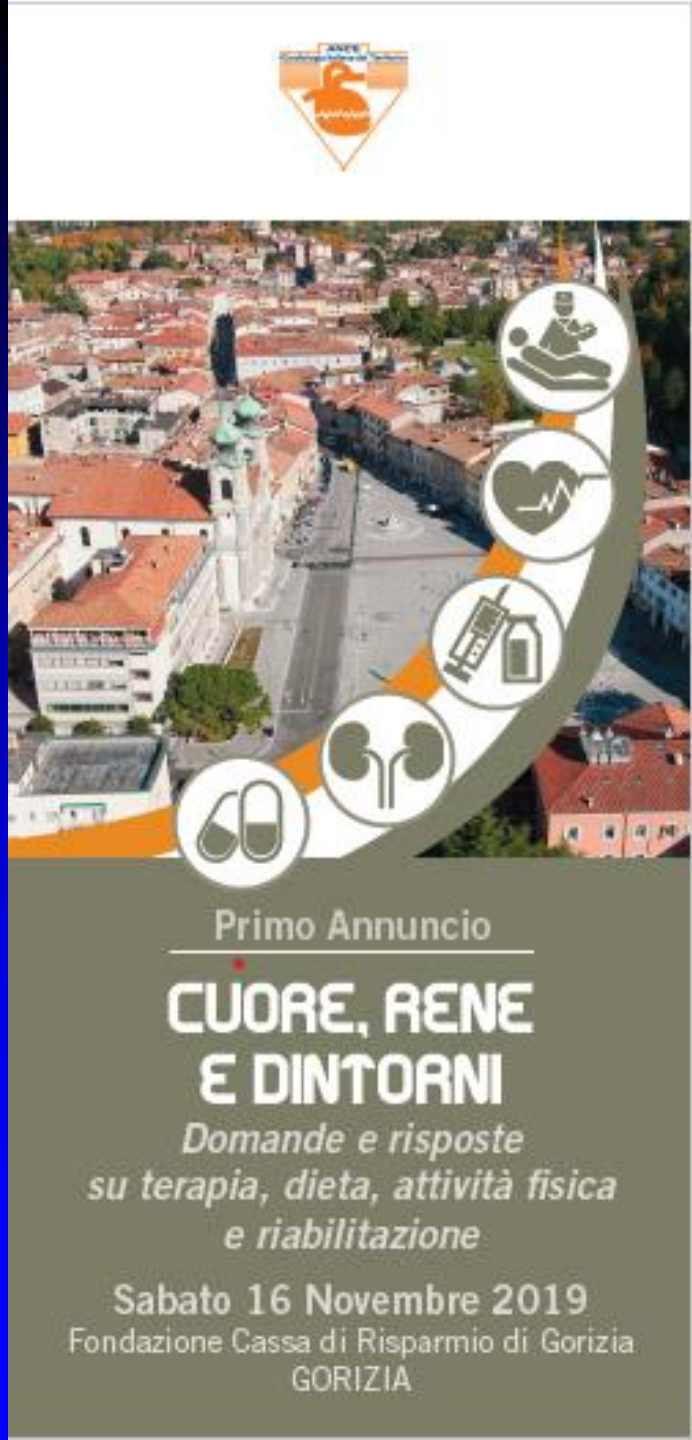
Gestione sul territorio della terapia antiaggregante e anticoagulante nel paziente iperteso e nel paziente nefropatico

dr. Roberto Marini

Responsabile Cardiologia

Policlinico Triestino «*Salus*» - Trieste



Linee guida europee 2016 sulla prevenzione delle malattie cardiovascolari nella pratica clinica

Sesta Task Force congiunta della Società Europea di Cardiologia e di altre Società sulla Prevenzione delle Malattie Cardiovascolari nella Pratica Clinica (costituita da rappresentanti di 10 società e da esperti invitati)

redatte con il contributo straordinario dell'Associazione Europea per la Prevenzione e Riabilitazione Cardiovascolare (EACPR)

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con il contributo di: Simone Binno (Italia)

Tabella 17. Farmaci da preferire per determinate condizioni.

Condizione	Farmaco
Danno d'organo asintomatico	
IVS	ACE-inibitori, calcioantagonisti, ARB
Aterosclerosi asintomatica	Calcioantagonisti, ACE-inibitori
Microalbuminuria	ACE-inibitori, ARB
Disfunzione renale	ACE-inibitori, ARB
Eventi CV clinici	
Pregresso ictus	Qualsiasi farmaco in grado di ridurre efficacemente la PA
Pregresso IM	Betabloccanti, ACE-inibitori, ARB
Angina pectoris	Betabloccanti, calcioantagonisti
Scompenso cardiaco	Diuretici, betabloccanti, ACE-inibitori, ARB, antagonisti dei recettori dei mineralcorticoidi
Aneurisma aortico	Betabloccanti
Fibrillazione atriale: prevenzione	Considerare ARB, ACE-inibitori, betabloccanti o antagonisti dei recettori dei mineralcorticoidi
Fibrillazione atriale: controllo della frequenza	Betabloccanti, calcioantagonisti non diidropiridinici
ESRD/proteinuria	ACE-inibitori, ARB
Arteriopatia periferica	ACE-inibitori, calcioantagonisti
Altro	
Ipertensione sistolica isolata (nell'anziano)	Diuretici, calcioantagonisti
Diabete mellito	ACE-inibitori, ARB
Gravidanza	Metildopa, betabloccanti, calcioantagonisti
Razza nera	Diuretici, calcioantagonisti

PERCHÉ LE NUOVE LINEE GUIDA?
DIMENSIONI DEL PROBLEMA

- La prevalenza globale dell'ipertensione arteriosa nel 2015 era stimata in circa *1.13 miliardi*
- La prevalenza complessiva negli adulti è circa *il 30-45%* con una prevalenza *> del 60%* nella popolazione con *età > 60 anni*
- Si stima che il numero della popolazione ipertesa incrementerà del *15-20% entro il 2025*
- La diagnosi di ipertensione arteriosa è spesso *misconosciuta*

Table 4. Factors influencing CV risk in patients with hypertension

Demographic characteristics and laboratory parameters
Sex[a] (men > women)
Age[a]
Smoking – current or past history[a]
Total cholesterol [a] and HDL-C
Uric acid
Diabetes[a]
Overweight or obesity
Family history of premature CVD (men aged < 55 years and women aged < 65 years)
Family or parental history of early onset hypertension
Early onset menopause
Sedentary lifestyle
Psychosocial and socioeconomic factors
Heart rate (resting values > 80 beats per min)

[a]CV risk factors included in the SCORE system

www.escardio.org/guidelines

2018 ESC/ESH Guidelines for the management of arterial hypertension
European Heart Journal (2018) doi:10.1093/eurheartj/ehy339
European Journal of Hypertension (2018) doi:10.1097/HJH.0000000000001940

STRATIFICAZIONE DEL RISCHIO CARDIOVASCOLARE

Il rischio cardiovascolare è strettamente dipendente dal grado di compromissione d'organo, definito per la prima volta con un nuovo acronimo: HMOD (Hypertension-mediated organ damage)

quantificare con chiarezza e precisione l'HMOD diventerà fondamentale a *fini prognostici*

Ipertrofia ventricolare sinistra
Microalbuminuria
Volume del filtrato glomerulare stimato < 60 ml/min/1.73 m²
Indice gamba-braccio < 0.9
Retinopatia avanzata

Malattia cardiovascolare, cerebrovascolare o renale
Malattia cereberovascolare
Coronaropatia
Placche aterosclerotiche visibili con tecniche di imaging
Scompenso cardiaco
Vasculopatia degli arti inferiori
Fibrillazione atriale

Figura 5: Interessamento d'organo nelle Linee Guida ESC/ESH 2018. La lista nella metà superiore è relativo al cosiddetto HMOD (Hypertension-mediated organ damage), fondamentale nel codificare il rischio cardiovascolare ed indirizzare la terapia. Modificato da rif. 2

mod. ESC-ESH 2018, Eur H Journal, 2018

FARMACI PER IL TRATTAMENTO DELL'IPERTENSIONE ARTERIOSA

Nelle precedenti linee guida dell'ESC erano raccomandate 5 classi di farmaci (*ACE-I, sartani, betabloccanti, Calcio-antagonisti, diuretici*) sulla base di:

-provata capacità di ridurre la PA

-riduzione degli eventi CV negli studi clinici

-ampia equivalenza sulla morbilità/mortalità CV totale

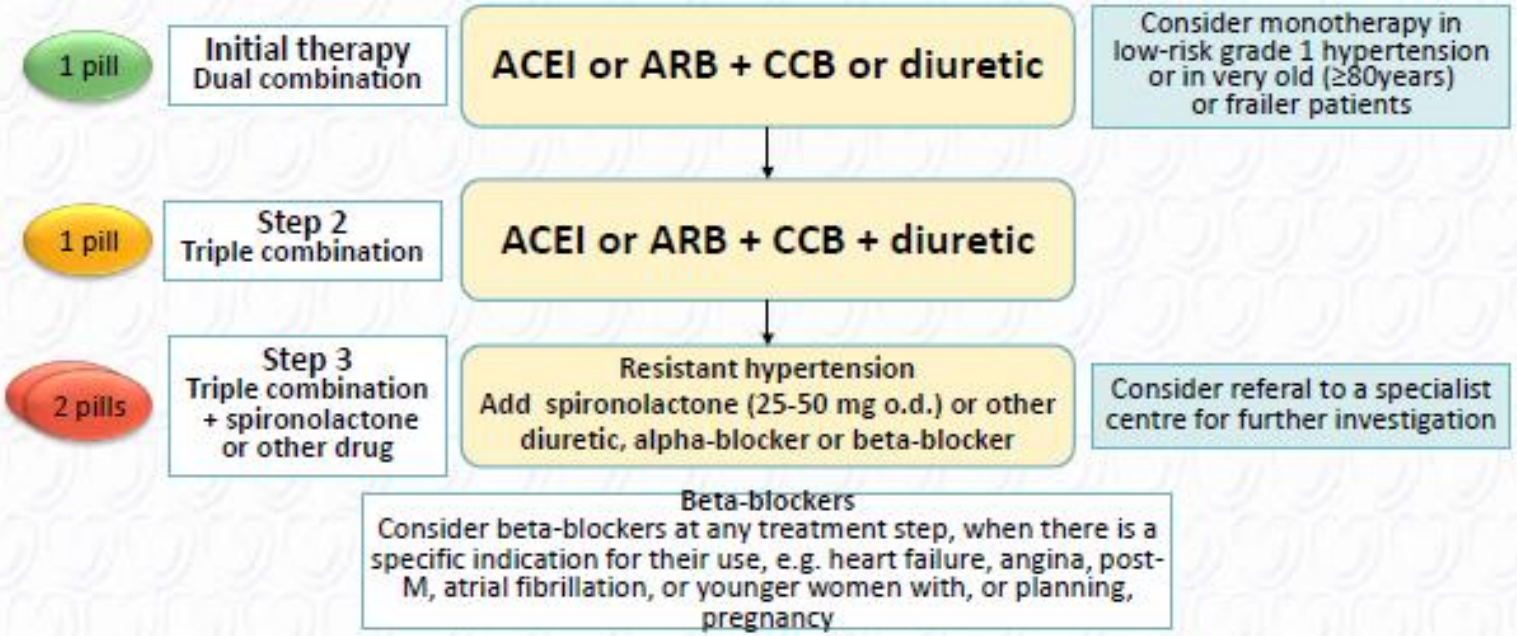
Le nuove linee guida raccomandano le stese 5 classi di farmaci

mod. ESC-ESH 2018, Eur H Journal, 2018

ESC European Society of Cardiology

European Society of Hypertension

Figure 4. Core drug-treatment strategy for uncomplicated hypertension. The core algorithm is also appropriate for most patients with HMOD, cerebrovascular disease, diabetes, or PAD



2018 ESC/ESH Guidelines for the management of arterial hypertension
European Heart Journal (2018) doi:10.1093/eurheartj/ehy339
European Journal of Hypertension (2018) doi:10.1097/HJH.0000000000001940

First step combination treatment in some specific conditions

- Diabetes: RAS blocker+CCB or D (IA)
- CAD: BB or CCB+RAS blocker (IA)
- CKD: RAS blocker+ CCB or D (loop D)
- Cerebrovascular Disease:RAS Blocker+CCB or D(IA)
- AF: BB and/or nondihCCB (IIaB)
- Hf(r/p*EF):RAS blocker+BB,D+Antialdo(IA)(*IIaB)
- COPD: RAS blocker+CCB
- LEAD: RAS blocker+CCB or D (*BB may be considered)
- Blacks: D+CCB (IB)

Definizione di fragilità

- **Fisk AA 1983**: paziente con problemi della funzione fisica e della cognitività e dei supporti sociali della gravità tale da richiede un supporto multidisciplinare.
- **Mayer-Oakes 1991**: paziente di età >75 aa con riduzione dello stato funzionale.
- **Winograd CH 1991:** paziente affetto da una delle seguenti condizioni: 1) ictus cerebrale 2) malattia cronica disabilitante 3) episodi confusionali 4) cadute 5) ridotta mobilità 6) polifarmacoterapia 7) incontinenza 8) malnutrizione 9) allettamento prolungato 10) problemi socio-economici e familiari.
- **Ory MG 1993:** grave compromissione della forza, della resistenza, dell'equilibrio e della mobilità.
- **Brown I 1995:** riduzione della capacità di svolgere attività pratiche e di gestire i rapporti sociali della vita quotidiana.
- **Gagnon AJ 1999**: soggetti >70 aa, dimessi dal un pronto soccorso ed a rischio di re-ospedalizzazioni multiple.
- **Roubenoff R 2000:** riduzione della massa e della forza muscolare

Chi è il soggetto "Fragile"?

Molto fragile !!

10 - 20% dei soggetti > 65 aa

46% dei soggetti > 85 aa

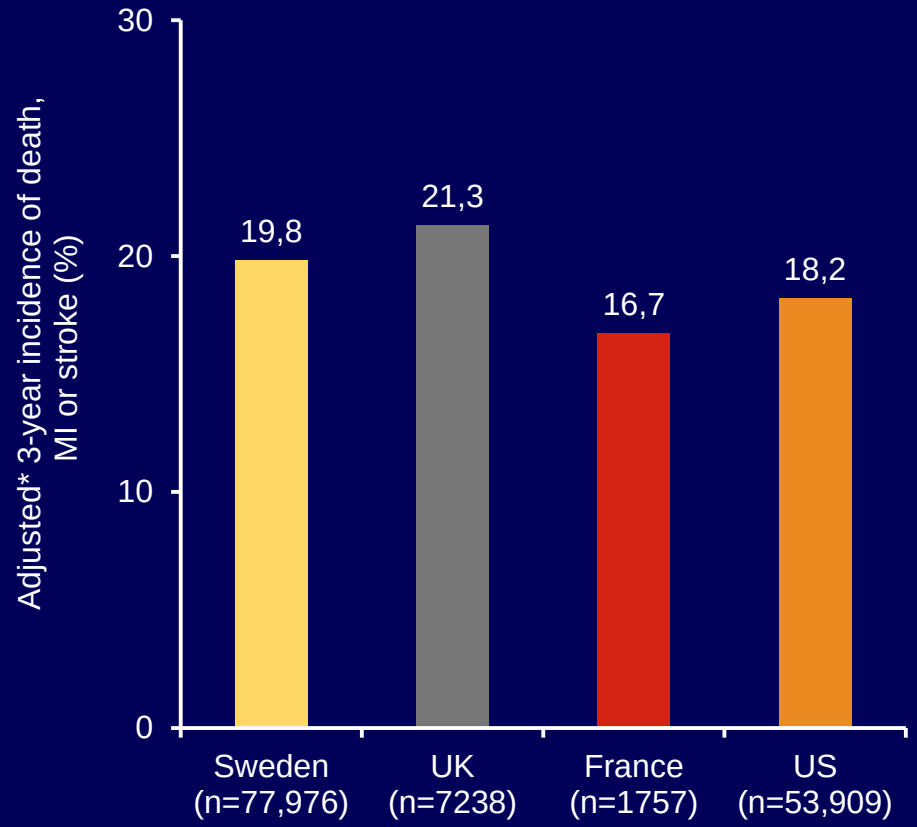
Fried L.P. in: Hazzard W.R. et al. Mc Graw Hill 1994

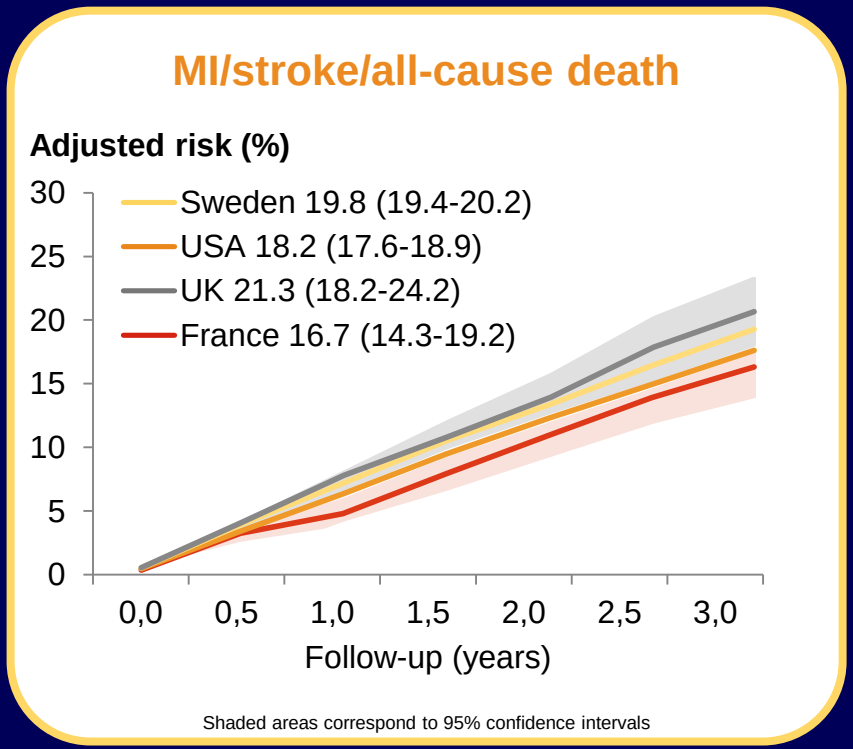
LA GESTIONE DEL PAZIENTE PANVASCOLARE IN CRONICO

La terapia antiaggregante dopo il 12 mese da una SCA: connessione tra ospedale e territorio

~1 in 5 patients were event free for the first year post-MI suffered an MI, stroke or death within 3 years

APOLLO 4-country analysis: adjusted incidence*[Rapsomaniki 2014]





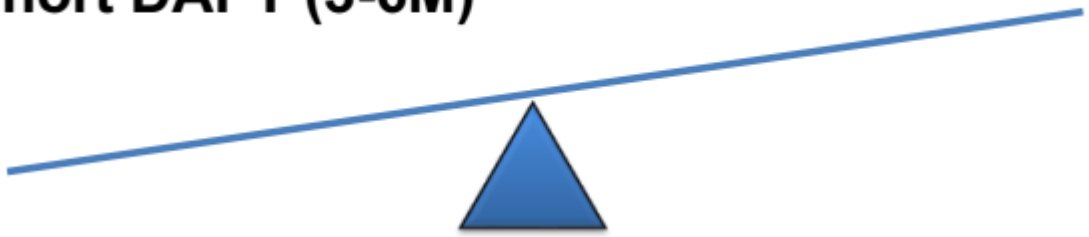
MI, myocardial infarction.

*Adjusted for differences in study populations; MI, myocardial infarction. Shaded areas / figures in brackets [95%CI]

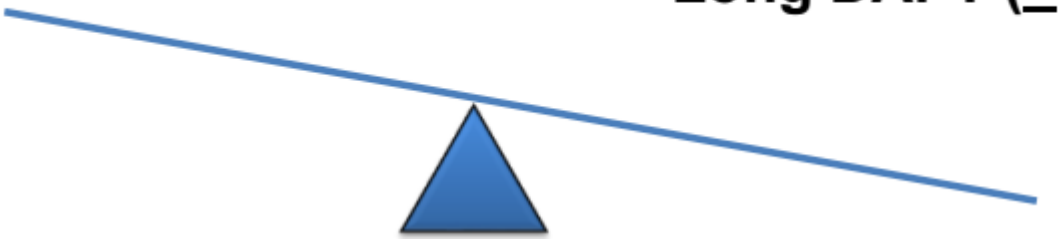
1. Rapsomaniki E *et al*. ESC Late Breaking Registry presentation 2014.

Risk vs. Benefit of DAPT

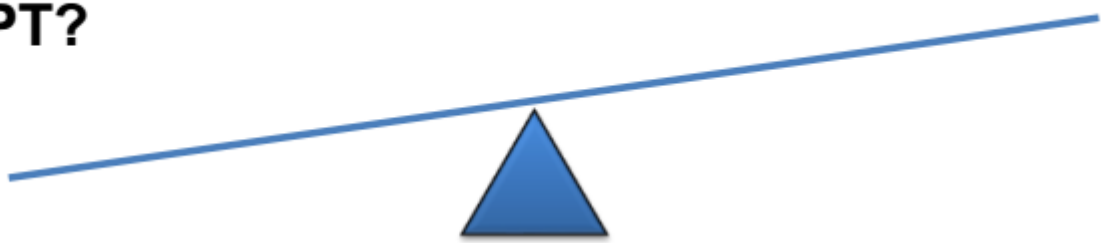
Short DAPT (3-6M)



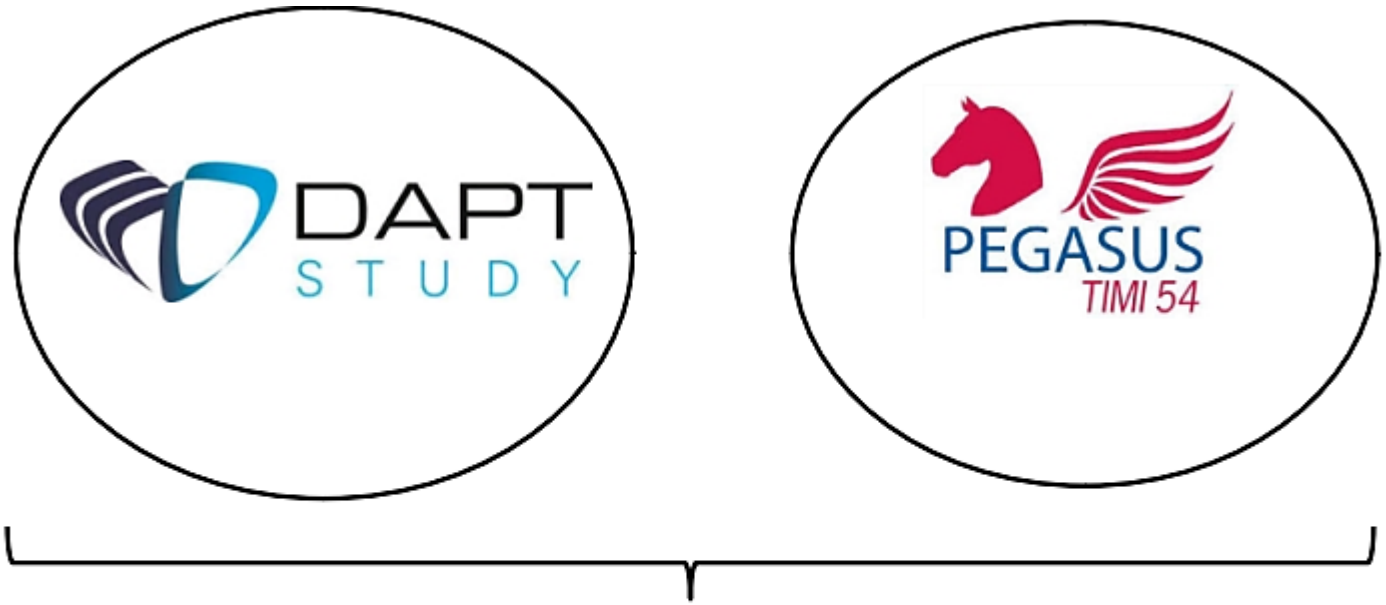
Long DAPT (≥12M)



Short DAPT
Or Long DAPT?



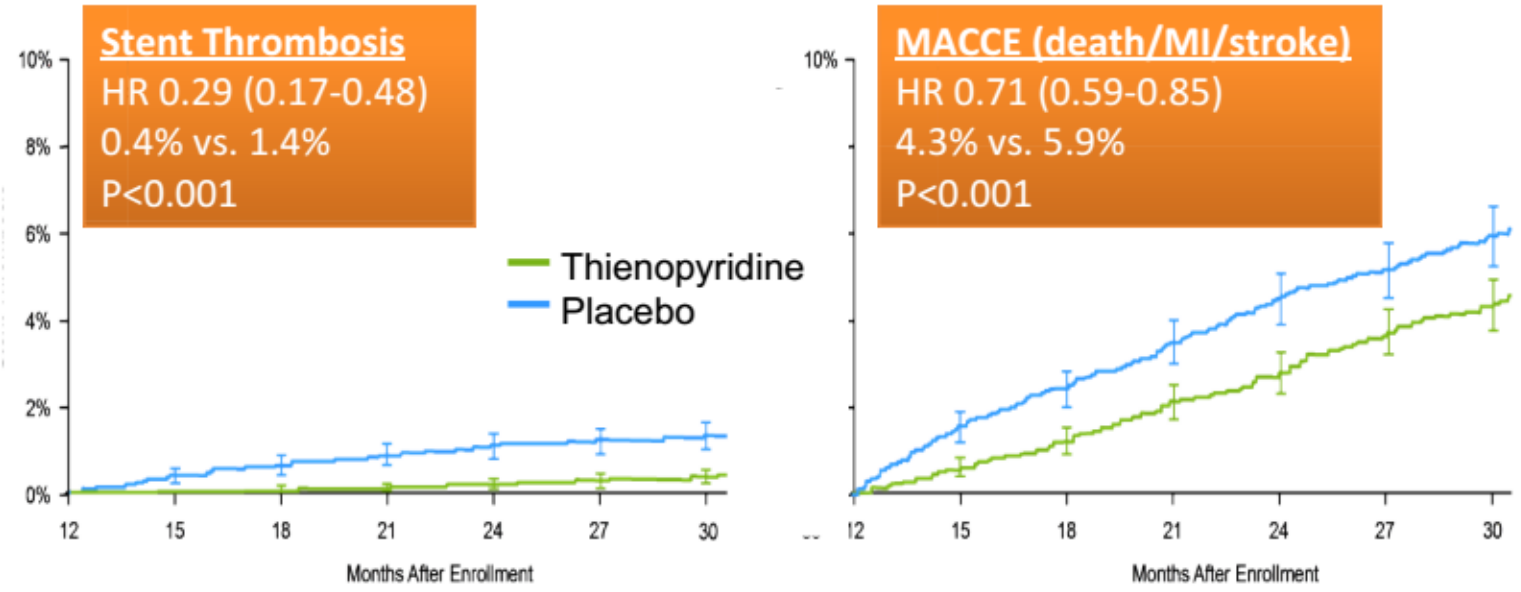
Antiplatelet Therapy Trials



Common Question: Does Ischemic Benefit outweigh Bleeding Risk of Late Dual Antiplatelet Therapy (1 or more years after stent, or MI)

Primary Results: Continued Thienopyridine vs Placebo 12 months after DES

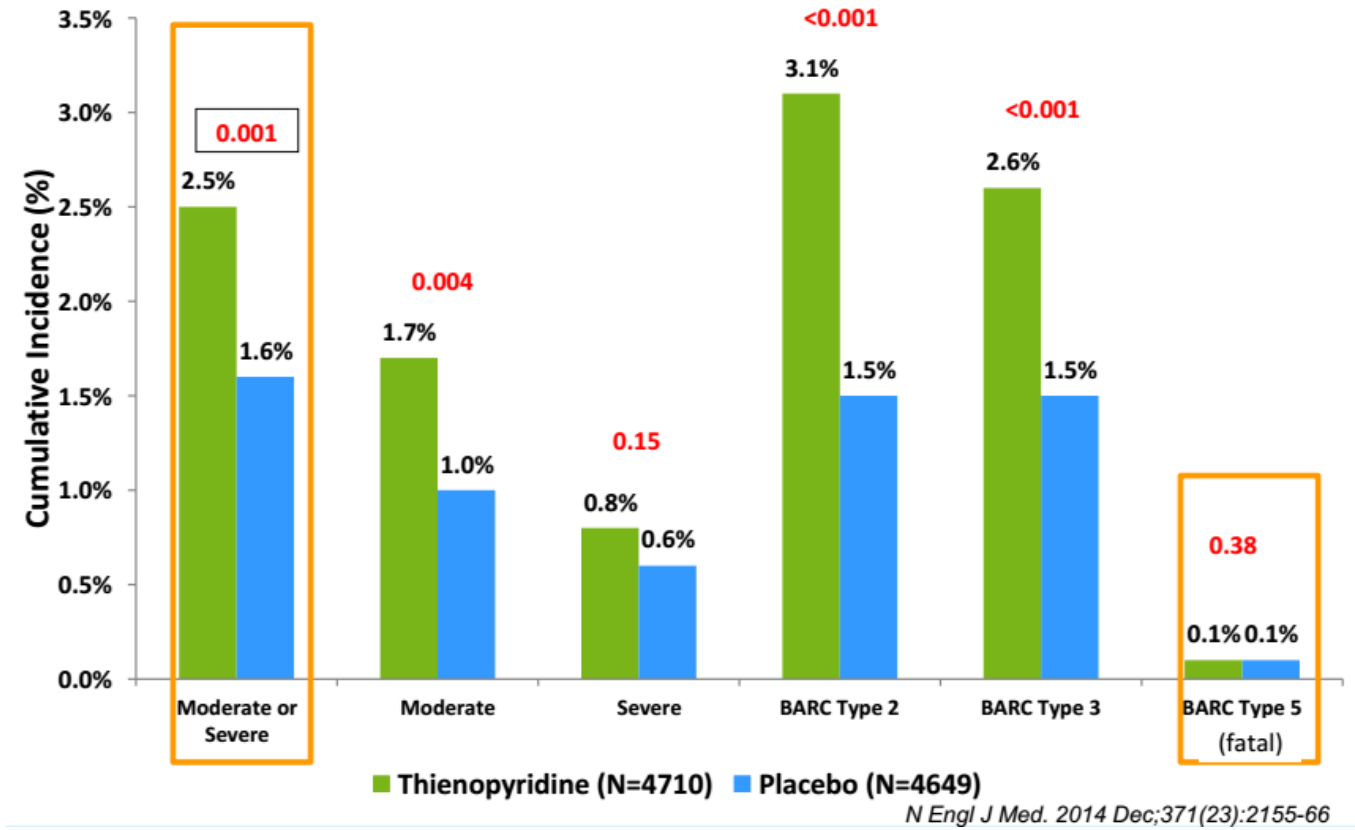
- N= 11648 total, 9961 DES treated randomized, 452 sites worldwide
- Continuing dual antiplatelet therapy beyond 12 months after coronary stenting reduced ischemic complications



Mauri, Kereiakes, Yeh et al. NEJM. 2014 Dec 4:371:2155-66.

DAPT STUDY

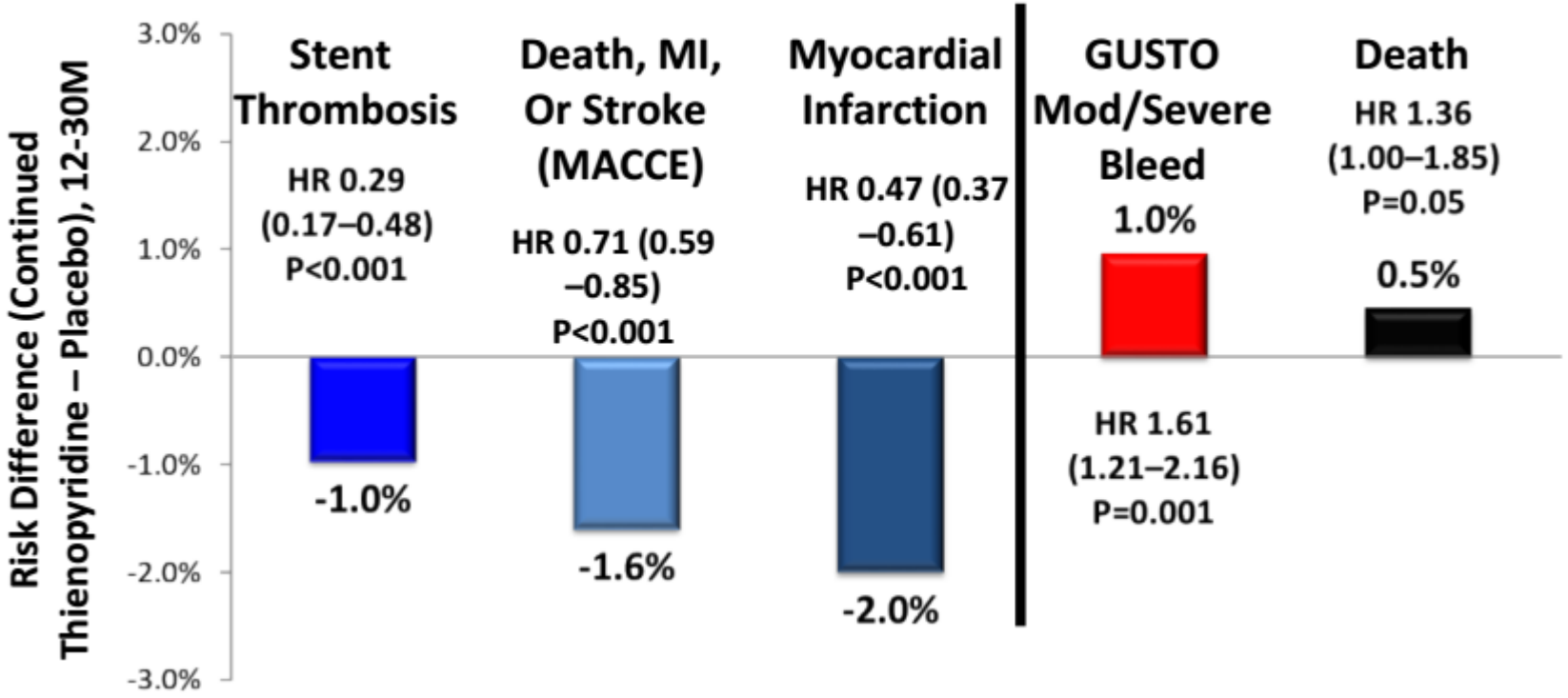
Primary Safety End Point (Moderate or Severe Bleeding): 12-30 Months



N Engl J Med. 2014 Dec;371(23):2155-66

DAPT STUDY

Continued Thienopyrine vs Placebo 1 year after PCI (N=11648)

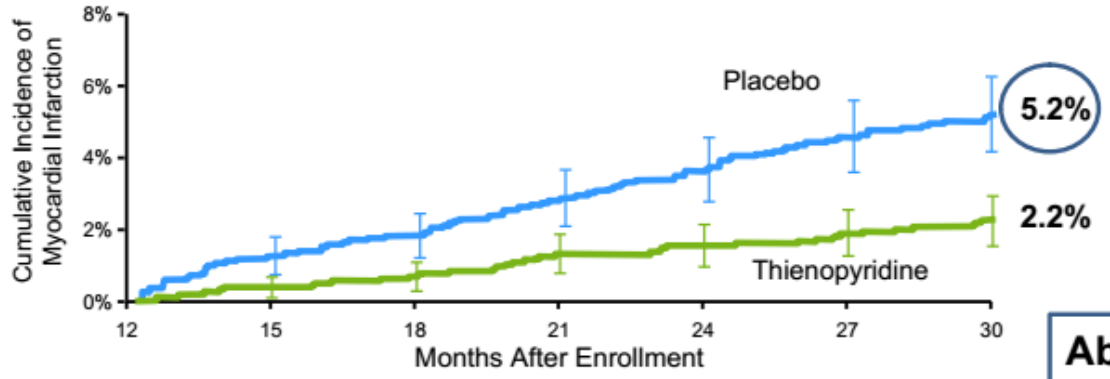


Mauri et al. NEJM. 2014 Dec 4:371:2155-66.

DAPT STUDY

Effect of Continued DAPT on MI by ACS presentation 1 year prior to randomization

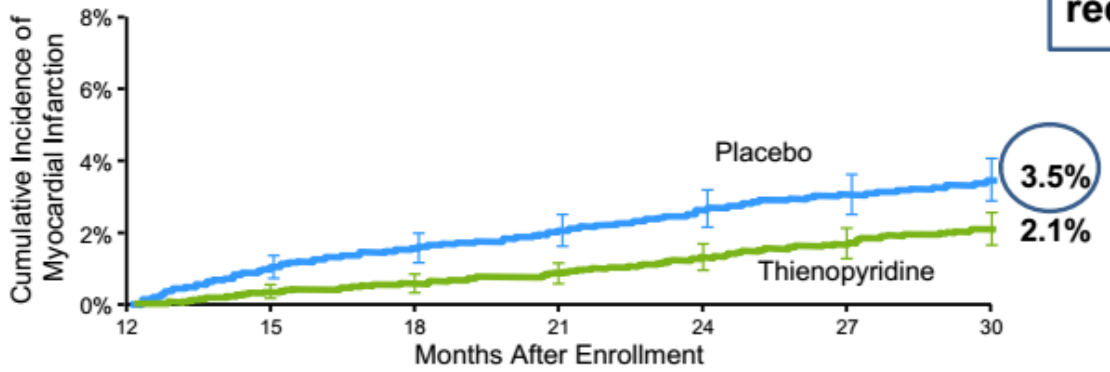
ACS Patients N=3576



HR 0.42 (0.29-0.62)
p<0.001

Absolute reduction greater in ACS, relative reduction similar

Non-ACS Patients N=8072

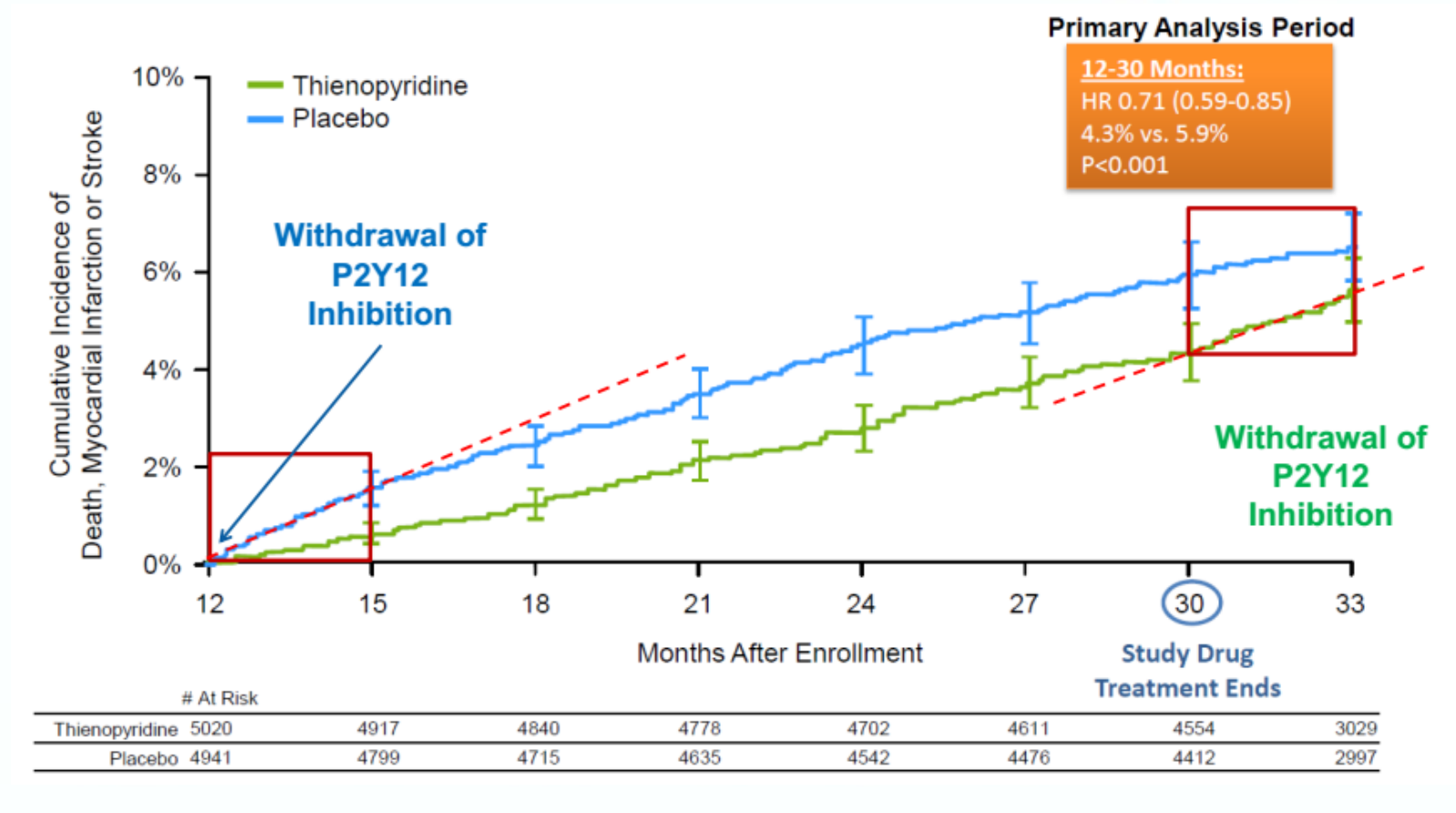


HR 0.60 (0.45-0.79)
p<0.001
P int =NS

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

DAPT STUDY

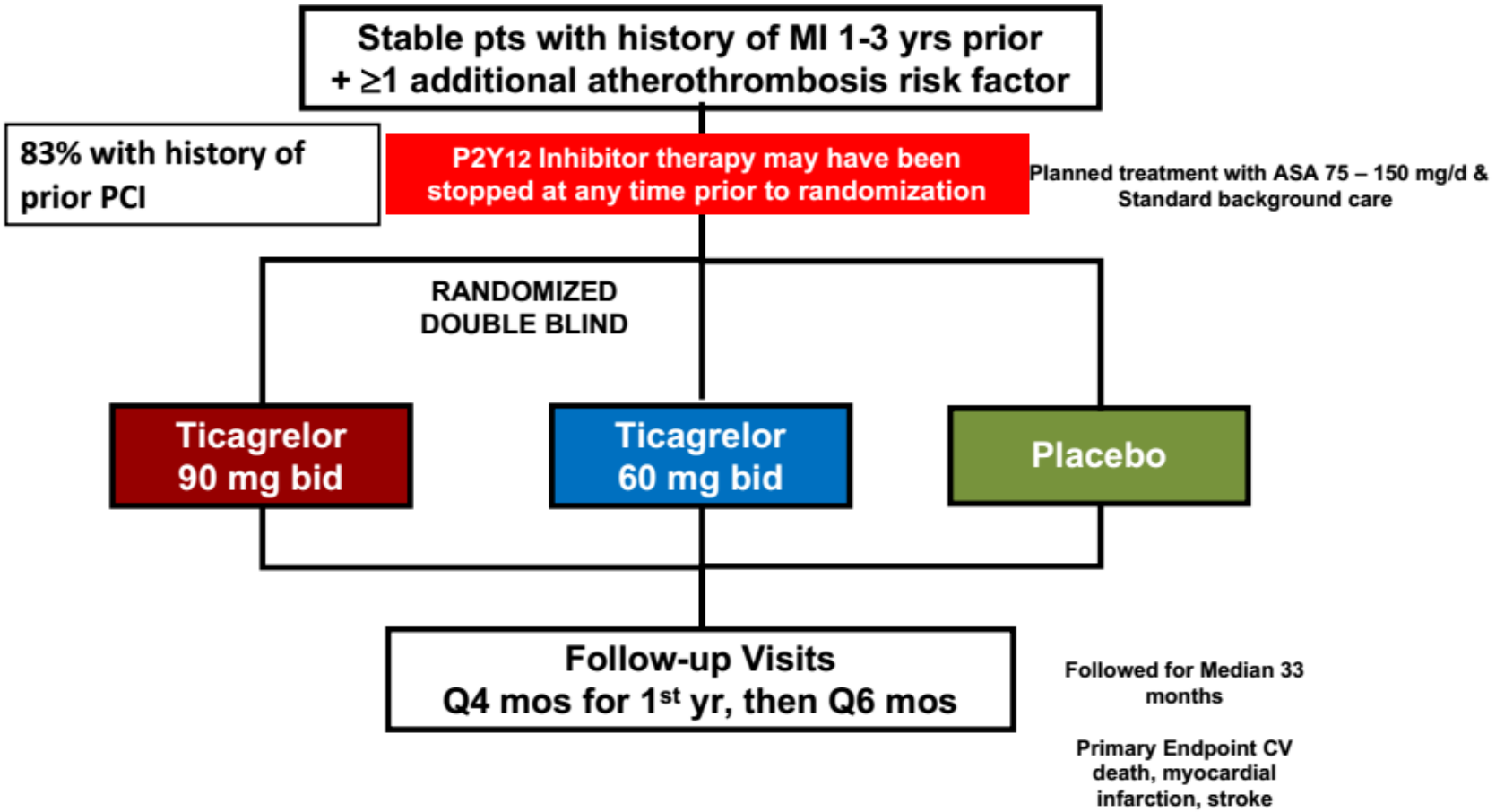
DAPT: Withdrawal of Thienopyridine 12 Months after Coronary Stenting



# At Risk								
Thienopyridine	5020	4917	4840	4778	4702	4611	4554	3029
Placebo	4941	4799	4715	4635	4542	4476	4412	2997

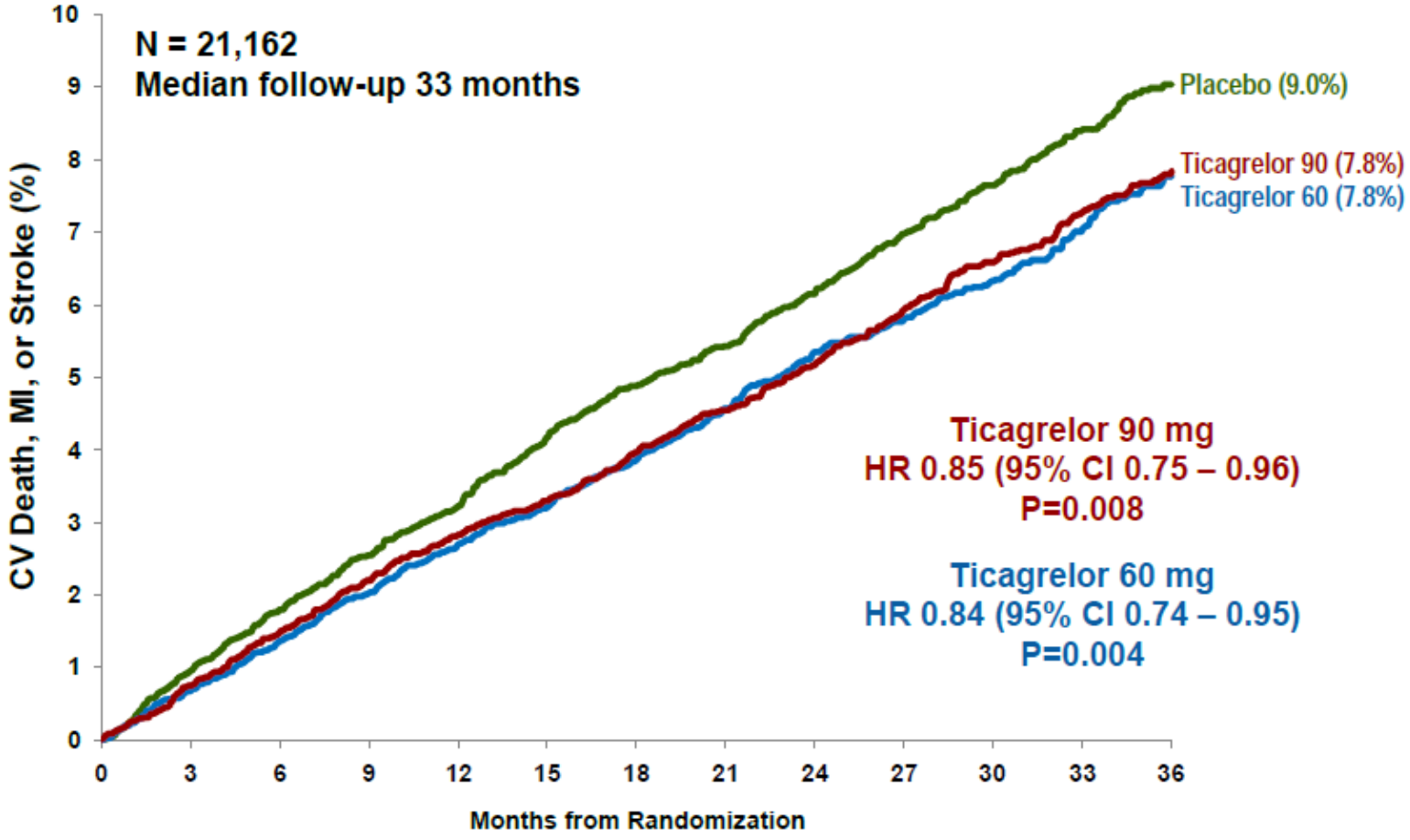
Mauri et al. NEJM 2014

Ticagrelor vs Placebo 1-3 y after MI



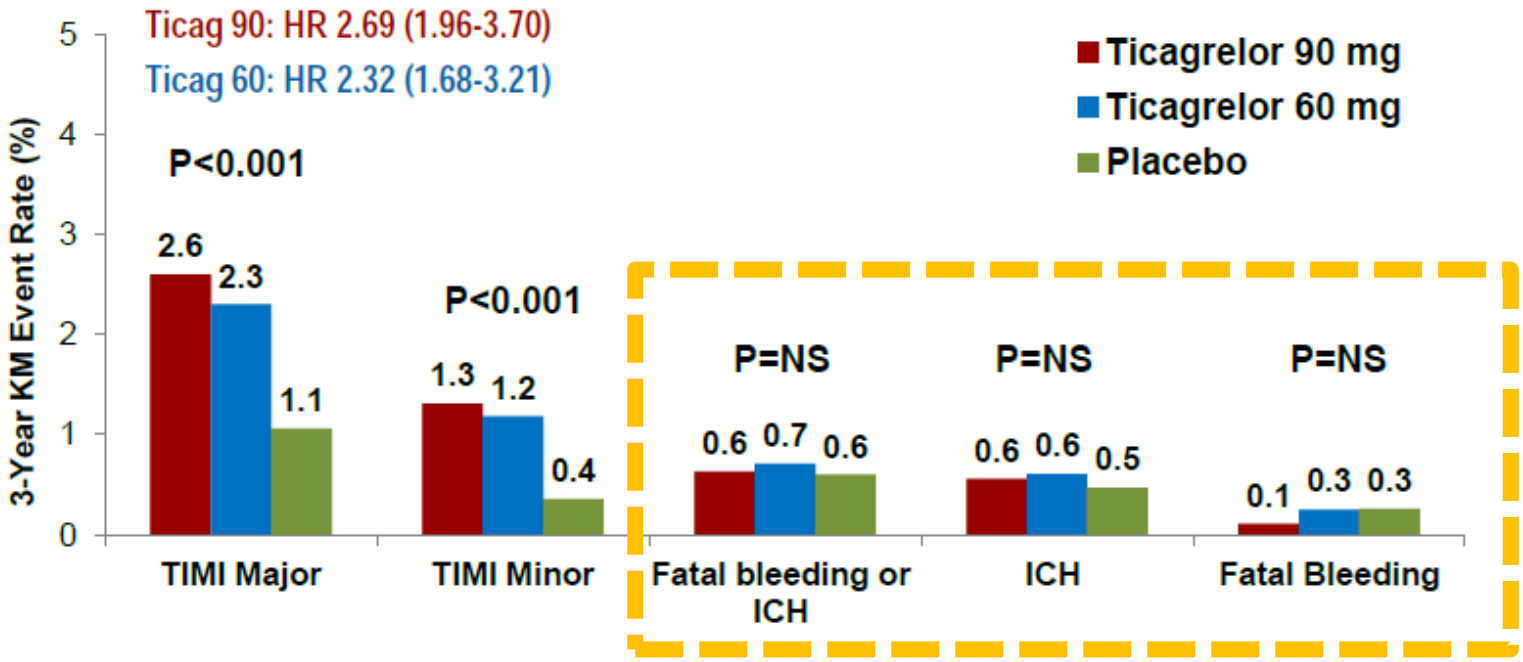
Bonaca MP et al. NEJM 2015

Primary Endpoint



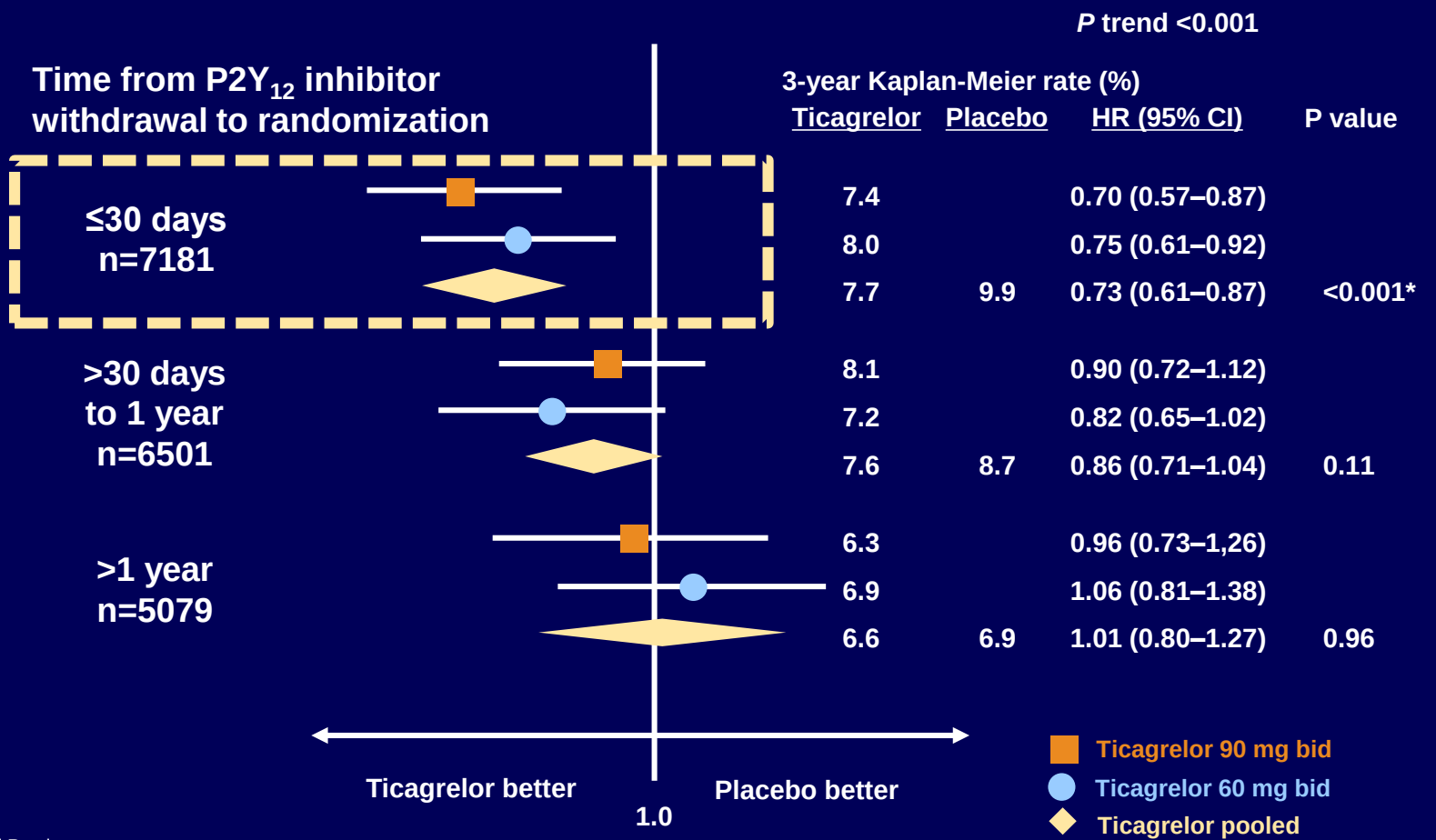
Bonaca et al. NEJM 2015 May 7;372(19):1791-800

Bleeding



Bonaca et al. NEJM 2015 May 7;372(19):1791-800

PEGASUS-TIMI 54: Effect of Ticagrelor on the Composite of CV Death, MI and Stroke at 3 years by Time from $P2Y_{12}$ Withdrawal



*Indicates nominal P value

Bonaca MP *et al. Eur Heart J* 2016;37:1133–1142

Efficacy and safety with ticagrelor in patients with prior myocardial infarction in the approved European label

Subgroup analysis from PEGASUS-TIMI 54

Background

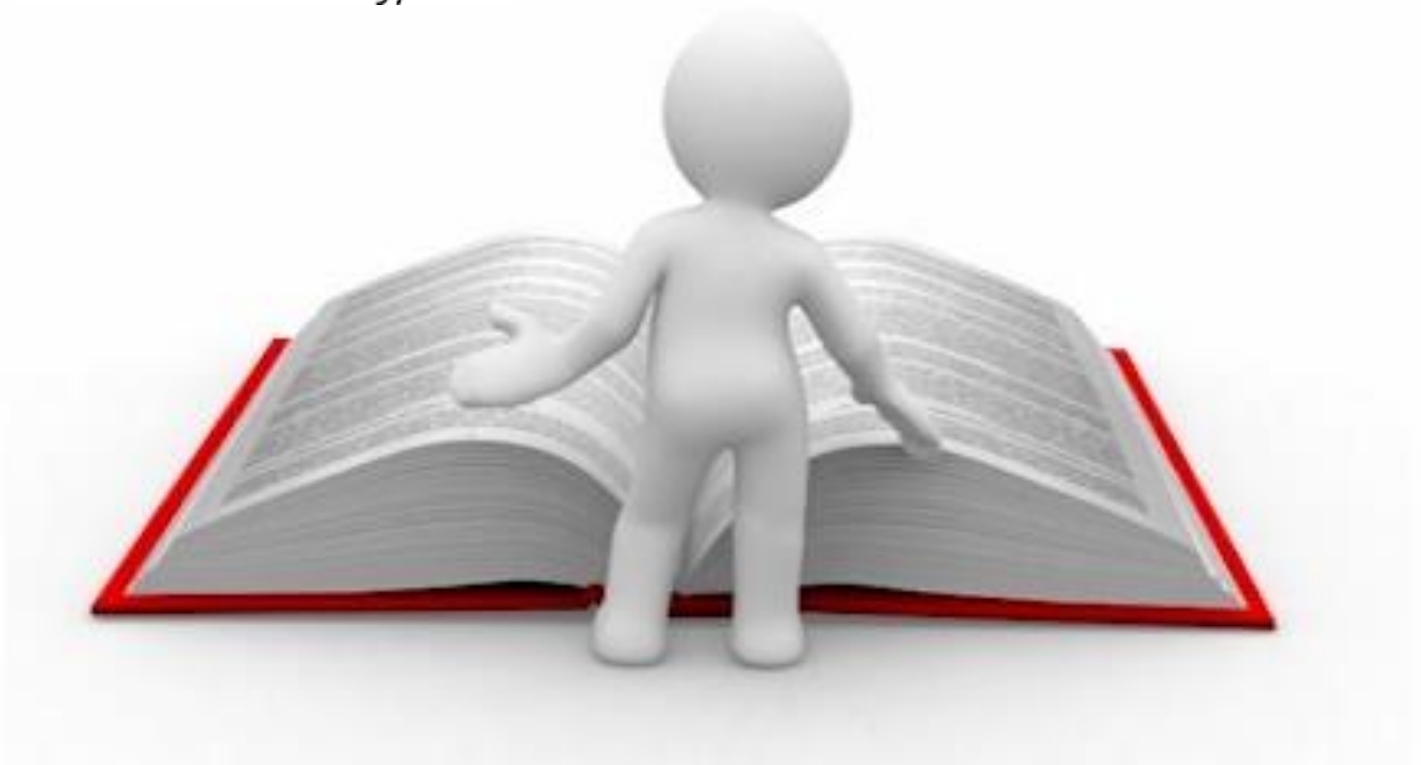
- The CHMP-EMA approved European label recommends that after the initial 1-year treatment with ticagrelor 90 mg bid in ACS patients, treatment with ticagrelor 60 mg bid may be started without interruption as continuation therapy
  - Treatment can also be initiated up to 2 years from the MI, or within 1 year after stopping previous ADP receptor inhibitor treatment
- This subgroup analysis reports on the efficacy and bleeding safety in the PEGASUS-TIMI 54 sub-population recommended for treatment in the European label

*Age ≥65 years, diabetes mellitus, second prior MI, multivessel CAD or chronic non-end-stage renal disease

Ticagrelor EU label http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001241/human_med_001398.jsp&mid=WC0b01ac058001d125
Dellborg M et al. *Eur Heart J* 2017;38(suppl):794–795. Abs P3670 (Presented at ESC 2017)

What Guidelines say?

ESC
European Society
of Cardiology



ASPIRIN

Aspirin: Timing and Formulation

Periprocedural and post-procedural antithrombotic therapy[a] in patients undergoing primary percutaneous coronary intervention

Recommendations	Class[b]	Level[c]
Antiplatelet therapy		
Aspirin (oral or i.v. if unable to swallow) is recommended as soon as possible for all patients without contraindications.[213,214]	I	B

ESC STEMI Guidelines 2017

STEMI Guidelines

Periprocedural and post-procedural antithrombotic therapy[a] in patients undergoing primary percutaneous coronary intervention

Recommendations	Class[b]	Level[c]
Antiplatelet therapy		
A potent $P2Y_{12}$ inhibitor (prasugrel or ticagrelor), or clopidogrel if these are not available or are contraindicated, is recommended before (or at latest at the time of) PCI and maintained over 12 months, unless there are contraindications such as excessive risk of bleeding.[186,187]	I	A
Cangrelor may be considered in patients who have not received $P2Y_{12}$ receptor inhibitors.[192–194]	IIb	A

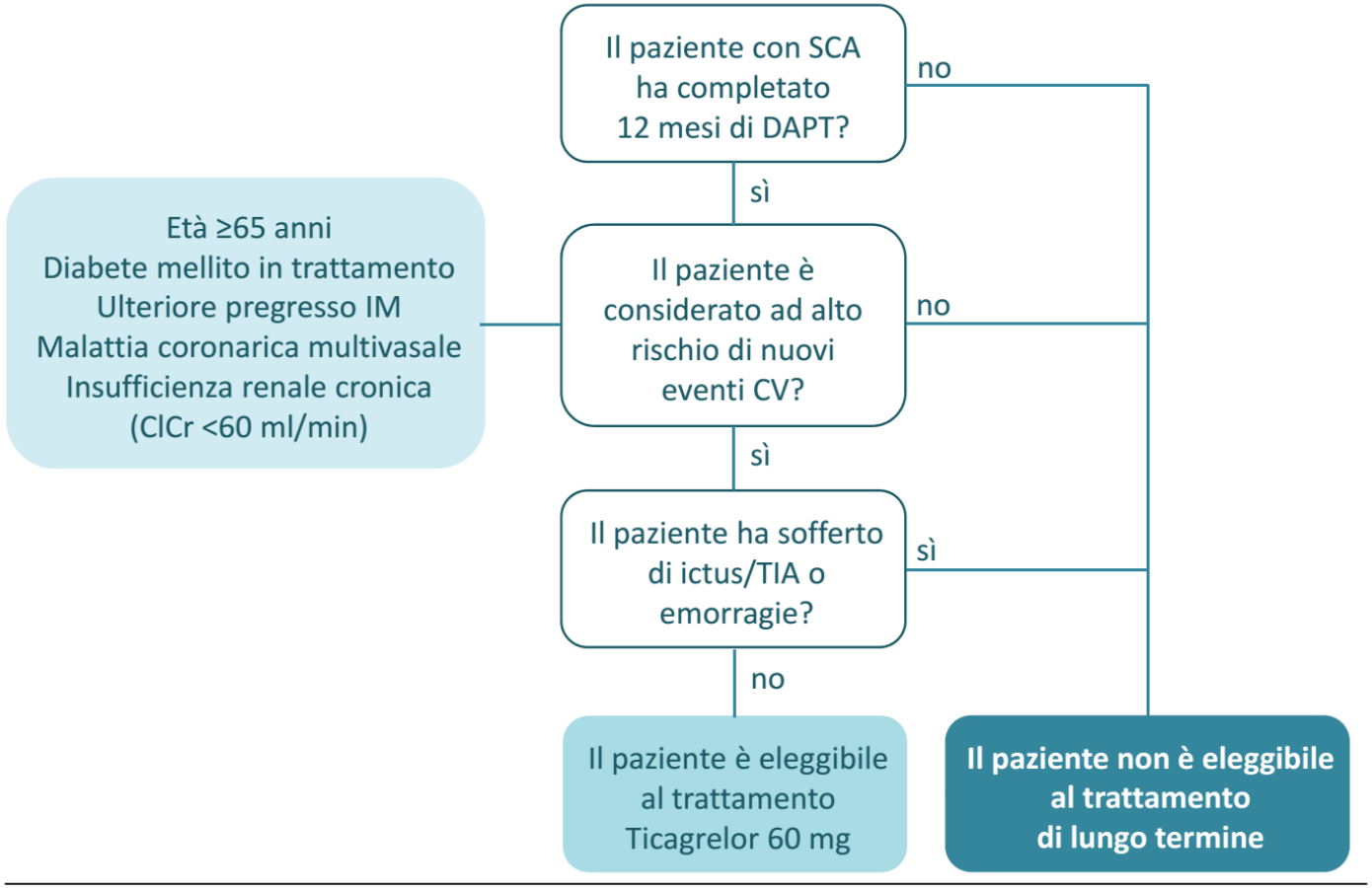
Dual antiplatelet therapy duration in patients with acute coronary syndrome treated with percutaneous coronary intervention *(continued)*

ESC European Society of Cardiology

Recommendations	Class	Level
In patients with ACS who have tolerated DAPT without a bleeding complication, continuation of DAPT for longer than 12 months may be considered.	IIb	A
In patients with MI and high ischaemic risk who have tolerated DAPT without a bleeding complication, ticagrelor 60 mg *b.i.d.* for longer than 12 months on top of aspirin may be preferred over clopidogrel or prasugrel.	IIb	B

2017 ESC Focused Update on DAPT in Coronary Artery Disease, developed in collaboration with EACTS
(European Heart Journal 2017 - doi:10.1093/eurheartj/ehx419)

Flow-chart decisionale



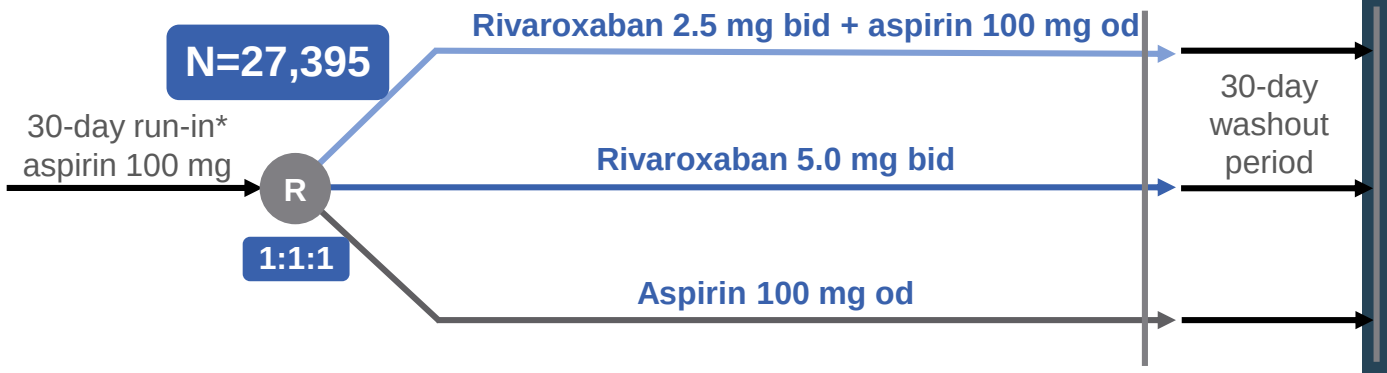
G Ital Cardiol (Rome). 2018 May;19(5):263-331.

Compass: study design

Objective: To determine the efficacy and safety of vascular dose rivaroxaban plus aspirin compared with aspirin alone for the prevention of MI, stroke and cardiovascular death in chronic CAD or PAD

Population:

Chronic
CAD (91%)
PAD (27%)



Factorial design ± pantoprazole#

Average follow-up: 23 months at early termination of study[2]

Final follow-up visit

Final washout period visit

Antithrombotic investigations‡ were stopped 1 year ahead of expectations in February 2017 due to overwhelming efficacy in the rivaroxaban 2.5 mg bid + aspirin arm[2]

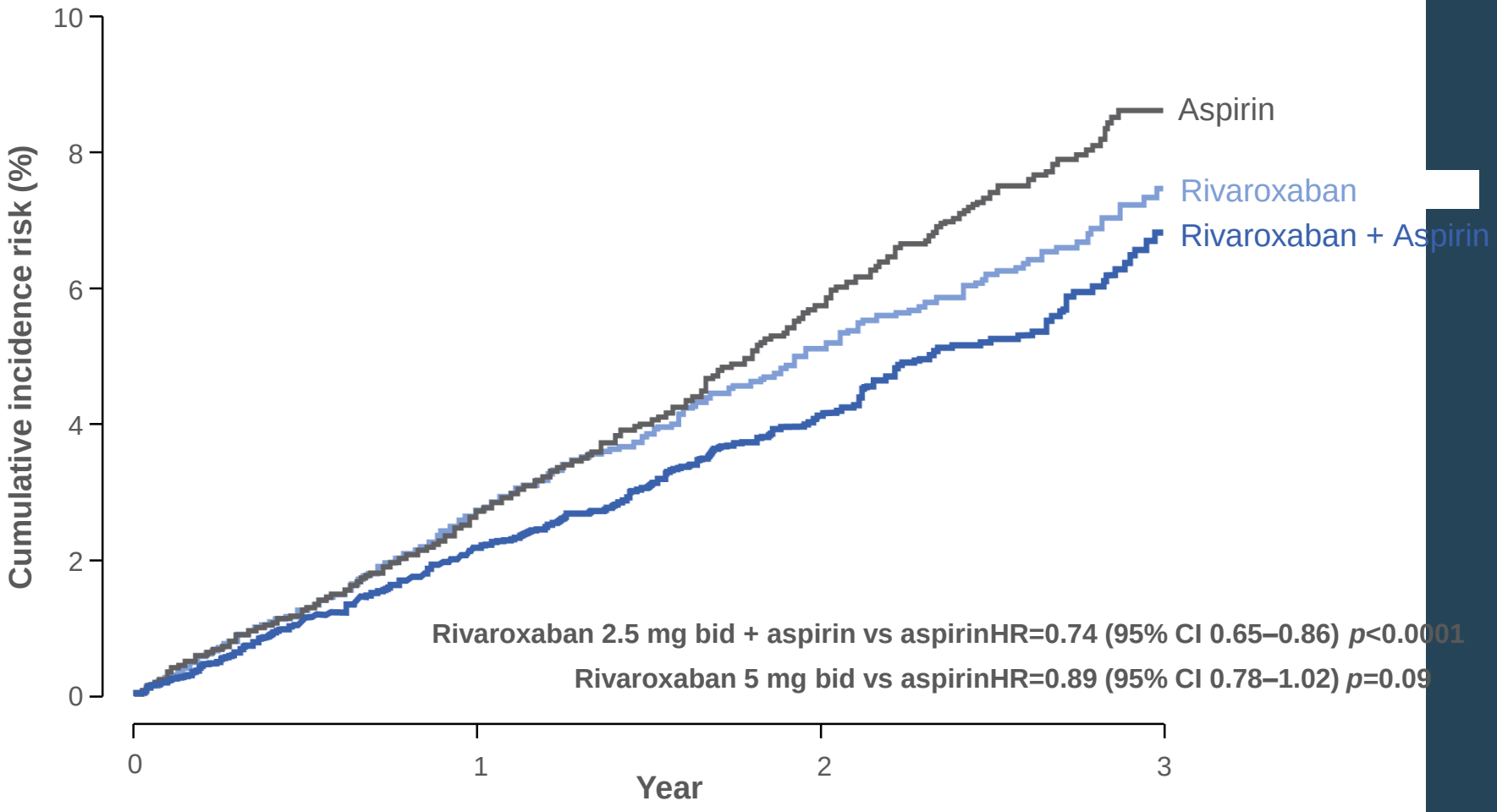
*The CAD analysis includes 1448 patients who entered COMPASS immediately post-CABG (with no run-in)[3]; #Patients who were not receiving a proton pump inhibitor (PPI) were randomized to pantoprazole or placebo (partial factorial design); ‡The PPI pantoprazole component of the study is continuing; data will be communicated once complete

1. Bosch J *et al*, *Can J Cardiol* 2017;33:1027–1035; 2. Eikelboom JW *et al*, *N Engl J Med* 2017;377:1319-1330;
3. Connolly SJ *et al*, *Lancet* 2017; doi:10.1016/S0140-6736(17)32816-7

COMPASS

Dual Pathway Inhibition with Rivaroxaban 2.5 mg bid + Aspirin Significantly Reduced MACE by 26% Versus Aspirin

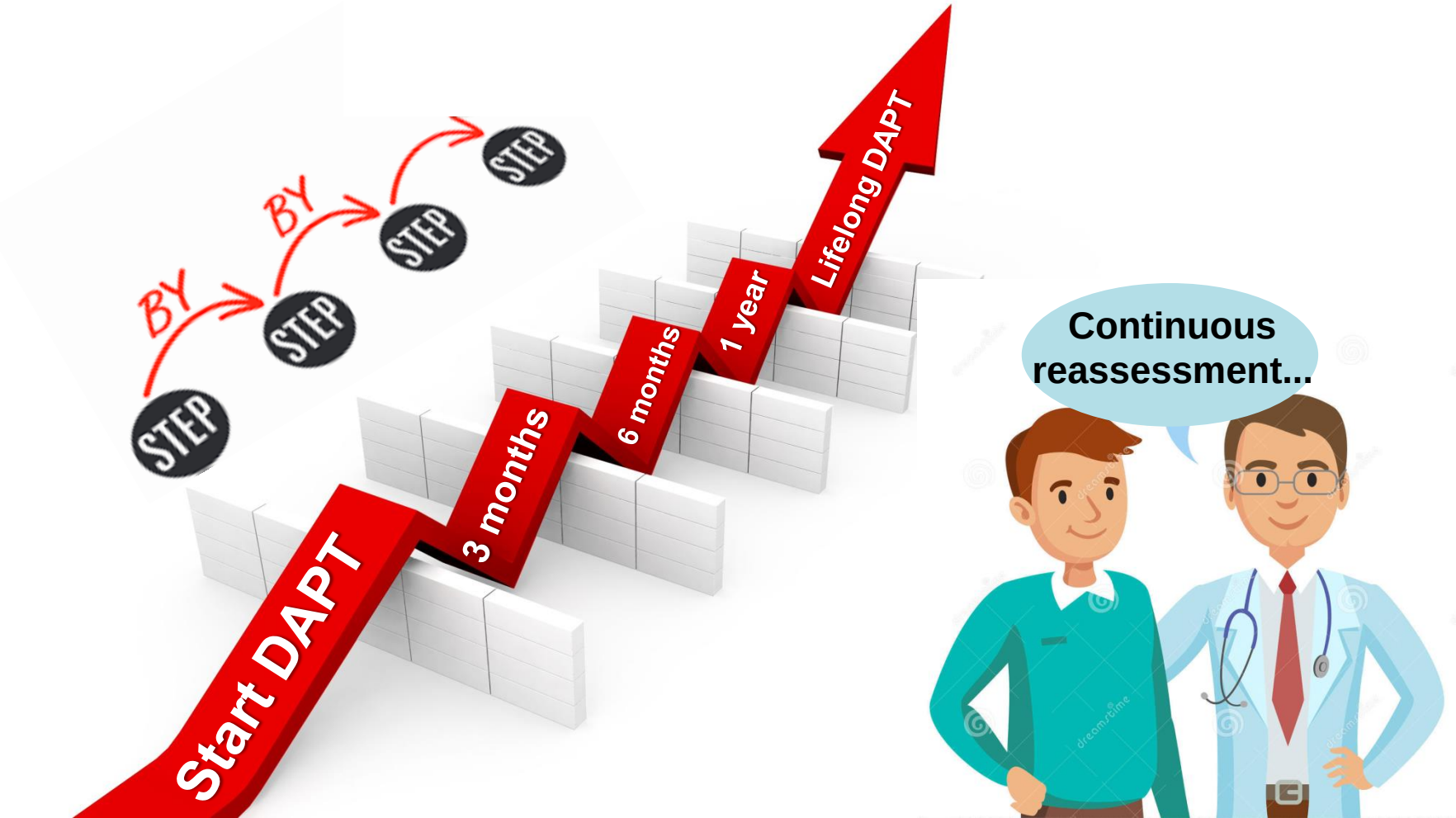
Stroke/MI/Cardiovascular death



Connolly SJ *et al*, *Lancet* 2017; doi:10.1016/S0140-6736(17)32816-7

COMPASS

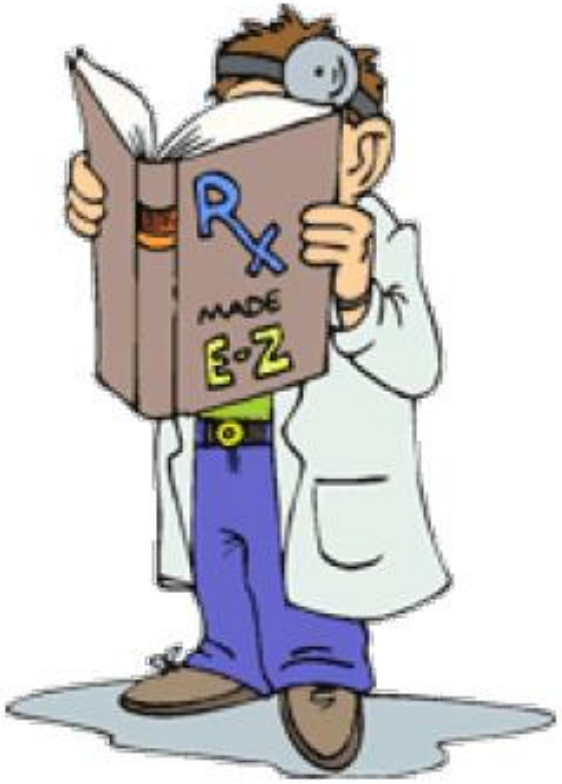
The risk for bleeding is dynamic and could change over time…



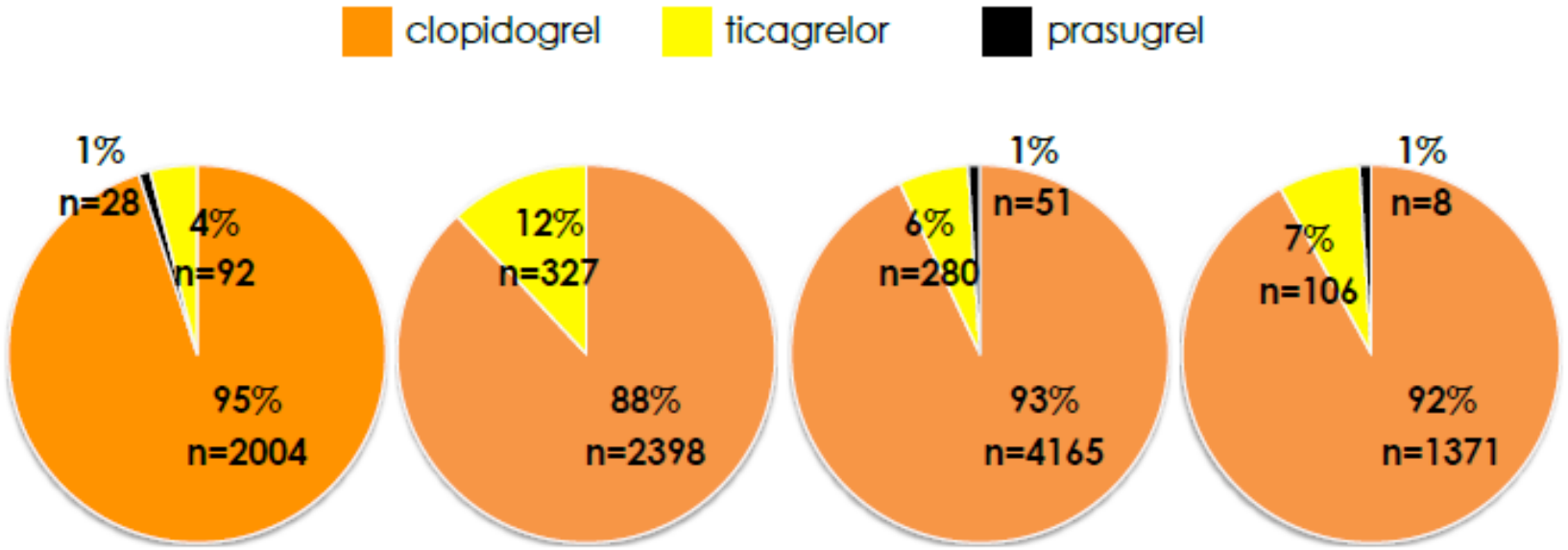
LA GESTIONE DEL PAZIENTE ANCHE FIBRILLANTE

Question 1

What to do with the $P2Y_{12}$-inhibitor (clopidogrel vs. ticagrelor/prasugrel)?



$P2Y_{12}$-inhibitors in RCT



PIONEER AF-PCI
Gibson CM et al.
N Engl J Med 2016;
375:2423-34

RE-DUAL PCI
Cannon CP et al.
N Engl J Med 2017;
377:1513-24

AUGUSTUS
Lopes RD et al.
N Engl J Med 2019;
380:1509-24

ENTRUST AF-PCI
Vranckx P et al.
Lancet 2019;
doi:10.1016/S0140-6736(19)31872-0

2018 EHRA, ESC WG Thrombosis, EAPCI, ACCA, HRS, APHRS, LAHRS, CASSA Consensus document

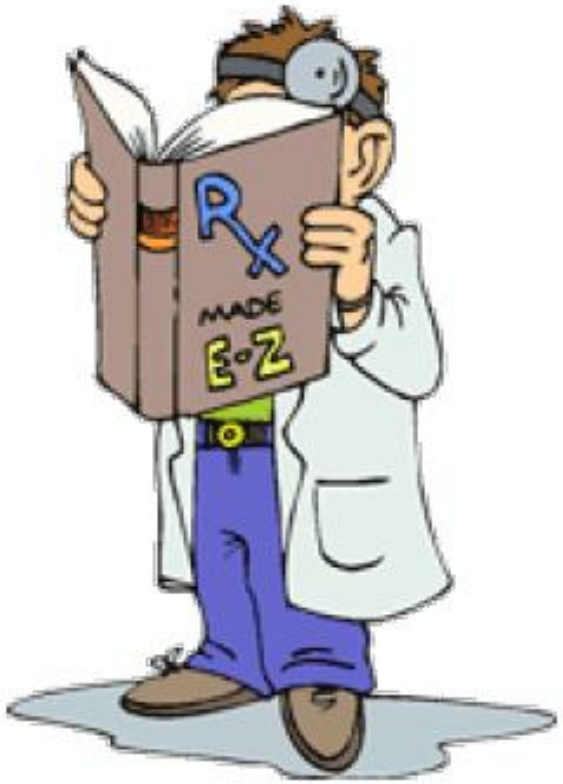
As regards $P2Y_{12}$ inhibitors:

1. *clopidogrel* ***is of choice***
2. *prasugrel and ticagrelor* ***should be avoided*** as part of triple therapy

Lip GYH et al. Europace 2019;21:192-3

Question 2

What regimen (double vs. triple)?



However, …

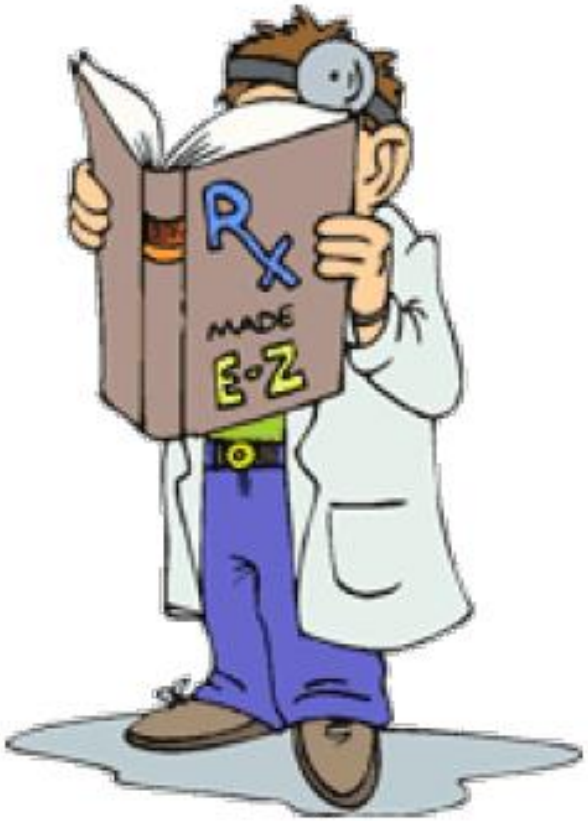
La vera domanda oggigiorno è …

… non quale regime antitrombotico, triplice o duplice, debba essere prescritto, ma piuttosto *per quanto tempo l'inevitabile, iniziale triplice terapia* debba essere mantenuta.

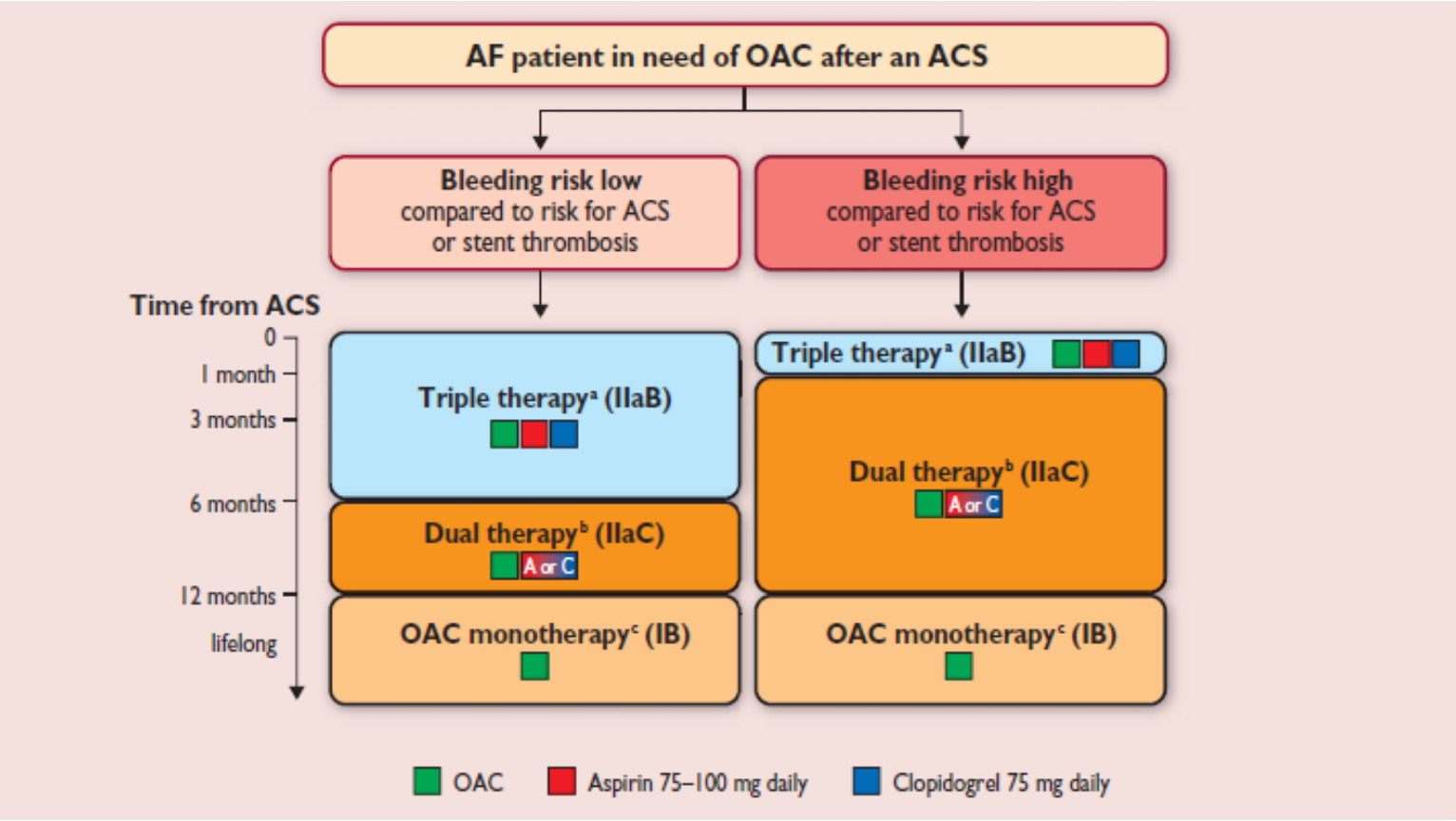
Rubboli A et al. G Ital Cardiol 2019;20:396

Question 3

Which OAC (VKA vs. NOAC)?

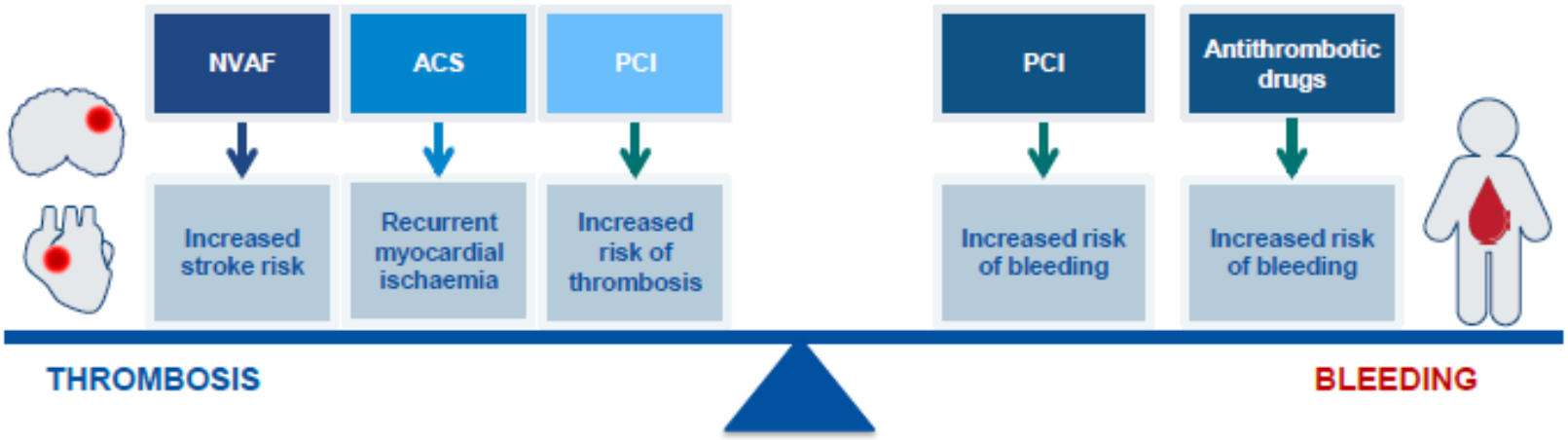


Antithrombotic therapy after an acute coronary syndrome in atrial fibrillation patients requiring anticoagulation



The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation
European Heart Journal (2018) 39, 1330–1393

Risk of thrombosis and bleeding in AF patients undergoing PCI



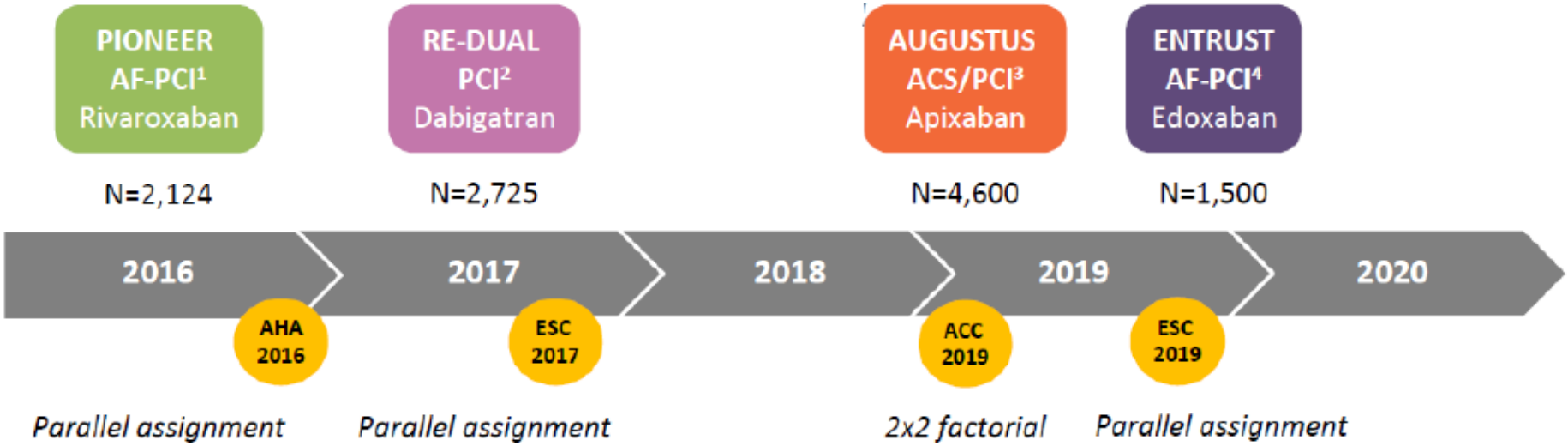
Bleeding is the most common non-cardiac complication of PCI

Antithrombotic therapy that minimizes the risk of bleeding complications might therefore be expected to result in better short- and long-term clinical outcomes after PCI

ACS, acute coronary syndrome

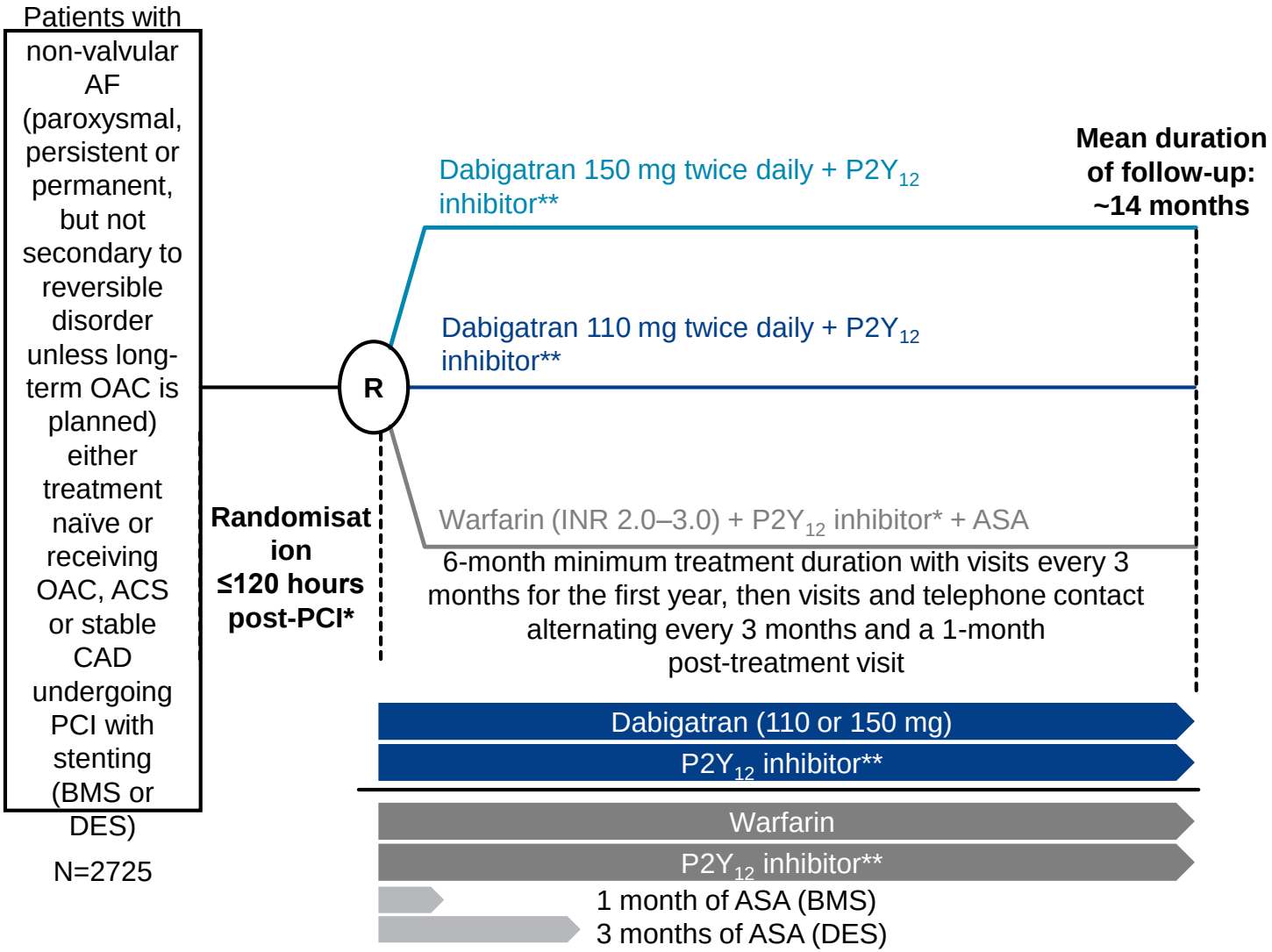
Lip et al. Europace 2018

Recent on Dual Therapy post-PCI/post-ACS in Patients with NVAF



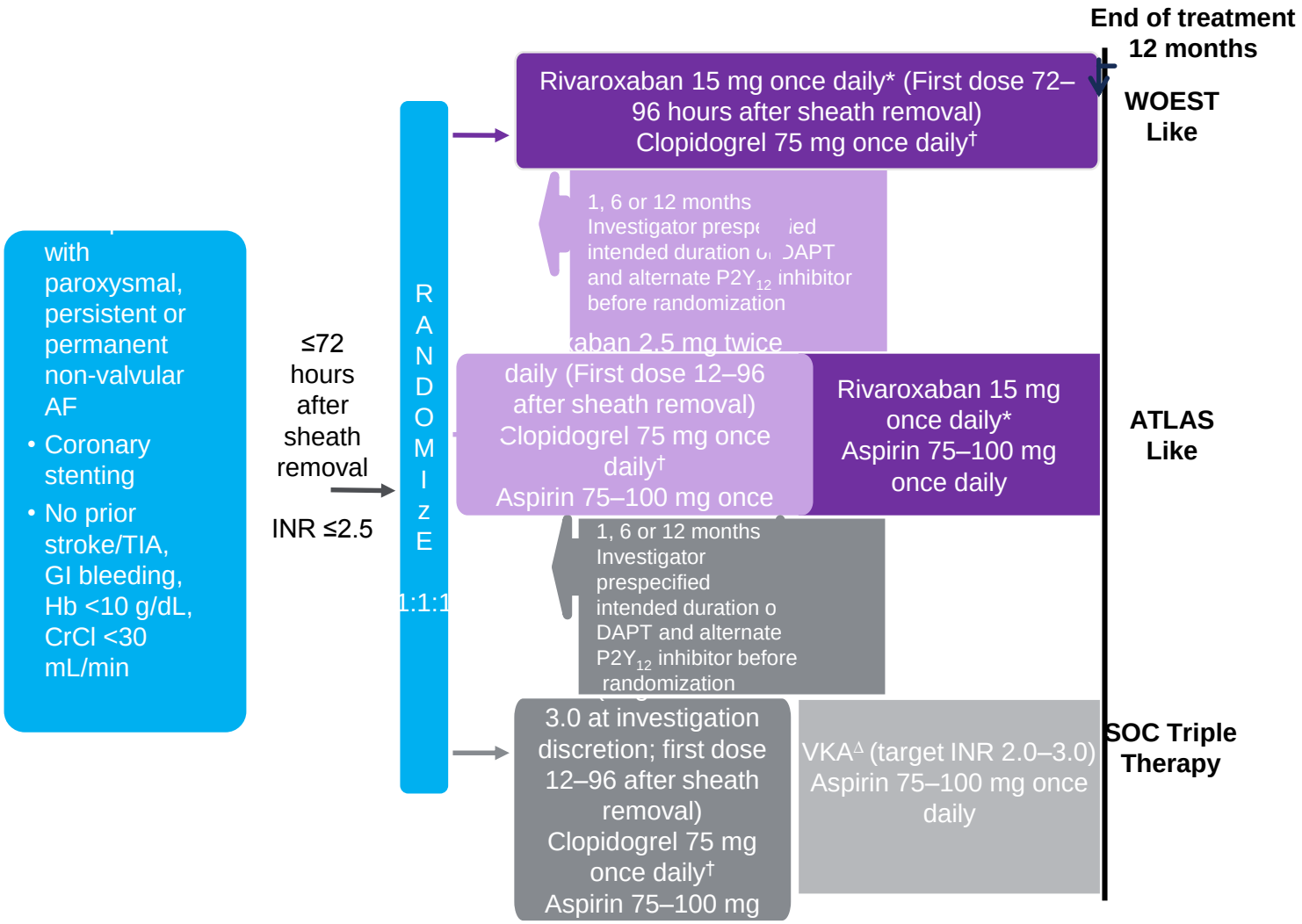
1. Gibson et al. N Engl J Med 2016; 2. Cannon et al. N Engl J Med 2017; 3. Lopes et al. N Engl J Med 2019 ; 4. Vranckx P, et al. Lancet 2019

RE-DUAL PCI



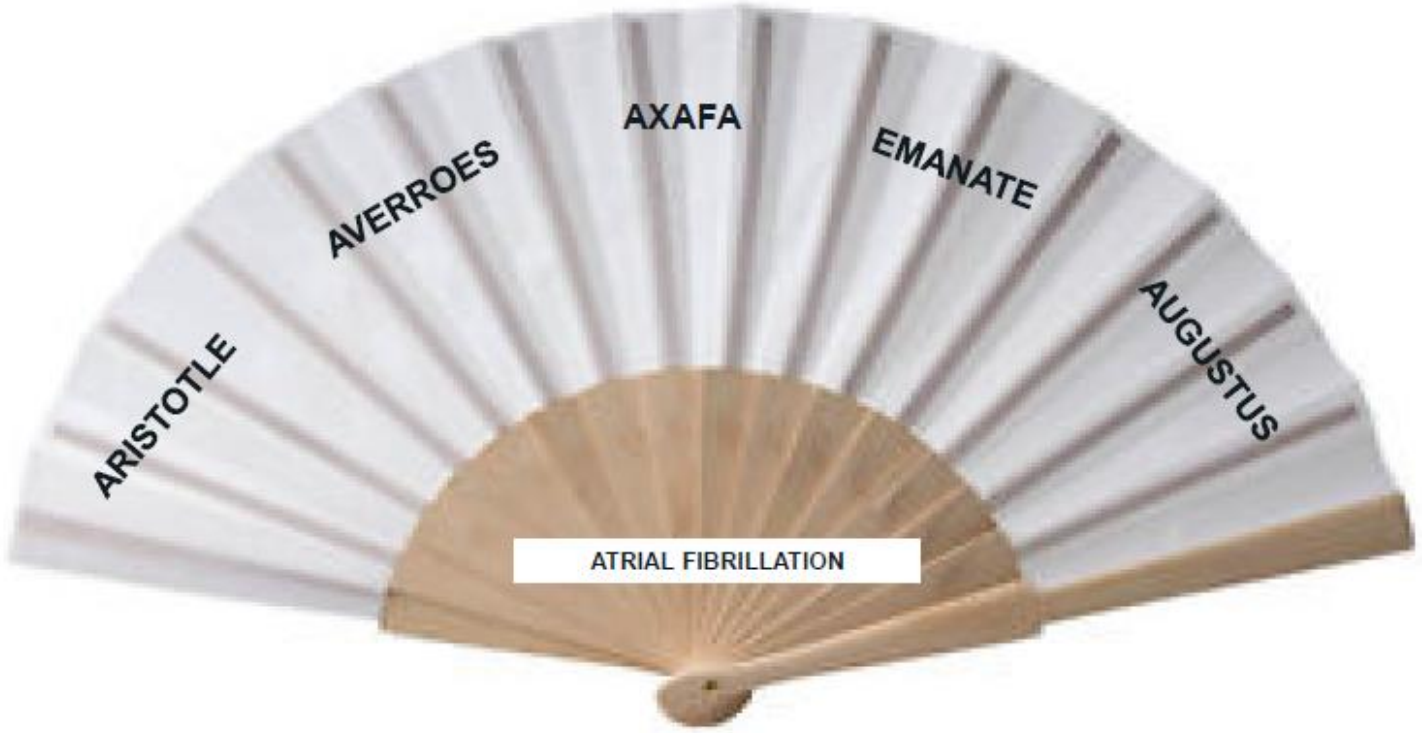
Multicentre, prospective randomised, open-label trial following PROBE design

PIONEER AF-PCI

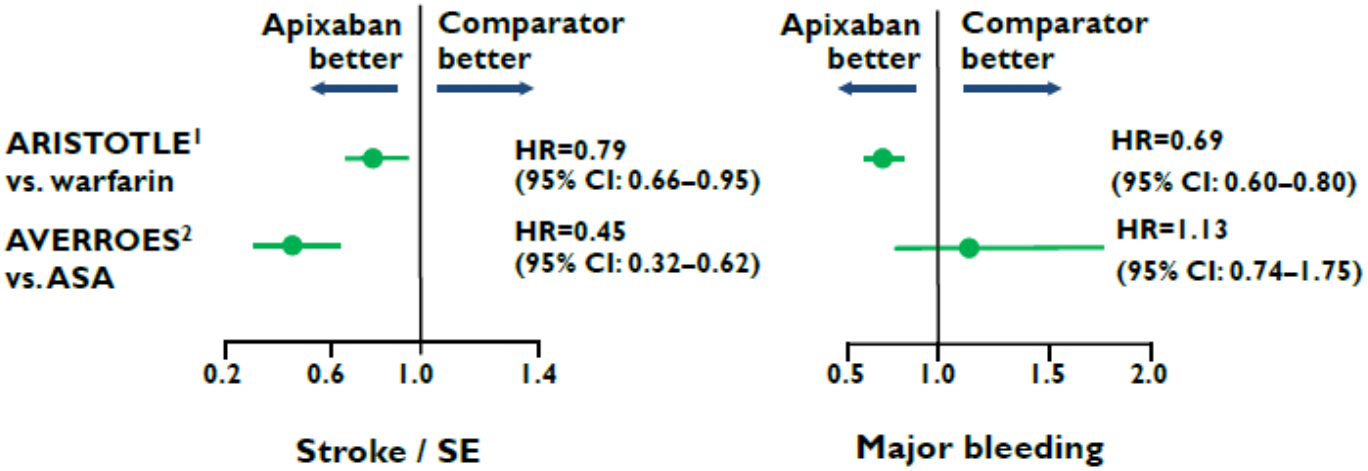


* Rivaroxaban dosed at 10 mg once daily in patients with CrCl of 30 to <50 mL/min
†Alternative $P2Y_{12}$ inhibitors prasugrel 10 mg once daily or ticagrelor 90 mg twice daily
‡Low-dose aspirin (75–100 mg/day)
ΔOpen-label VKA
GI, gastrointestinal; WOEST, what is the optimal antiplatelet and anticoagulant therapy in patients with oral anticoagulation and coronary stenting
Gibson et al. Am Heart J 2015;169:474–8. e5

Apixaban in AF: from Clinical Trials...



Clinical validation of apixaban in stroke prevention in AF



AF, atrial fibrillation; ASA, acetyl salicylic acid; HR, hazard ratio; SE, systemic embolism.

- 1. Granger CB, et al. New Engl J Med 2011;365:981-92; 2. Connolly SJ, et al. New Engl J Med 2011;364:806-17.

ENGAGE-AF: Sottoanalisi sui pazienti anziani

Journal of the American Heart Association

American Heart Association | American Stroke Association

Efficacy and Safety of Edoxaban in Elderly Patients With Atrial Fibrillation in the ENGAGE AF–TIMI 48 Trial

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Kato et al. J Am Heart Assoc (2016) 5:e003432

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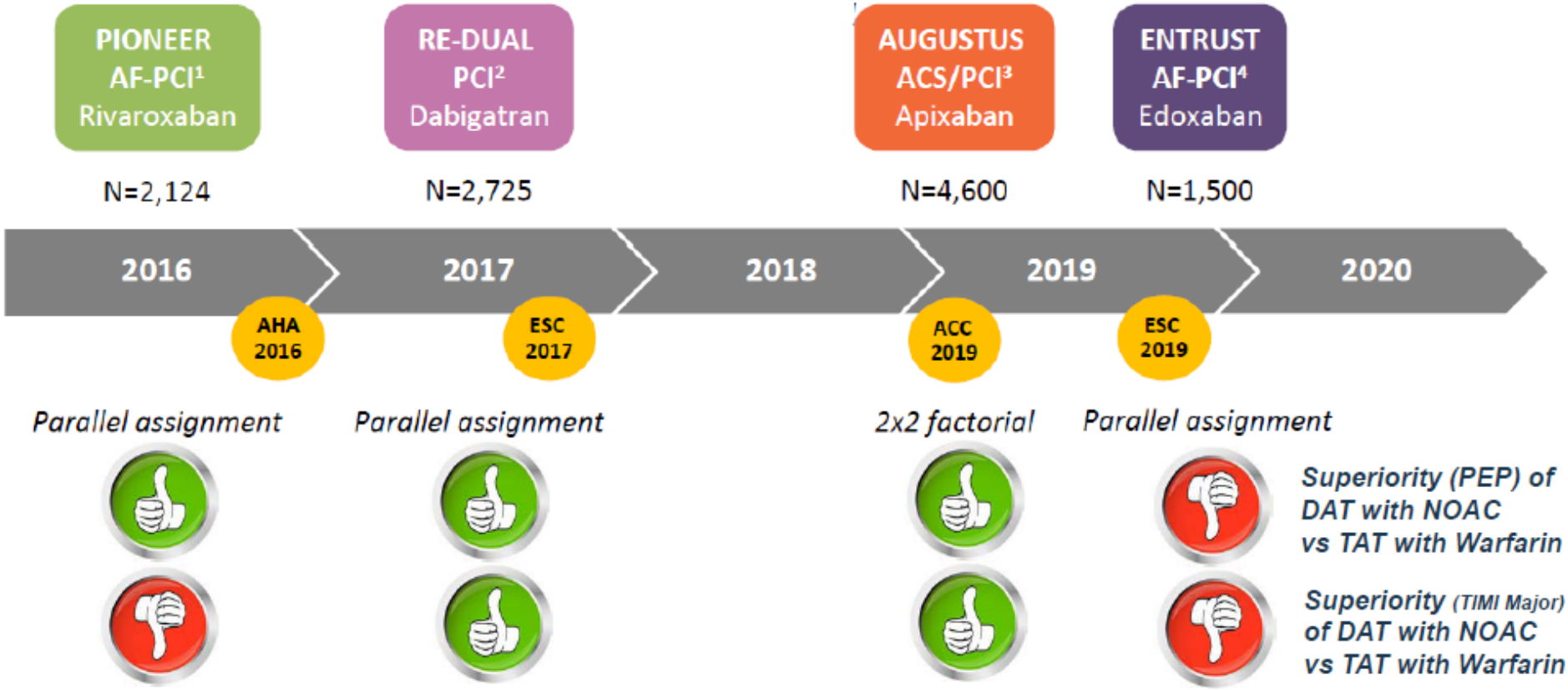
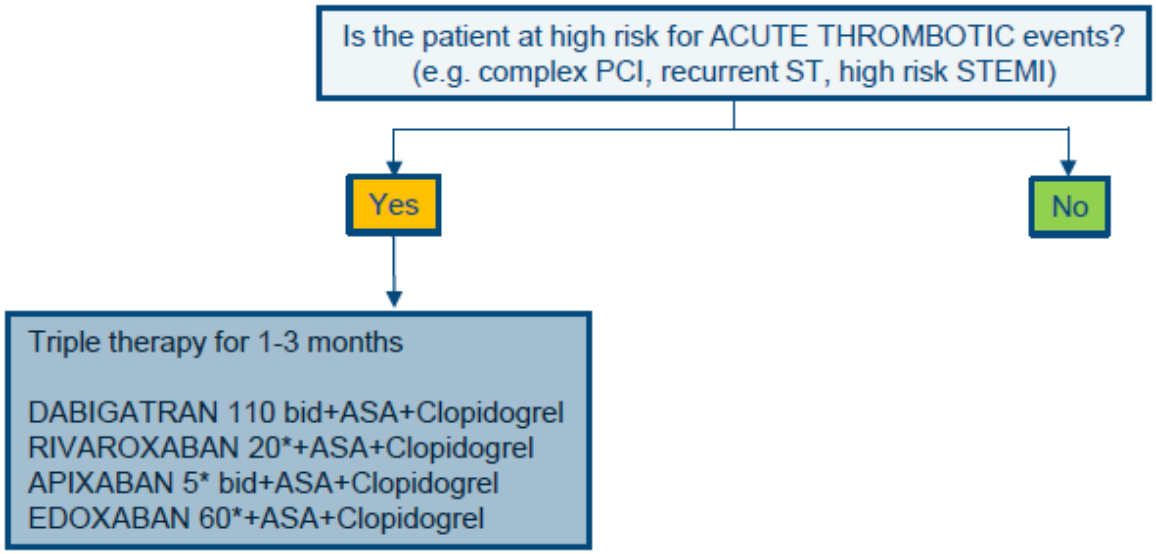


1. Gibson et al. N Engl J Med 2016; 2. Cannon et al. N Engl J Med 2017; 3. Lopes et al. N Engl J Med 2019 ; 4. Vranckx P, et al. Lancet 2019

Antithrombotic Therapy in Post-PCI Patients with AF: My Personal Evidence-Based Approach



*dose adjustment if needed

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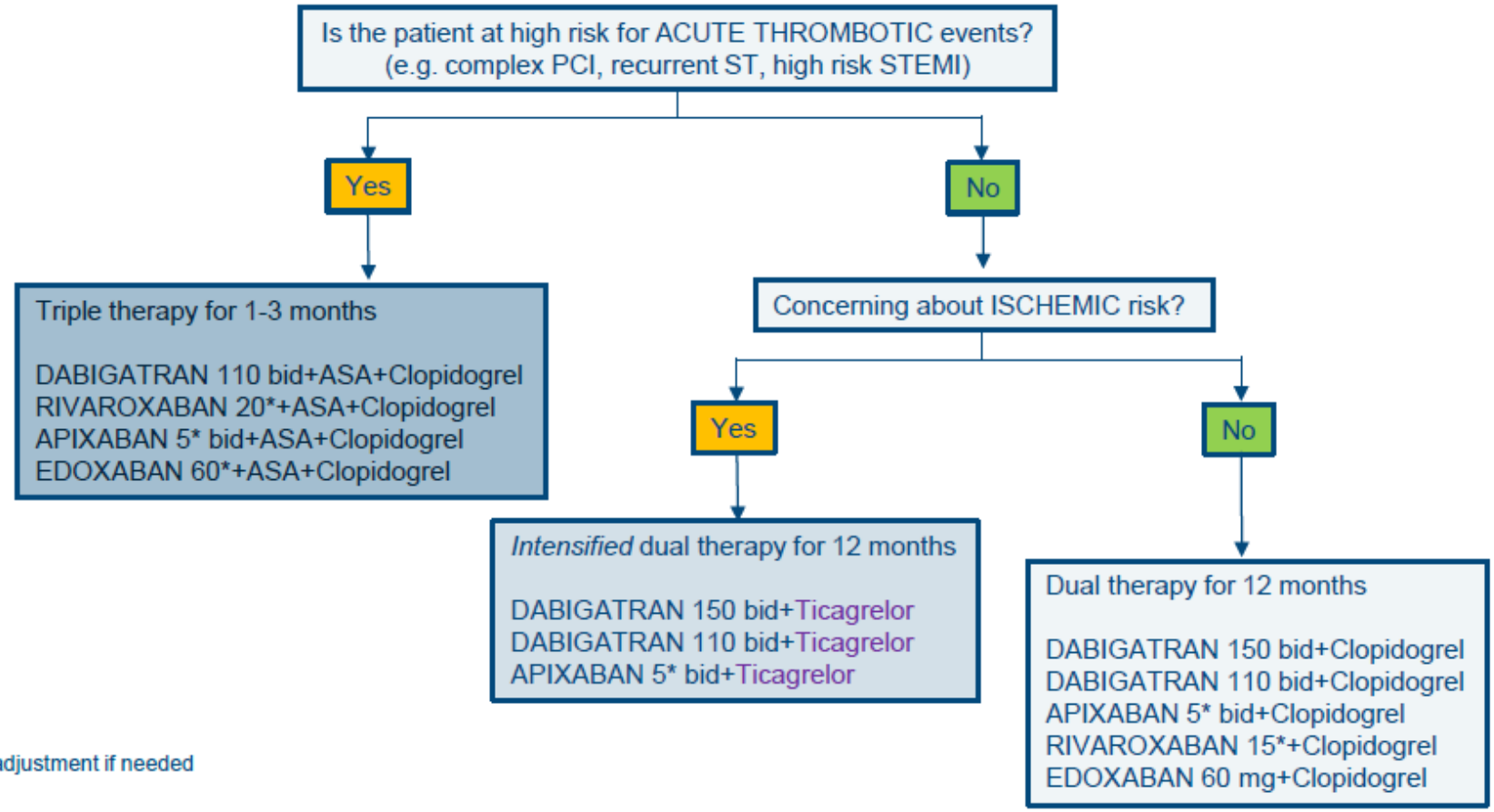

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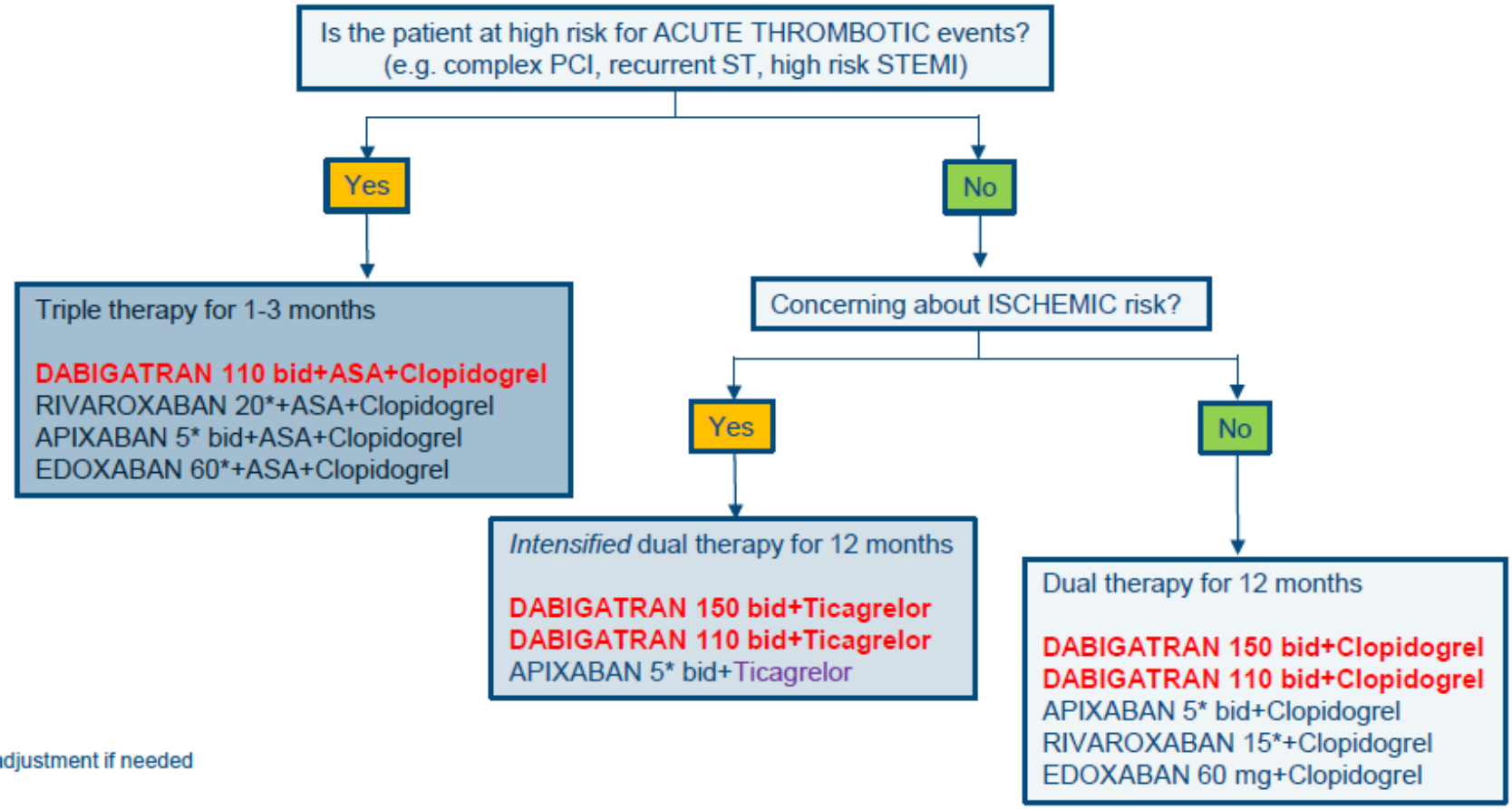

*dose adjustment if needed

Position paper ANMCO: Gestione della dimissione ospedaliera

Mauro Mennuni[1] (Coordinatore), Michele Massimo Gulizia[2] (Coordinatore), Gianfranco Alunni[3], Antonio Francesco Amico[4], Francesco Maria Bovenzi[5], Roberto Caporale[6], Furio Colivicchi[7], Andrea Di Lenarda[8], Giuseppe Di Tano[9], Sabrina Egman[10], Francesco Fattirolli[11], Domenico Gabrielli[12], Giovanna Geraci[13], Giovanni Gregorio[14], Gian Francesco Mureddu[15], Federico Nardi[16], Donatella Radini[8], Carmine Riccio[17], Fausto Rigo[18], Marco Sicuro[19], Stefano Urbinati[20], Guerrino Zuin[18]

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G Ital Cardiol 2016;17(9):657-686

FROM CLINICAL TRIALS TO CLINICAL PRACTICE…

DAPT STUDY

PEGASUS TIMI 54

LA «*BUONA*» DIMISSIONE

Tabella 25. Standard educativi da completare prima della dimissione per il paziente con sindrome coronarica acuta.

- Spiegazione
  - della diagnosi e delle procedure da effettuare
  - dei farmaci, del loro dosaggio, della loro azione; uso dei nitrati perlinguali
  - delle conseguenze gravi della sospensione dei farmaci
  - del piano d'azione in caso di recidiva di dolore toracico
  - dell'importanza del follow-up
  - dei fattori di rischio e importanza della loro correzione
  - del fumo come fattore di rischio cardiovascolare
- Riesame
  - delle indicazioni dietetiche
  - del programma di esercizi fisici domiciliari
  - dell'importanza della riabilitazione
- Tempistica
  - del ritorno al lavoro
  - della guida di veicoli
  - dell'attività sessuale
- Il paziente ha compreso e condiviso il piano di cura

Tabella 17. Informazioni da raccogliere per la ricognizione terapeutica.

- Nome commerciale e/o principio attivo
- Forma farmaceutica
- Dosaggio
- Posologia giornaliera
- Data di inizio e durata della terapia
- Data e ora dell'ultima dose assunta
- Via di somministrazione
- Trattamenti a carattere sperimentale
- Assunzione di omeopatici, fitoterapici e integratori
- Presenza di allergie o intolleranze
- Terapie pregresse ed eventuali effetti indesiderati
- Assunzione di alimenti (pompelmo, caffè, tè, frutta e verdura) che possano interferire con la terapia
- Peso e altezza del paziente
- Eventuale assunzione di alcool, fumo e uso di droghe
- Utilizzo di dispositivi medici medicati
- Ogni altro dato ritenuto significativo

G Ital Cardiol 2016;17(9):657-686

GRAZIE!