SINDROME CORONARICA ACUTA

Terapia antiaggregante e anticoagulante
Quale e per quanto tempo

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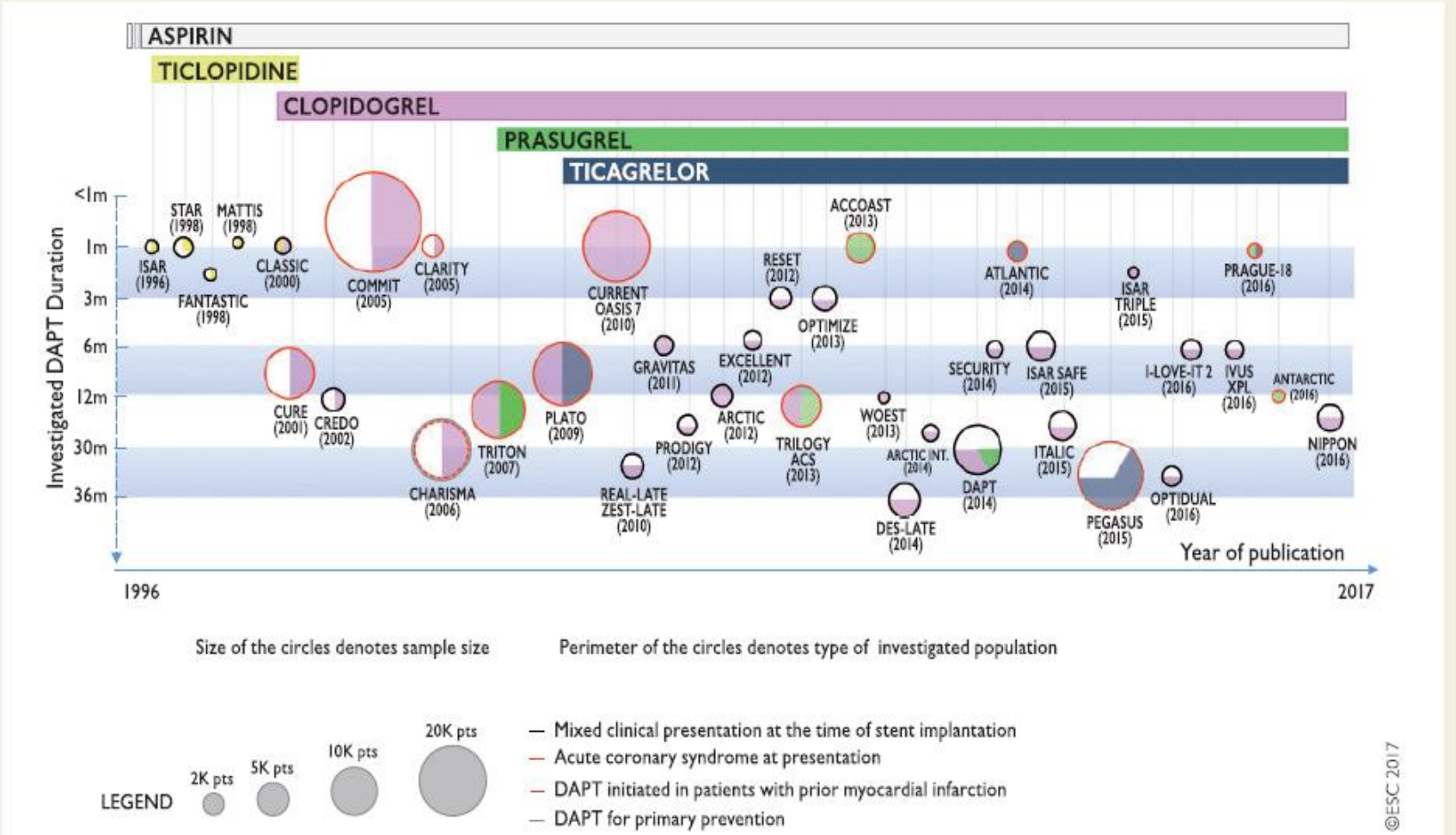
STUDI SUGLI ANTIAGGREGANTI



Terapia antiaggregante
Quale e per quanto tempo

Sindrome coronarica acuta (angina instabile, NSTEMI, STEMI)

→ acido acetilsalicilico (75-100 mg/die)

\+

clopidogrel (75 mg/die)
ticagrelor (90 mg x 2/die)
prasugrel (10 mg/die)

} per 12 mesi

→ se elevato rischio di sanguinamento duplice terapia antiaggregante per soli 6 mesi

→ in casi selezionati duplice terapia antiaggregante > 12 mesi

Recommendations for post-interventional and maintenance treatment in patients with non-ST-elevation acute coronary syndromes and ST-elevation myocardial infarction undergoing percutaneous coronary intervention

Recommendations	Class[a]	Level[b]
In patients with ACS treated with coronary stent implantation, DAPT with a $P2Y_{12}$ inhibitor on top of aspirin is recommended for 12 months unless there are contraindications such as an excessive risk of bleeding (e.g. PRECISE-DAPT ≥25).[701,702,722,723]	I	A
In patients with ACS and stent implantation who are at high risk of bleeding (e.g. PRECISE-DAPT ≥25), discontinuation of $P2Y_{12}$ inhibitor therapy after 6 months should be considered.[729,730]	IIa	B
In patients with ACS treated with BRS, DAPT should be considered for at least 12 months and up to the presumed full absorption of the BRS, based on an individual assessment of bleeding and ischaemic risk.	IIa	C
De-escalation of $P2Y_{12}$ inhibitor treatment (e.g. with a switch from prasugrel or ticagrelor to clopidogrel) guided by platelet function testing may be considered as an alternative DAPT strategy, especially for ACS patients deemed unsuitable for 12-month potent platelet inhibition.[717]	IIb	B
In patients with ACS who have tolerated DAPT without a bleeding complication, continuation of DAPT for longer than 12 months may be considered.[700,731]	IIb	A
In patients with MI and high ischaemic risk[c] 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.[732–734]	IIb	B

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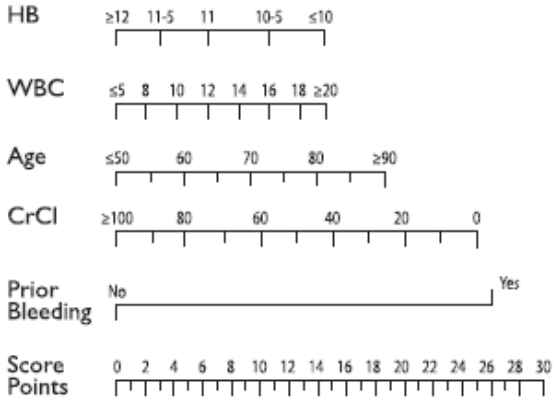
Table 3 Risk scores validated for dual antiplatelet therapy duration decision-making

	PRECISE-DAPT score[18]	DAPT score[15]	
Time of use	At the time of coronary stenting	After 12 months of uneventful DAPT	
DAPT duration strategies assessed	Short DAPT (3–6 months) vs. Standard/long DAPT (12–24 months)	Standard DAPT (12 months) vs. Long DAPT (30 months)	
Score calculation[a]		Age ≥75 65 to <75 <65 Cigarette smoking Diabetes mellitus MI at presentation Prior PCI or prior MI Paclitaxel-eluting stent Stent diameter <3 mm CHF or LVEF <30% Vein graft stent	 –2 pt –1 pt 0 pt +1 pt +1 pt +1 pt +1 pt +1 pt +1 pt +2 pt +2 pt
Score range	0 to 100 points	–2 to 10 points	
Decision making cut-off suggested	Score ≥25 → Short DAPT Score <25 → Standard/long DAPT	Score ≥2 → Long DAPT Score <2 → Standard DAPT	
Calculator	www.precisedaptscore.com	www.daptstudy.org	

CHF = congestive heart failure; CrCl = creatinine clearance; DAPT = dual antiplatelet therapy; Hb = haemoglobin; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention; PRECISE-DAPT = PREdicting bleeding Complications In patients undergoing Stent implantation and subsEquent Dual Anti Platelet Therapy; WBC = white blood cell count.

[a]For the PRECISE-DAPT score use the score nomogram: mark patient's value for each of the five clinical variables of the score and draw a vertical line to the 'Point' axis to determine the number of points obtained for each clinical variable. Then summate the points obtained for each clinical variable to the total score. A practical case example for score calculation is provided in Web Figure 1 of the Web Addenda.

For the DAPT score summate positive points for each value and subtract values for age to the total score.

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Long-Term Use of Ticagrelor in Patients with Prior Myocardial Infarction

PEGASUS TIMI 54

21.162 pazienti, età > 50 anni, con infarto miocardico da 1 a 3 anni prima

con almeno 1 delle seguenti caratteristiche:
età > 65 anni, diabete mellito, insufficienza renale, malattia coronarica plurivasale, secondo infarto miocardico

Randomizzati a
- → sola ASA
- → ASA + Ticagrelor 90 mg x 2
- → ASA + Ticagrelor 60 mg x 2

- con ASA + Ticagrelor riduzione significativa dell'end point composito di morte cardiovascolare, infarto e ictus
- con ASA + Ticagrelor maggiori sanguinamenti rispetto a sola ASA

→ beneficio clinico netto nei pazienti ad elevato rischio ischemico con Ticagrelor 60 mg x 2

Quali anticoagulanti?

- Antagonista vitamina K: warfarin
- Nuovi anticoagulanti diretti:
  - Dabigatran (150 mg x 2, 110 mg x 2)
  - Rivaroxaban (20 mg, 15 mg)
  - Apixaban (5 mg x 2, 2,5 mg x 2)
  - Edoxaban (60 mg, 30 mg)

Terapia antiaggregante e anticoagulante
Quale e per quanto tempo

Quando associare terapia antiaggregante e anticoagulante?

→ aumentato rischio di sanguinamento di 2-3 volte rispetto alla sola terapia anticoagulante

→ quando la sindrome coronarica acuta si associa a:

- fibrillazione atriale
- trombosi endoventricolare sinistra
- protesi valvolari cardiache meccaniche
- tromboembolismo venoso

→ la triplice terapia deve essere fatta per il minor tempo possibile valutando sia il rischio ischemico che il rischio emorragico

Terapia antiaggregante e anticoagulante
Quale e per quanto tempo

Perché associare terapia antiaggregante e anticoagulante?

→ aumentato rischio di sanguinamento

- La duplice terapia antiaggregante è necessaria per prevenire la trombosi dello stent, ma non sufficiente per la prevenzione dell'ictus e viceversa gli anticoagulanti orali sono essenziali per la prevenzione dell'ictus, ma non utili per prevenire nuovi eventi coronarici, soprattutto nella fase acuta e subacuta

- L'associazione di almeno un antiaggregante all'anticoagulante è raccomandata dalle linee guida fino a 12 mesi dopo una sindrome coronarica acuta

Quale terapia antiaggregante associare all'anticoagulante?

Alla terapia anticoagulante con warfarin o con i nuovi anticoagulanti orali + acido acetilsalicilico si associa il **clopidogrel**

In assenza di studi clinici randomizzati e per l'aumentato rischio emorragico, l'uso di prasugrel o ticagrelor nella triplice terapia dovrebbe essere evitato

Quale terapia anticoagulante associare alla terapia antiaggregante?

Warfarin se:

- protesi meccaniche cardiache
- primi 3 mesi dopo sostituzione valvolare con protesi biologica
- primi 3 mesi dopo valvuloplastica mitralica chirurgica
- protesi biologiche in sede mitralica in stenosi reumatica
- trombosi endoventricolare sinistra

Nuovi anticoagulanti orali da preferire nella fibrillazione atriale "non valvolare"

Table 8 Strategies to avoid bleeding complications in oral anticoagulation patients

Assess ischaemic and bleeding risks using validated risk predictors (e.g. CHA_2DS_2-VASc, ABC, and HAS-BLED) with a focus on modifiable risk factors.
Keep triple therapy duration as short as possible; dual therapy after PCI (OAC and clopidogrel) to be considered instead of triple therapy.
One should consider the use of a NOAC instead of a VKA when NOACs are not contraindicated.
Consider a target INR in the lower part of the recommended target range and maximize time in the therapeutic range (i.e. >65%) when a VKA is used.
Clopidogrel is the $P2Y_{12}$ inhibitor of choice.
Use low-dose (≤100 mg daily) aspirin.
Routine use of PPIs.

Adapted from Valgimigli et al[410]

ABC = Age, Biomarkers, Clinical history; CHA2DS2-VASc = Congestive heart failure, Hypertension, Age ≥75 years (doubled), Diabetes mellitus, prior Stroke or transient ischaemic attack or thromboembolism (doubled), Vascular disease, Age 65–74 years, Sex category (female); HAS-BLED = Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR, Elderly, Drugs/alcohol concomitantly; INR = international normalized ratio; NOAC = non-vitamin K antagonist OAC; OAC = oral anticoagulant; PPIs = proton pump inhibitors; VKA = vitamin K antagonist.

HAS-BLED score for bleeding risk on oral anticoagulation in atrial fibrillation

Letter	Clinical Characteristic	Score (if present)
H	Hypertension (systolic ≥ 160 mmHg) – on treatment	1
A	Abnormal renal function (Dialysis, transplant, Cr > 2.6 mg/dL or > 200 µmol/L)	1
A	Abnormal liver function (Cirrhosis or bilirubin >2xNormal or AST/ALT/AP >3xNormal)	1
S	Stroke in past	1
B	Prior major bleeding or predisposition to bleeding	1
L	Labile INRs (Unstable/high INRs, time in therapeutic range <60%)	1
E	Elderly – age ≥ 65 years	1
D	Drugs: Medication usage predisposing to bleeding (antiplatelet agents, NSAIDs)	1
D	Drugs: Concomitant alcohol intake (≥8 drinks/week)	1
	Total HAS-BLED Score	Maximum score = 9

The risk of major bleeding within 1 year in patients with AF enrolled in the Euro Heart Study

Risk	Score Range	Annual risk of bleeding (%)
Low	0	1.13
Moderate	1 – 2	1 – 2
High	3+	2 – 12

A score of 3 or more indicates increased one year bleed risk on anticoagulation sufficient to justify caution or more regular review. The risk is for intracranial bleed, bleed requiring hospitalization or a hemoglobin drop > 2 g/L or that needs transfusion.

Table 9 High-risk features for ischaemic events

Prior stent thrombosis on adequate antiplatelet therapy
Stenting of the last remaining patent coronary artery
Diffuse multivessel disease, especially in diabetic patients
Chronic kidney disease (i.e. creatinine clearance <60 mL/min)
At least three stents implanted
At least three lesions treated
Bifurcation with two stents implanted
Total stented length >60 mm
Treatment of a chronic total occlusion
History of STEMI

STEMI = ST-elevation myocardial infarction.

Table 6 **Unfavourable patient profile for a combination of oral anticoagulant and antiplatelet therapy**

• Short life expectancy
• Ongoing malignancy
• Poor expected adherence
• Poor mental status
• End stage renal failure
• Advanced age
• Prior major bleeding/prior haemorrhagic stroke
• Chronic alcohol abuse
• Anaemia
• Clinically significant bleeding on dual antithrombotic therapy

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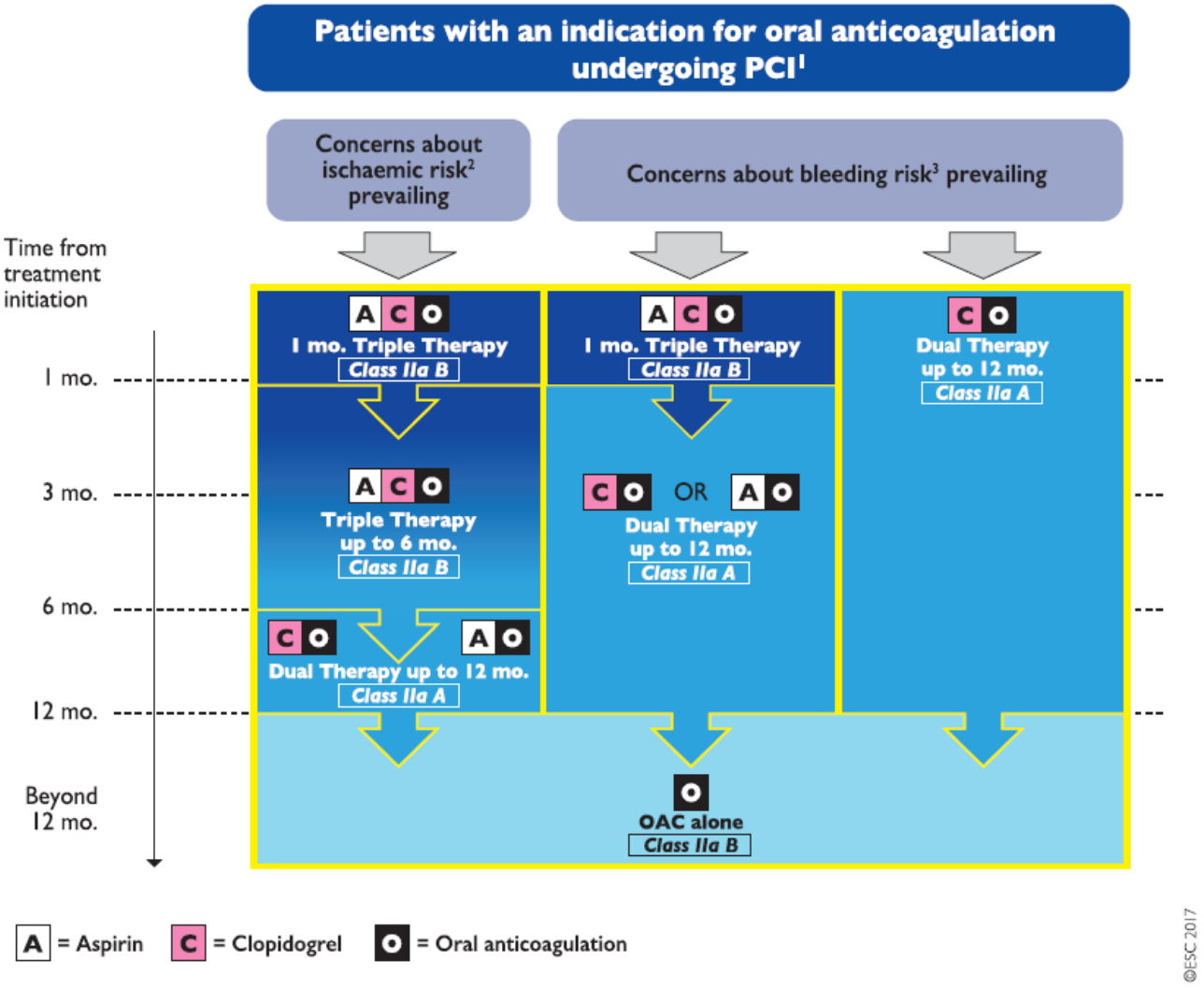
Recommendations for combination therapy with oral anticoagulants and antiplatelets

Recommendations	Class[a]	Level[b]	Ref[c]
After elective coronary stenting for stable coronary artery disease in AF patients at risk of stroke, combination triple therapy with aspirin, clopidogrel and an oral anticoagulant should be considered for 1 month to prevent recurrent coronary and cerebral ischaemic events.	IIa	B	522, 524
After an ACS with stent implantation in AF patients at risk of stroke, combination triple therapy with aspirin, clopidogrel and an oral anticoagulant should be considered for 1–6 months to prevent recurrent coronary and cerebral ischaemic events.	IIa	C	520
After an ACS without stent implantation in AF patients at risk of stroke, dual treatment with an oral anticoagulant and aspirin or clopidogrel should be considered for up to 12 months to prevent recurrent coronary and cerebral ischaemic events.	IIa	C	
The duration of combination antithrombotic therapy, especially triple therapy, should be kept to a limited period, balancing the estimated risk of recurrent coronary events and bleeding.	IIa	B	520
Dual therapy with any oral anticoagulant plus clopidogrel 75 mg/day may be considered as an alternative to initial triple therapy in selected patients.	IIb	C	524, 525

ACS = acute coronary syndromes; AF = atrial fibrillation; OAC = oral anticoagulant.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendations.

LG ESC FA 2016

Terapia antiaggregante e anticoagulante
Per quanto tempo?



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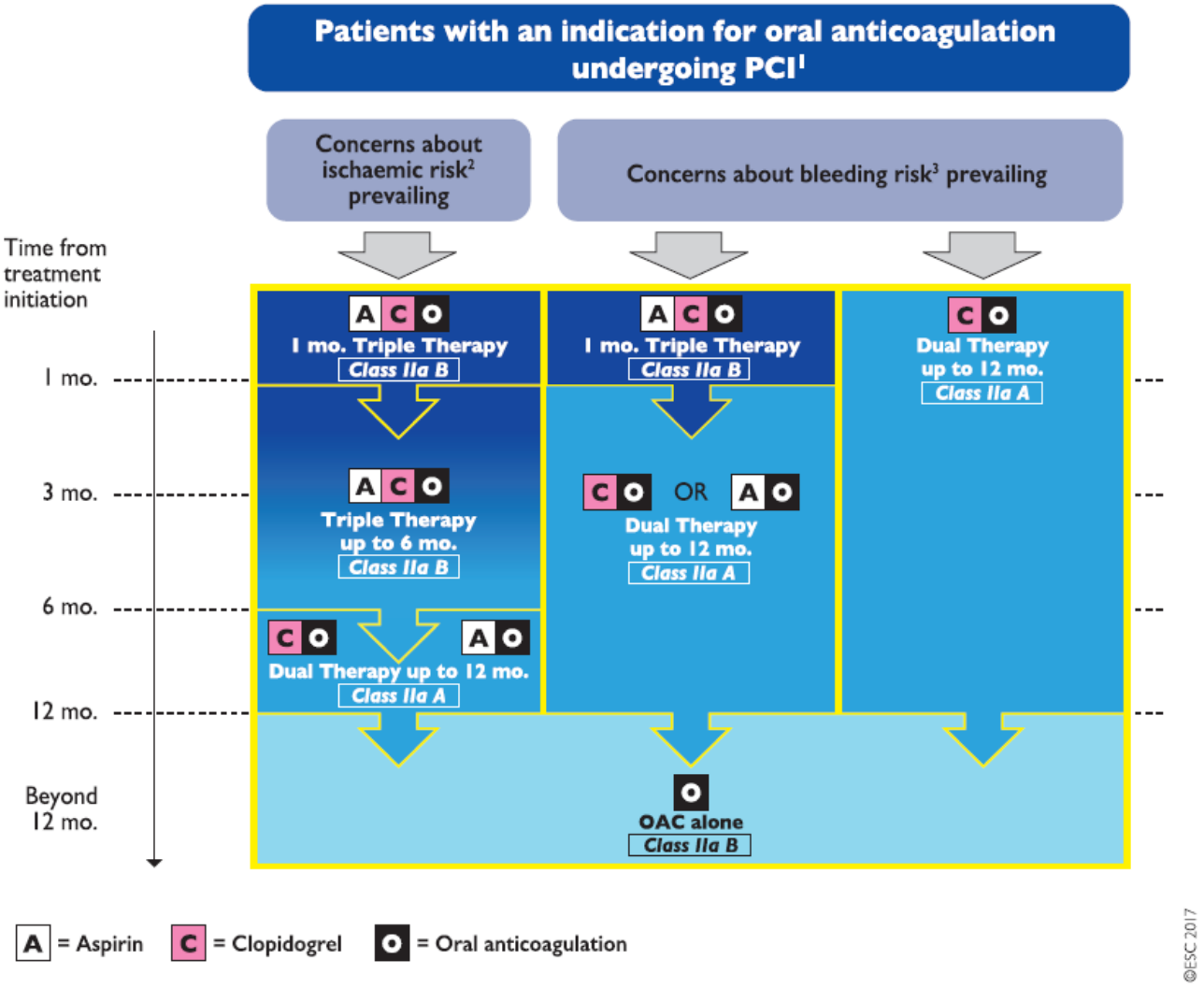

Use of clopidogrel with or without aspirin in patients taking oral anticoagulant therapy and undergoing percutaneous coronary intervention: an open-label, randomised, controlled trial

Willem J M Dewilde, Tom Oirbans, Freek W A Verheugt, Johannes C Kelder, Bart J G L De Smet, Jean-Paul Herrman, Tom Adriaenssens, Mathias Vrolix, Antonius A C M Heestermans, Marije M Vis, Jan G P Tijsen, Arnoud W van 't Hof, Jurriën M ten Berg, for the WOEST study investigators

WOEST trial – Lancet 2013

573 pazienti sottoposti ad angioplastica e con indicazione a TAO (FA, protesi meccanica)

Outcome principale → sanguinamenti

Randomizzati a → warfarin + clopidogrel

→ warfarin + ASA + clopidogrel

Follow-up di 1 anno

Sanguinamenti 2.2% vs 12%

SCA nel 25-30% dei pazienti

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 22, 2016 VOL. 375 NO. 25

Prevention of Bleeding in Patients with Atrial Fibrillation Undergoing PCI

PIONEER AF PCI

2124 pazienti con FA sottoposti ad angioplastica randomizzati a:

- Rivaroxaban 15 mg + clopidogrel
- Rivaroxaban 2,5 mg x 2 + ASA + clopidogrel
- Warfarin + ASA + Clopidogrel

→ meno sanguinamenti con Rivaroxaban, stessa incidenza di morte cardiovascolare/stroke/infarto

SCA nel 50% dei pazienti

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 19, 2017 VOL. 377 NO. 16

Dual Antithrombotic Therapy with Dabigatran after PCI in Atrial Fibrillation

RE-DUAL PCI trial

2725 pazienti con FA sottoposti ad angioplastica

- Warfarin + ASA + inibitore P2Y12
- Dabigatran 150 mg x 2 + inibitore P2Y12
- Dabigatran 110 x 2 + inibitore P2Y12

→ Ridotto rischio di sanguinamento con Dabigatran rispetto alla triplice terapia, soprattutto con il dosaggio 110 x 2

→ Aumento non significativo eventi ischemici con 110 x 2

SCA nel 50% dei pazienti

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Antithrombotic Therapy after Acute Coronary Syndrome or PCI in Atrial Fibrillation

AUGUSTUS trial – NEJM march 2019

4614 pazienti con FA, SCA e/o PCI e indicazione a 6 mesi di clopidogrel

Randomizzati ad una media di 6 giorni dall'evento acuto a:

Warfarin vs Apixaban e ASA vs placebo

→ Nel gruppo Apixaban senza ASA minori sanguinamenti e ridotte ospedalizzazioni senza differenze significative nell'incidenza di eventi ischemici

→ Nel gruppo ASA incidenza di morte o ospedalizzazioni ed eventi ischemici simile al gruppo placebo

37% SCA e angioplastica, 24% SCA terapia medica, 39% angioplastica elettiva

Evaluation of the safety and efficacy of an edoxaban-based antithrombotic regimen in patients with atrial fibrillation following successful percutaneous coronary intervention (PCI) with stent placement: Rationale and design of the ENTRUST-AF PCI trial

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1500 pazienti con FA sottoposti ad angioplastica

Randomizzati a
- Edoxaban 60 mg (o 30 mg) + inibitore P2Y12
- warfarin + ASA + inibitore P2Y12

TAKE HOME MESSAGES

- la terapia antiaggregante e anticoagulante deve essere individualizzata in base alle caratteristiche del paziente (rischio ischemico vs rischio emorragico)
- triplice terapia per il minor tempo possibile
- possibile terapia duale (dalla dimissione)
- importanza della aderenza alla terapia per i NOAC
- monitoraggio:
  - → emocromo, funzione renale, funzione epatica
  - → se warfarin → INR tra 2.0 e 2.5