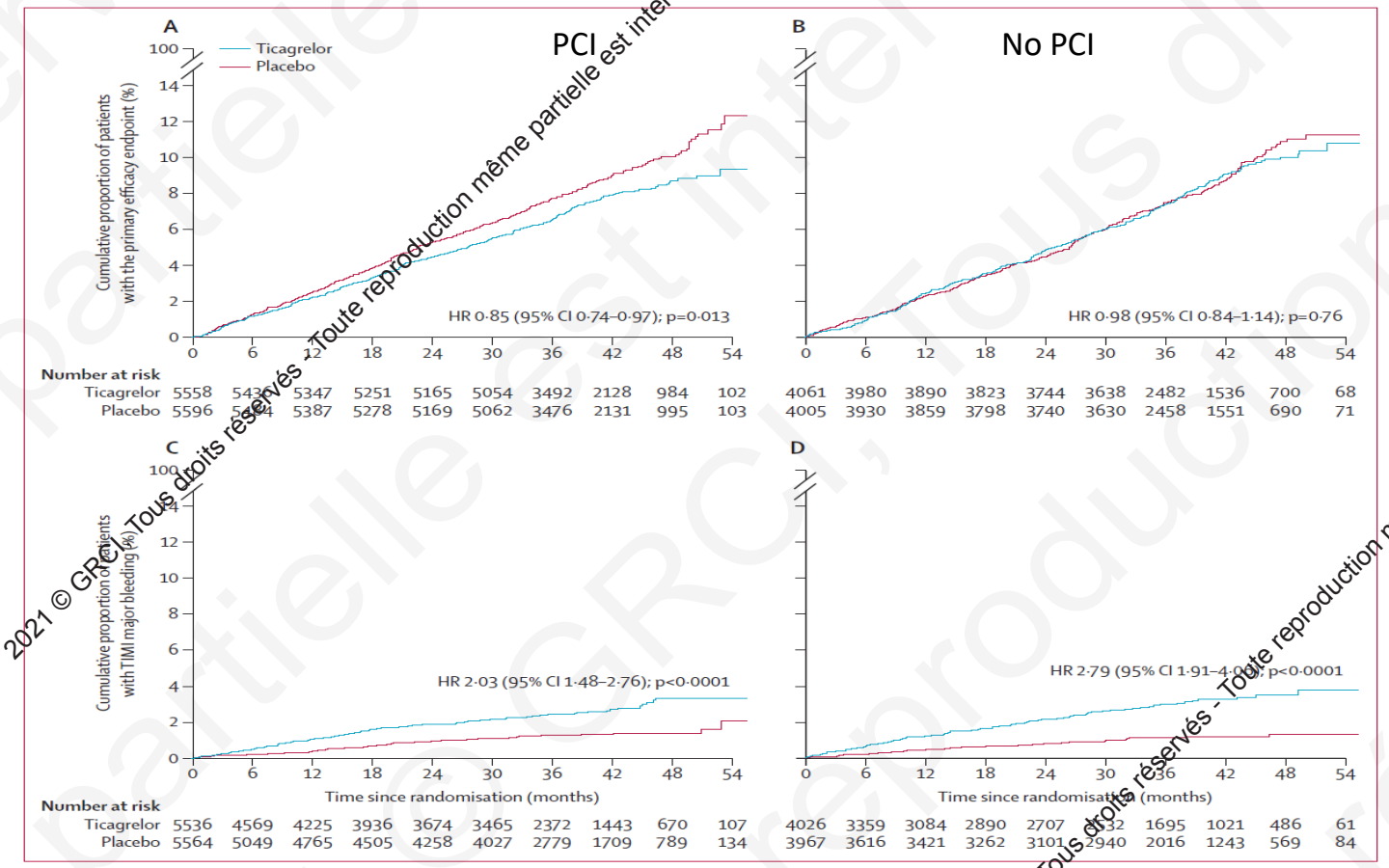


Figure 1: Kaplan-Meier event curves for the primary efficacy endpoint in patients with a history of PCI (A) and no history of PCI (B), and TIMI major bleeding in patients with a history of PCI (C) and no history of PCI (D)
PCI=percutaneous coronary intervention. HR=hazard ratio.

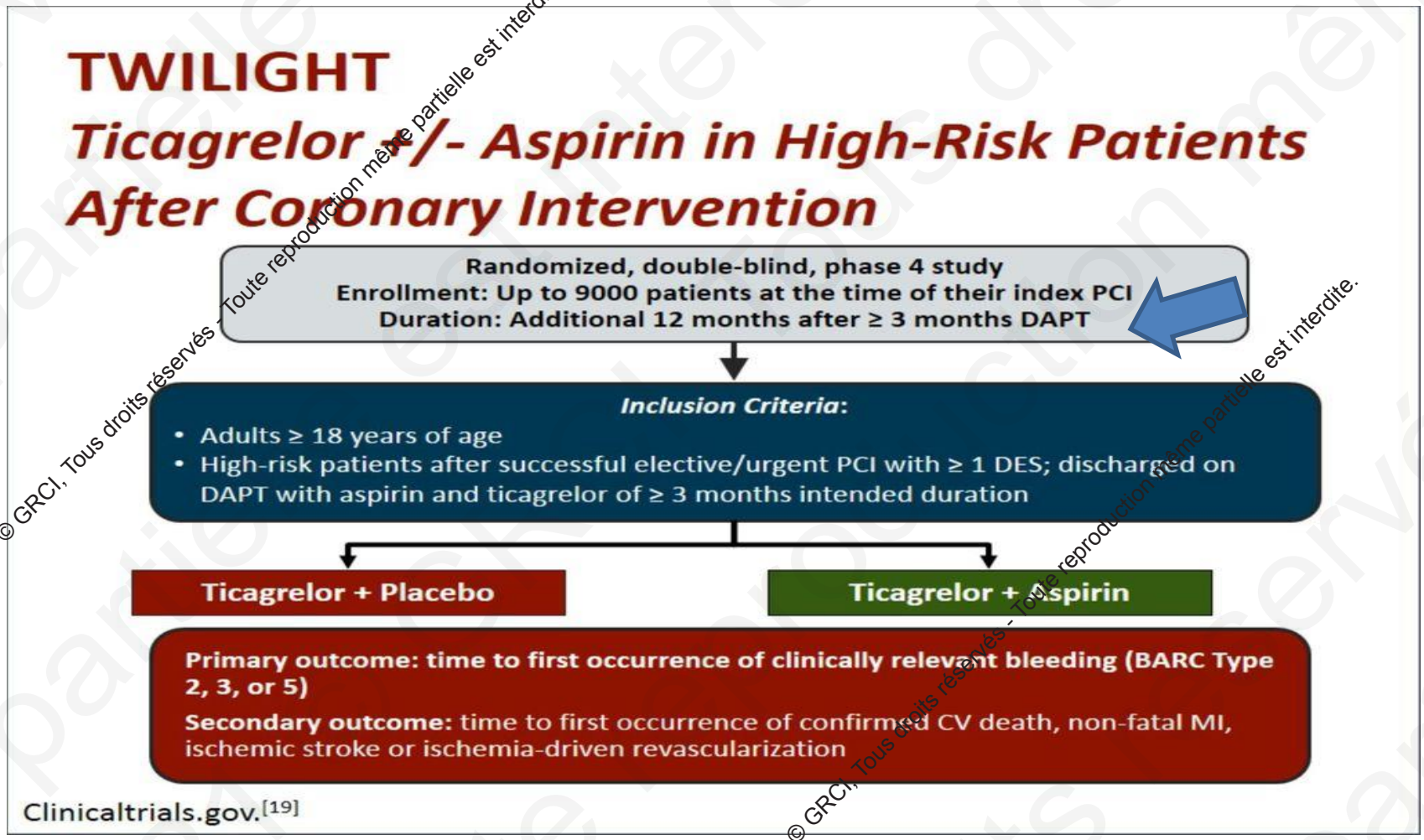
THEMIS PCI

MACE

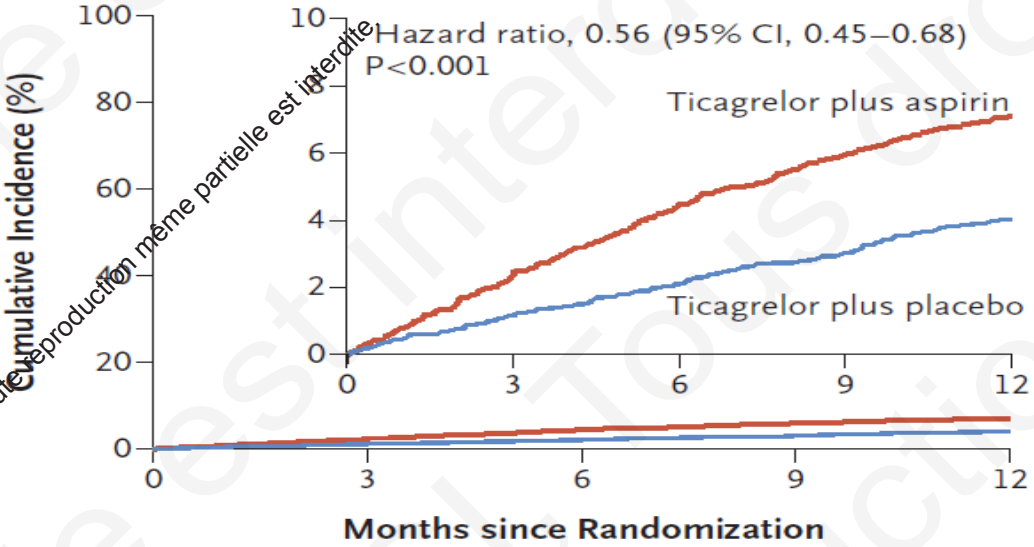
BLEEDING

Bhatt et al, Lancet 2019

Ticagrelor seul 3 mois après ATL (elective ou urgente)



Mehran et al, NEJM 2019



No. at Risk

Ticagrelor plus aspirin	3564	3454	3357	3277	3213
Ticagrelor plus placebo	3555	3474	3424	3366	3321

Figure 2. Kaplan–Meier Estimates of the Incidence of BARC Type 2, 3 or 5 Bleeding 1 Year after Randomization (Intention-to-Treat Population).

The hazard ratio shown is for ticagrelor plus placebo versus ticagrelor plus aspirin. Bleeding Academic Research Consortium (BARC) types range from 0 (no bleeding) to 5 (fatal bleeding). The inset shows the same data on an expanded y axis. CI denotes confidence interval.

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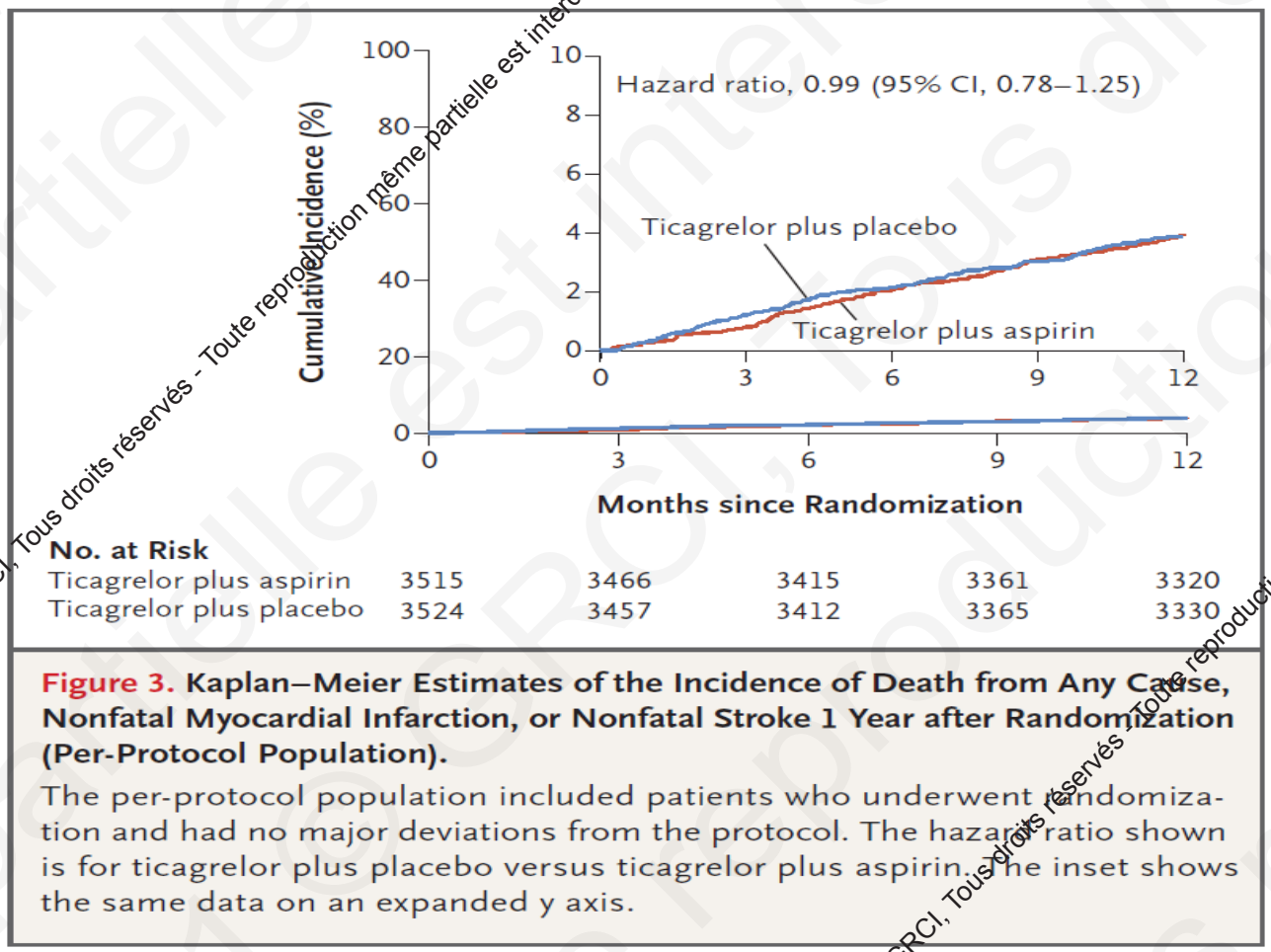

Figure 3. Kaplan–Meier Estimates of the Incidence of Death from Any Cause, Nonfatal Myocardial Infarction, or Nonfatal Stroke 1 Year after Randomization (Per-Protocol Population).

The per-protocol population included patients who underwent randomization and had no major deviations from the protocol. The hazard ratio shown is for ticagrelor plus placebo versus ticagrelor plus aspirin. The inset shows the same data on an expanded y axis.

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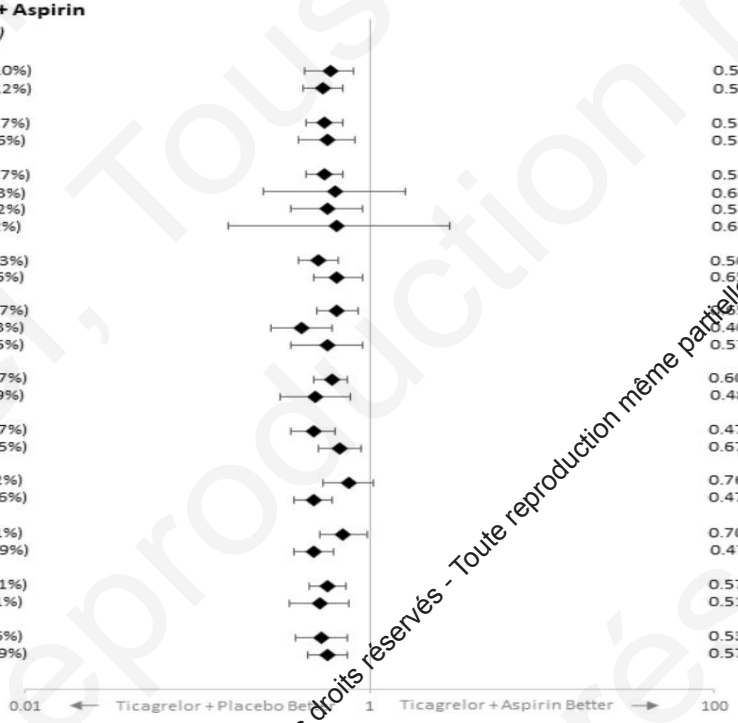
Figure S2. Subgroup Analysis for Primary Endpoint of BARC 2, 3, or 5 Bleeding in ITT Cohort*

Subgroups	No. of patients	Ticagrelor + Placebo	Ticagrelor + Aspirin	HR [95% CI]
		no. of events (% of patients)		
Age (years)				
<65	3400	59 (3.5%)	100 (6.0%)	0.59 [0.42 – 0.81]
≥65	3719	82 (4.5%)	150 (8.2%)	0.54 [0.41 – 0.70]
Sex				
Male	5428	99 (3.7%)	178 (6.7%)	0.55 [0.43 – 0.70]
Female	1688	42 (5.0%)	72 (8.6%)	0.57 [0.39 – 0.83]
Race/Ethnicity				
White	4923	104 (4.3%)	189 (7.7%)	0.55 [0.43 – 0.70]
Black	269	7 (5.5%)	11 (8.3%)	0.63 [0.24 – 1.66]
Asian	1784	27 (3.0%)	46 (5.2%)	0.57 [0.35 – 0.92]
Other	143	3 (4.0%)	4 (6.2%)	0.65 [0.15 – 2.90]
Diabetes Mellitus				
No	4499	83 (3.8%)	164 (7.3%)	0.50 [0.39 – 0.66]
Yes	2620	58 (4.5%)	86 (6.6%)	0.65 [0.47 – 0.91]
Region of Enrollment				
North America	2972	83 (5.7%)	126 (8.7%)	0.65 [0.49 – 0.85]
Europe	2509	32 (2.6%)	79 (6.3%)	0.40 [0.27 – 0.61]
Asia	1638	26 (3.2%)	45 (5.5%)	0.57 [0.35 – 0.92]
CKD (eGFR <60 ml/min)				
No	5690	113 (4.0%)	188 (6.7%)	0.60 [0.47 – 0.75]
Yes	1145	25 (4.5%)	50 (8.9%)	0.48 [0.30 – 0.78]
BMI (kg/m²)				
Below median	3559	64 (3.7%)	135 (7.7%)	0.47 [0.35 – 0.63]
Above median	3531	77 (4.4%)	113 (6.5%)	0.67 [0.50 – 0.90]
Indication for PCI				
Stable	2503	60 (4.8%)	75 (6.2%)	0.76 [0.54 – 1.06]
ACS	4614	81 (3.6%)	175 (7.6%)	0.47 [0.36 – 0.61]
Total stent length (mm)				
<30	3036	64 (4.4%)	93 (6.1%)	0.70 [0.51 – 0.97]
≥30	4082	77 (3.8%)	157 (7.9%)	0.47 [0.36 – 0.62]
Prior MI				
No	5079	104 (4.2%)	179 (7.1%)	0.57 [0.45 – 0.73]
Yes	2040	37 (3.7%)	71 (7.1%)	0.51 [0.34 – 0.76]
Multivessel Disease				
No	2422	47 (4.1%)	94 (7.6%)	0.53 [0.37 – 0.75]
Yes	4697	94 (4.0%)	156 (6.9%)	0.57 [0.44 – 0.74]



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Conclusion

- Le traitement antiagrégant plaquettaire des diabétiques parait équivalent à celui des non diabétiques
- Beaucoup d'interrogations sur l'aspirine mais pas encore de réponses
- Concernant les P2Y12, il ne semble pas y avoir de différence notable.
- La prolongation du DAPT notamment avec ticagrelor parait l'option la plus logique si le risque de saignement n'est pas trop augmenté

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