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Clopidogrel

When Balance is Important Between Efficacy and Safety

Khaled El Nady

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Professor of Cardiology AFCM

2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

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Periprocedural and postprocedural antithrombotic therapyc in patients undergoing primary percutaneous coronary intervention

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Recommendations	Class	Level
Antiplatelet therapy		
A potent $P2Y_{12}$ inhibitor (prasugrel or ticagrelor), or clopidogrel if these are not available or are contra-indicated, is recommended before (or at latest at the time of) PCI and maintained over 12 months unless there are contra-indications such as excessive risk of bleeding.	I	A
Aspirin (oral or i.v, if unable to swallow) is recommended as soon as possible for all patients without contra-indications.	I	B
GP IIb/IIIa inhibitors should be considered for bailout if there is evidence of no-reflow or a thrombotic complication.	IIa	C
Cangrelor may be considered in patients who have not received $P2Y_{12}$ receptor inhibitors.	IIb	A

Doses of antiplatelet and anticoagulant co-therapies in primary PCI

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Doses of antiplatelet and parenteral anticoagulant co-therapies in primary PCI	
Antiplatelet therapies	
Aspirin	Loading dose of 150-300 mg orally or of 75-250 mg i.v. if oral ingestion is not possible, followed by a maintenance dose of 75-100 mg/day.
Clopidogrel	Loading dose of 600 mg orally, followed by a maintenance dose of75 mg/day.
Prasugrel	Loading dose of 60 mg orally, followed by a maintenance dose of 10 mg/day. In patients with body weight ≤60 kg, a maintenance dose of 5 mg/day is recommended. Prasugrel is contra-indicated in patients with previous stroke. In patients ≥75 years, prasugrel is generally not recommended, but a dose of 5 mg/day should be used if treatment is deemed necessary.

Maintenance antithrombotic strategy after ST-elevation myocardial infarction

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Recommendations	Class	Level
Antiplatelet therapy with low-dose aspirin (75–100 mg) is indicated.	I	A
DAPT in the form of aspirin plus ticagrelor or prasugrel (or clopidogrel if ticagrelor or prasugrel is not available or is contra-indicated) is recommended for 12 months after PCI unless there are contra-indications such as excessive risk of bleeding.	I	A
A PPI in combination with DAPT is recommended in patients at high risk of gastrointestinal bleeding.	I	B
In patients with an indication for oral anticoagulation, oral anti-coagulants are indicated in addition to antiplatelet therapy.	I	C

Maintenance antithrombotic strategy after ST-elevation myocardial infarction *(continued)*

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Recommendations	Class	Level
In high ischaemic risk patients who have tolerated DAPT without a bleeding complication, treatment with DAPT in the form of ticagrelor 60 mg twice a day on top of aspirin for longer than 12 months may be considered for up to 3 years.	IIb	B
In low bleeding risk patients who receive aspirin and clopidogrel, low-dose rivaroxaban (2.5 mg twice daily) may be considered.	IIb	B
The use of ticagrelor or prasugrel is not recommended as part of triple antithrombotic therapy with aspirin and oral anticoagulation.	III	C

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2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation

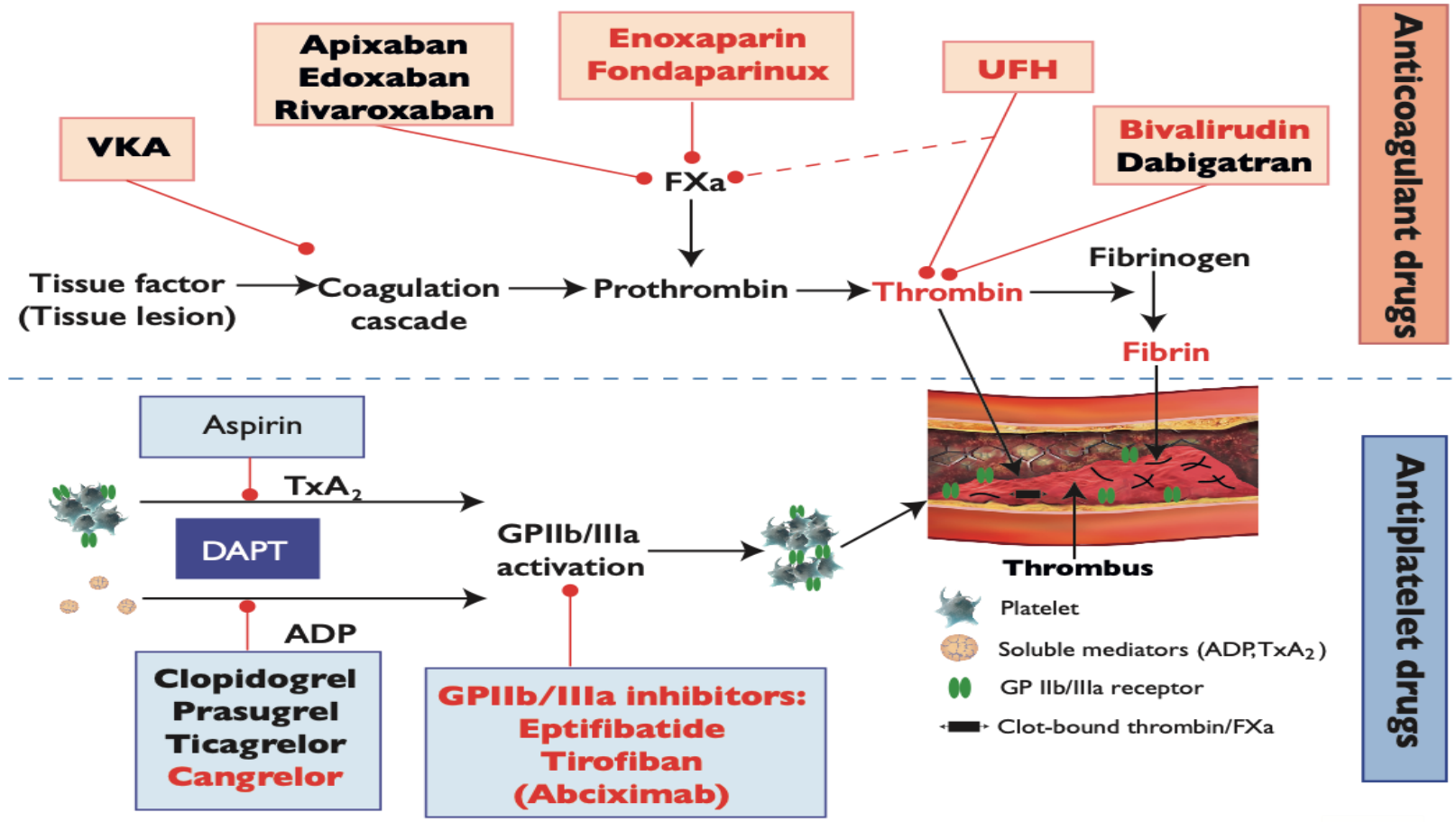

Figure 6

Antithrombotic treatments in non-ST-segment elevation acute coronary syndrome patients: pharmacological targets. Drugs with oral administration are shown in black letters and drugs with preferred parenteral administration in red. Abciximab (in brackets) is not supplied anymore.

www.escardio.org/guidelines

2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation (European Heart Journal 2020 - doi/10.1093/eurheartj/ehaa575)

Table 6 Dose regimen of antiplatelet and anticoagulant drugs in non-ST-segment elevation acute coronary syndrome patients[a] (1)

I. Antiplatelet drugs	
Aspirin	LD of 150–300 mg orally or 75–250 mg i.v. if oral ingestion is not possible, followed by oral MD of 75–100 mg o.d.
$P2Y_{12}$ receptor inhibitors (oral or i.v.)	
Clopidogrel	LD of 300–600 mg orally, followed by a MD of 75 mg o.d., no specific dose adjustment in CKD patients.
Prasugrel	LD of 60 mg orally, followed by a MD of 10 mg o.d. In patients with body weight <60 kg, a MD of 5 mg o.d. is recommended. In patients aged ≥75 years, prasugrel should be used with caution, but a dose of 5 mg o.d. should be used if treatment is deemed necessary. No specific dose adjustment in CKD patients. Prior stroke is a contraindication for prasugrel.

[a]All dosing regimens refer to doses given for the respective drugs for protection against thrombosis within the arterial system.

www.escardio.org/guidelines

2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation (European Heart Journal 2020 - doi/10.1093/eurheartj/ehaa575)

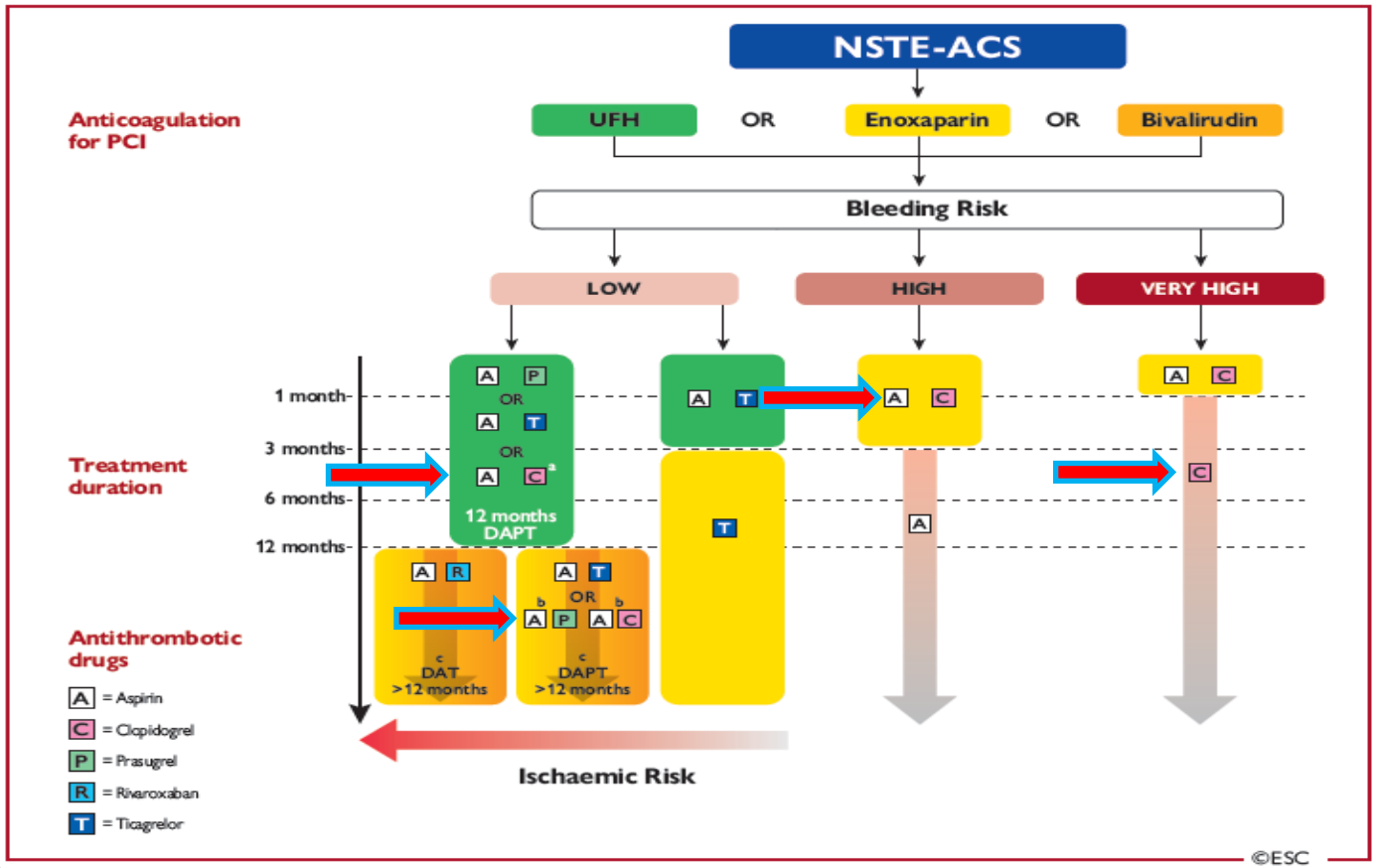

Figure 7 (1)

Algorithm for antithrombotic therapy in non-ST-segment elevation acute coronary syndrome patients without atrial fibrillation undergoing percutaneous coronary intervention.

= Class I = Class IIa = Class IIb

Very HBR is defined as recent bleeding in the past month and/or not deferrable planned surgery.

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2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation (European Heart Journal 2020 - doi/10.1093/eurheartj/ehaa575)

Recommendations for combining antiplatelet agents and anticoagulants in non-ST-segment elevation acute coronary syndrome patients requiring chronic oral anticoagulation (4)

Recommendations	Class	Level
Patients undergoing coronary stenting		
Antiplatelet treatment (continued)		
In patients treated with a VKA (e.g. mechanical prosthetic valves), clopidogrel alone should be considered in selected patients (HAS-BLED ≥3 or ARC-HBR met and low risk of stent thrombosis) for up to 12 months.	IIa	B
When rivaroxaban is used and concerns about HBR prevail over stent thrombosis or ischaemic stroke, rivaroxaban 15 mg o.d. should be considered in preference to rivaroxaban 20 mg o.d. for the duration of concomitant SAPT or DAPT.	IIa	B

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2020 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation (European Heart Journal 2020 - doi/10.1093/eurheartj/ehaa575)

2019 ESC Guidelines on the diagnosis and management of chronic coronary syndromes

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Patients with angina and/or dyspnoea and coronary artery disease - Event prevention (1)

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Recommendations	Class	Level
Antithrombotic therapy in patients with CCS and in sinus rhythm		
Aspirin 75-100 mg daily is recommended in patients with a previous MI or revascularization.	I	A
Clopidogrel 75 mg daily is recommended as an alternative to aspirin in patients with aspirin intolerance.	I	B
Clopidogrel 75 mg daily may be considered in preference to aspirin in symptomatic or asymptomatic patients, with either PAD or a history of ischaemic stroke or transient ischaemic attack.	IIb	B
Aspirin 75-100 mg daily may be considered in patients without a history of MI or revascularization, but with definitive evidence of CAD on imaging.	IIb	C

Patients with angina and/or dyspnoea and coronary artery disease - Event prevention (3)

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Recommendations	Class	Level
Antithrombotic therapy post-PCI in patients with CCS and in sinus rhythm		
Aspirin 75-100 mg daily is recommended following stenting.	I	A
Clopidogrel 75 mg daily following appropriate loading (e.g. 600 mg or >5 days of maintenance therapy) is recommended, in addition to aspirin, for 6 months following coronary stenting, irrespective of stent type, unless a shorter duration (1-3 months) is indicated due to risk or the occurrence of life-threatening bleeding.	I	A
Clopidogrel 75 mg daily following appropriate loading (e.g. 600 mg or >5 days of maintenance therapy) should be considered for 3 months in patients with a higher risk of life-threatening bleeding.	IIa	A

Patients with angina and/or dyspnoea and coronary artery disease - Event prevention (6)

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Recommendations	Class	Level
Antithrombotic therapy in patients with CCS and AF		
Long-term OAC therapy (NOAC or VKA with time in therapeutic range >70%) should be considered in patients with AF and a CHA_2DS_2-VASc score[a] of 1 in males and 2 in females.	IIa	B
Aspirin 75-100 mg daily (or clopidogrel 75 mg daily) may be considered in addition to long-term OAC therapy in patients with AF, history of MI, and at high risk of recurrent ischaemic events[b] who do not have a high bleeding risk.[c]	IIb	B

[a] Congestive HF, hypertension, age ≥75 years (2 points), diabetes, prior stroke/transient ischaemic attack/embolus (2 points), vascular disease (CAD on imaging or angiography, prior MI, PAD, or aortic plaque), age 65-74 years, and female sex.
[b] Diffuse multivessel CAD with at least one of the following: diabetes mellitus requiring medication, recurrent MI, PAD, or CKD with eGFR 15-59 mL/min/1.73 m^2.
[c] Prior history of intracerebral haemorrhage or ischaemic stroke, history of other intracranial pathology, recent gastrointestinal bleeding or anaemia due to possible gastrointestinal blood loss, other gastrointestinal pathology associated with increased bleeding risk, liver failure, bleeding diathesis or coagulopathy, extreme old age or frailty, or renal failure requiring dialysis or with eGFR <15 mL/min/1.73 m^2.

Patients with angina and/or dyspnoea and coronary artery disease - Event prevention (7)

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Recommendations	Class	Level
Antithrombotic therapy in post-PCI patients with AF or another indication for an OAC		
It is recommended that peri-procedural aspirin and clopidogrel are administered to patients undergoing coronary stent implantation.	I	C
In patients who are eligible for a NOAC, it is recommended that a NOAC (apixaban 5 mg b.i.d., dabigatran 150 mg b.i.d., edoxaban 60 mg o.d., or rivaroxaban 20 mg o.d.)[a] is used in preference to a VKA in combination with antiplatelet therapy.	I	A

[a] See summary of product characteristics for reduced doses or contraindications for each NOAC in patients with CKD, body weight <60 kg, age >75-80 years, and/or drug interactions.

Patients with angina and/or dyspnoea and coronary artery disease - Event prevention (10)

ESC European Society of Cardiology

Recommendations	Class	Level
Antithrombotic therapy in post-PCI patients with AF or another indication for an OAC		
Dual therapy with an OAC and either ticagrelor or prasugrel may be considered as an alternative to triple therapy with an OAC, aspirin, and clopidogrel in patients with a moderate or high risk of stent thrombosis,[a] irrespective of the type of stent used.	IIb	C
The use of ticagrelor or prasugrel is not recommended as part of triple antithrombotic therapy with aspirin and an OAC.	III	C

[a] Risk of stent thrombosis encompasses (i) the risk of thrombosis occurring and (ii) the risk of death should stent thrombosis occur, both of which relate to anatomical, procedural, and clinical characteristics. Risk factors for CCS patients include stenting of left main stem, proximal LAD, or last remaining patent artery; suboptimal stent deployment; stent length >60 mm; diabetes mellitus; CKD; bifurcation with two stents implanted; treatment of chronic total occlusion; and previous stent thrombosis on adequate antithrombotic therapy.

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European Heart Journal (2018) **39**, 763–821
doi:10.1093/eurheartj/ehx095

ESC GUIDELINES

2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

Management of antithrombotic treatment in patients with carotid artery stenosis

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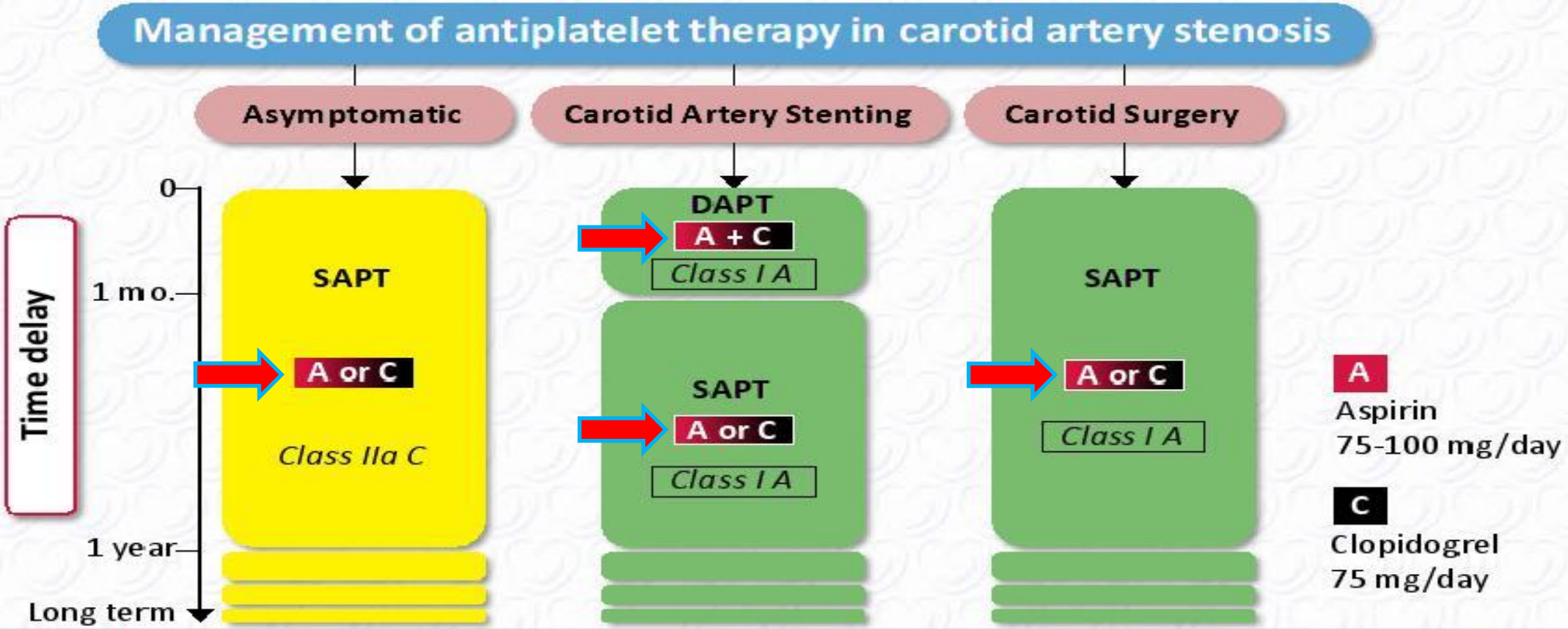

www.escardio.org/guidelines 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with ESVS (European Heart Journal 2017; doi:10.1093/eurheartj/ehx095)

Antithrombotic therapy in patients with LEAD requiring oral anticoagulation

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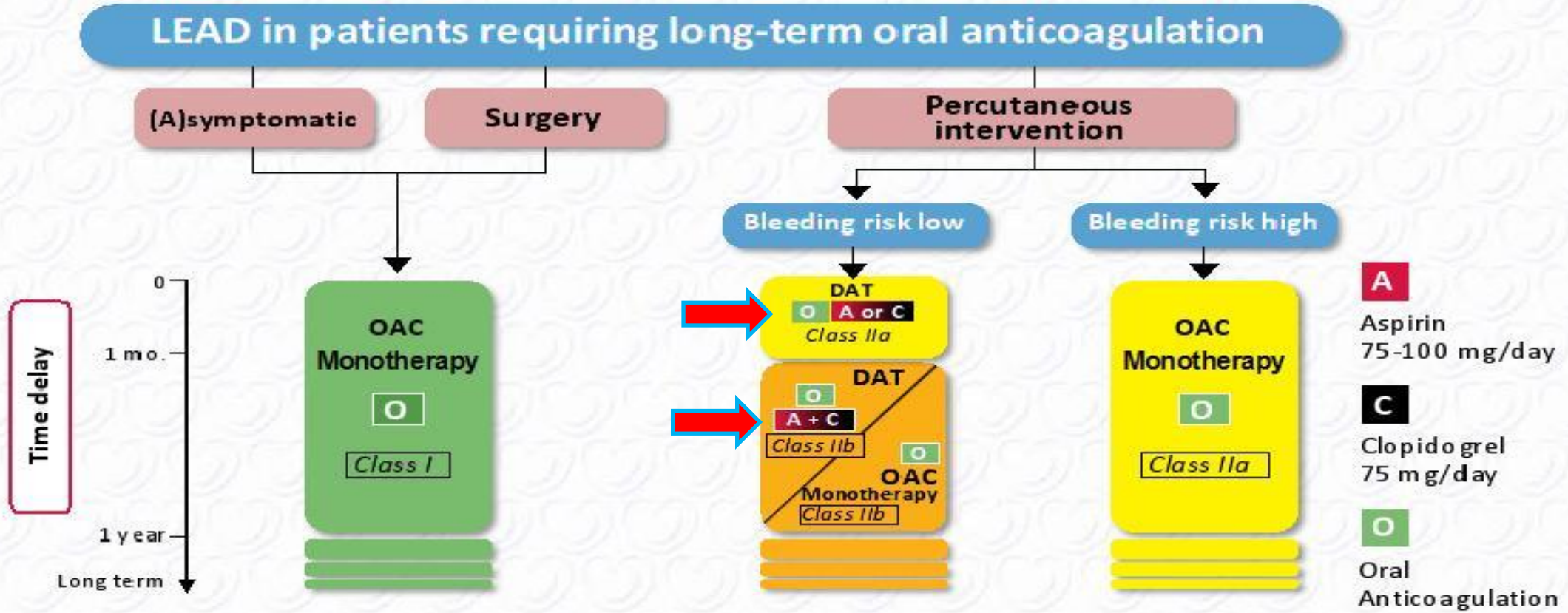


2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with ESVS (European Heart Journal 2017; doi:10.1093/eurheartj/ehx095)

Association of Ticagrelor vs. Clopidogrel With Major Adverse Coronary Events (MACE) in Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention

Objective : To compare the risk of MACE with ticagrelor vs clopidogrel in patients with ACS treated with PCI, to compare major bleeding and dyspnea, and to evaluate the association between $P2Y_{12}$ inhibitor adherence and MACE.

Subjects : 11,185 individuals who underwent PCI.

- **Ticagrelor** (n= 4,076, 36.4%)
- **Clopidogrel** (n= 7,109, 63.6%)

Follow up period : 1 year

JAMA Intern Med. 2020;180(3):420-428. doi:10.1001/jamainternmed.2019.6447

Association of Ticagrelor vs. Clopidogrel With Major Adverse Coronary Events (MACE) in Patients With Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention

Conclusion :

Patients with ACS who underwent PCI, outpatient use of **ticagrelor** was not associated with a statistically significant reduction in MACE vs **clopidogrel**; **however, it was associated with more major bleeding and dyspnea.**

Table 4. Association of Clopidogrel vs Ticagrelor With Outcomes Within 1 Year After Percutaneous Coronary Intervention for Acute Coronary Syndrome in Propensity Score–Matched Cohort

Outcome	No. (%) Clopidogrel Group (n = 3711)	Ticagrelor Group (n = 3711)	*P* Value	HR (95% CI)
MACE	368 (9.9)	380 (10.2)	.64	1.00 (0.86-1.17)
All-cause death	54 (1.5)	61 (1.6)	.51	1.10 (0.75-1.61)
ACS	228 (6.1)	235 (6.3)	.74	1.02 (0.84-1.24)
Coronary revascularization	168 (4.5)	157 (4.2)	.53	0.86 (0.67-1.09)
PCI	121 (3.3)	114 (3.1)	.64	0.90 (0.68-1.19)
CABG	50 (1.3)	44 (1.2)	.53	0.74 (0.47-1.15)
Stent thrombosis	7 (0.2)	18 (0.5)	.03	2.57 (1.07-6.16)[a]
Composite of all-cause death, ACS, or stroke	290 (7.8)	299 (8.1)	.70	1.02 (0.86-1.21)
Ischemic stroke	18 (0.5)	17 (0.5)	.87	0.94 (0.48-1.86)
Major bleed	182 (4.9)	261 (7.0)	<.001	1.52 (1.24-1.87)[a]
Intracranial	3 (0.1)	3 (0.1)	>.99	1.00 (0.14-7.10)
Gastrointestinal	53 (1.4)	95 (2.6)	<.001	2.10 (1.44-3.06)[a]
Pulmonary	81 (2.2)	105 (2.8)	.08	1.32 (0.97-1.80)
Urologic	29 (0.8)	37 (1.0)	.32	1.32 (0.79-2.22)
Other	32 (0.9)	38 (1.0)	.47	1.29 (0.78-2.11)
Dyspnea	46 (1.2)	116 (3.1)	<.001	2.42 (1.70-3.45)[a]

JAMA Intern Med. 2020;180(3):420-428. doi:10.1001/jamainternmed.2019.6447

Comparing Ticagrelor Vs. Clopidogrel in Patients With a History of Cerebrovascular Diseasee

Table 1. Ticagrelor Versus Clopidogrel on the Outcome of Stroke in PLATO[1,2]

Evidence	Ticagrelor (n=9333)	Clopidogrel (n=9291)	RR, NNH, *P* Value
PLATO*	125 (1.30%)	106 (1.14%)	1.17 NNH=491 (*P*=0.22)
FDA CRR	138 (1.48%)	111 (1.19%)	1.24 NNH=352 (*P*=0.09)

RR indicates relative risk; NNH, number needed to harm; FDA, Food and Drug Administration; CRR, complete response review.

*Data from reference 1.

Stroke. 2012;43:3409-3410

Comparing Ticagrelor Vs. Clopidogrel in Patients With a History of Cerebrovascular Diseasee

Conclusion:

Compared with clopidogrel-treated patients with a history of cerebrovascular disease, patients on ticagrelor are at:

- **A 2-fold** increased risk for a recurrent stroke or TIA.
- **A 2-fold** increased risk for an intracranial hemorrhage complication.
- **A 10-fold** increased risk for a fatal intracranial hemorrhage .

Stroke. 2012;43:3409-3410

Comparing Ticagrelor Vs. Clopidogrel in Patients With a History of Cerebrovascular Diseasee

Table 2. Ticagrelor Versus Clopidogrel in Patients With a History of Cerebrovascular Disease in PLATO[2,4]

Outcome	Ticagrelor	Clopidogrel	RR, *P* Value
Stroke/TIA	8.1%	4.0%	>2 (*P*=0.24)
Major or life-threatening intracranial hemorrhage	27 (0.3%)	14 (0.15%)	2 (*P*=0.05)
Fatal intracranial hemorrhage	11 (0.12%)	1 (0.0%)	10 (*P*=0.02)
Outpatient intracranial hemorrhagic events	17 (0.19%)	10 (0.11%)	1.73 (*P*=0.19)
Intracranial hemorrhagic events*	4/564 (0.9%)	4/588 (0.7%)	1.00 (0.25–3.99; *P*=0.96)

RR indicates relative risk; TIA, transient ischemic attack.
*Data from reference 4.

Stroke. 2012;43:3409-3410

Comparison Between Ticagrelor and Clopidogrel in Elderly Patients With an Acute Coronary Syndrome

- **Observational analysis of all patients ≥80 years who were discharged alive with aspirin combined with either clopidogrel or ticagrelor after a MI between 2010 and 2017 registered in the national registry SWEDEHEART.**

- **No. of Patients : 14,005 Ps.**
  - **Clopidogrel (n= 8434, 60.2%)**
  - **Ticagrelor (n=5571, 39.8%)**

Circulation. 2020;142:1700–1708. DOI: 10.1161 Circulation

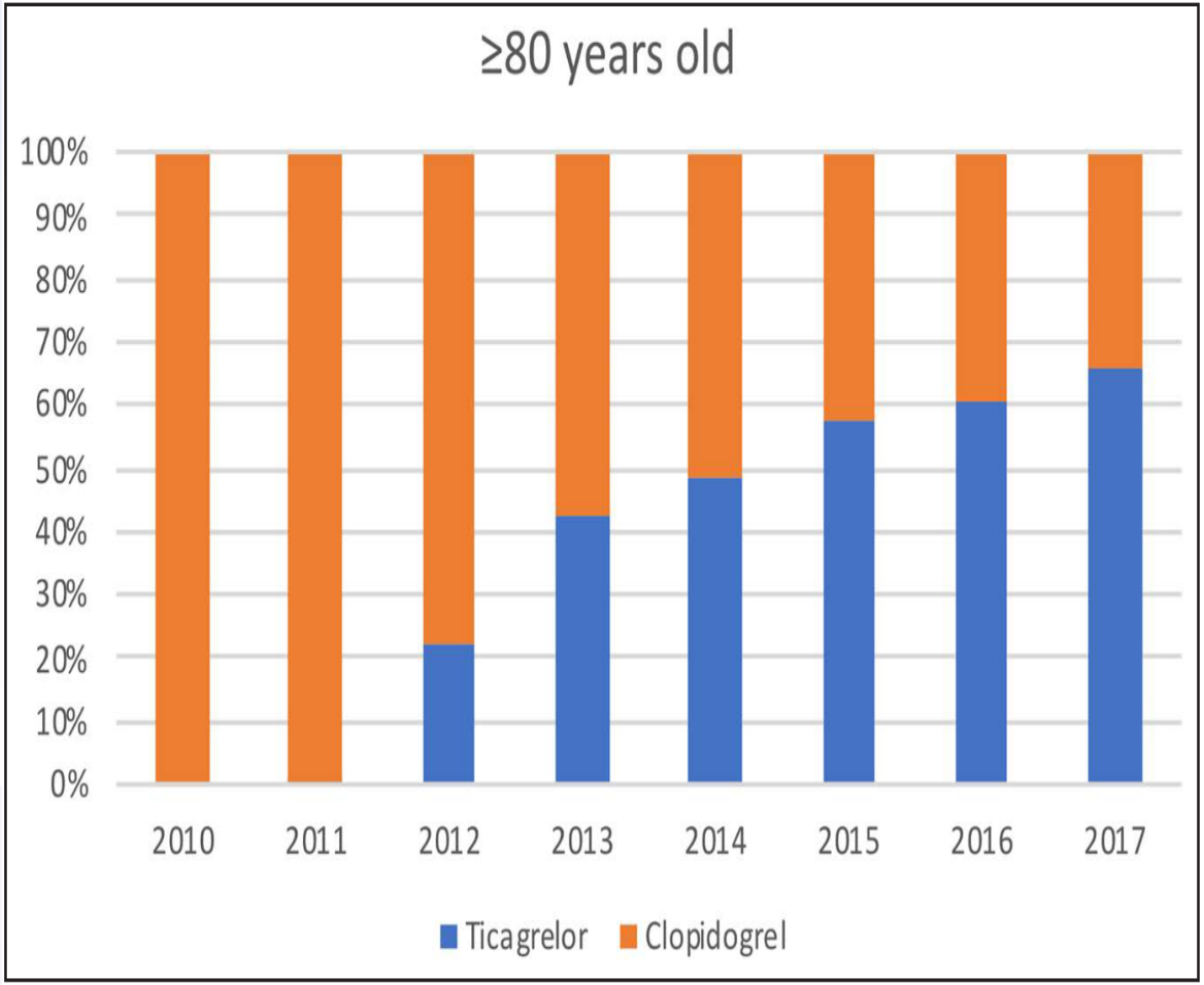
Clinical Perspective

What Is New?

- In this observational analysis from the SWEDE-HEART registry (Swedish Web-System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies), we found that ≥80-year-old patients may have a different benefit-risk ratio when treated with ticagrelor compared with clopidogrel when discharged after a myocardial infarction.
- Specifically, we found that patients ≥80 years old had a 17% increased risk of death and a 48% higher risk of bleeding when discharged on ticagrelor versus clopidogrel after a myocardial infarction, whereas there was a 20% lower risk of a new myocardial infarction and a 28% lower risk of stroke.

What Are the Clinical Implications?

- Selecting a combination of aspirin with a P2Y12 inhibitor (either clopidogrel or ticagrelor) at discharge after a myocardial infarction should be made cautiously among elderly patients ≥80 years old, who may have a different risk-benefit than younger individuals.
- A randomized clinical trial in the elderly is needed to confirm these findings.



Circulation. 2020;142:1700–1708. DOI: 10.1161

Circulation

Comparison Between Ticagrelor and Clopidogrel in Elderly Patients With an Acute Coronary Syndrome

Conclusion :

Ticagrelor use among elderly patients with MI was associated with higher risk of bleeding and death compared with Clopidogrel.

Circulation. 2020;142:1700–1708. DOI: 10.1161

Circulation

Randomized Controlled Trial > Int J Clin Pharmacol Ther. 2009 Dec;47(12):780-4.

doi: 10.5414/cpp47780.

Bioequivalence of two oral formulations of clopidogrel tablets in healthy male volunteers

O El Ahmady [1], M Ibrahim, A M Hussein, R T Bustami

Affiliations + expand

PMID: 19954717 DOI: 10.5414/cpp47780

Bioequivalence of two oral formulations of clopidogrel tablets in healthy male volunteers

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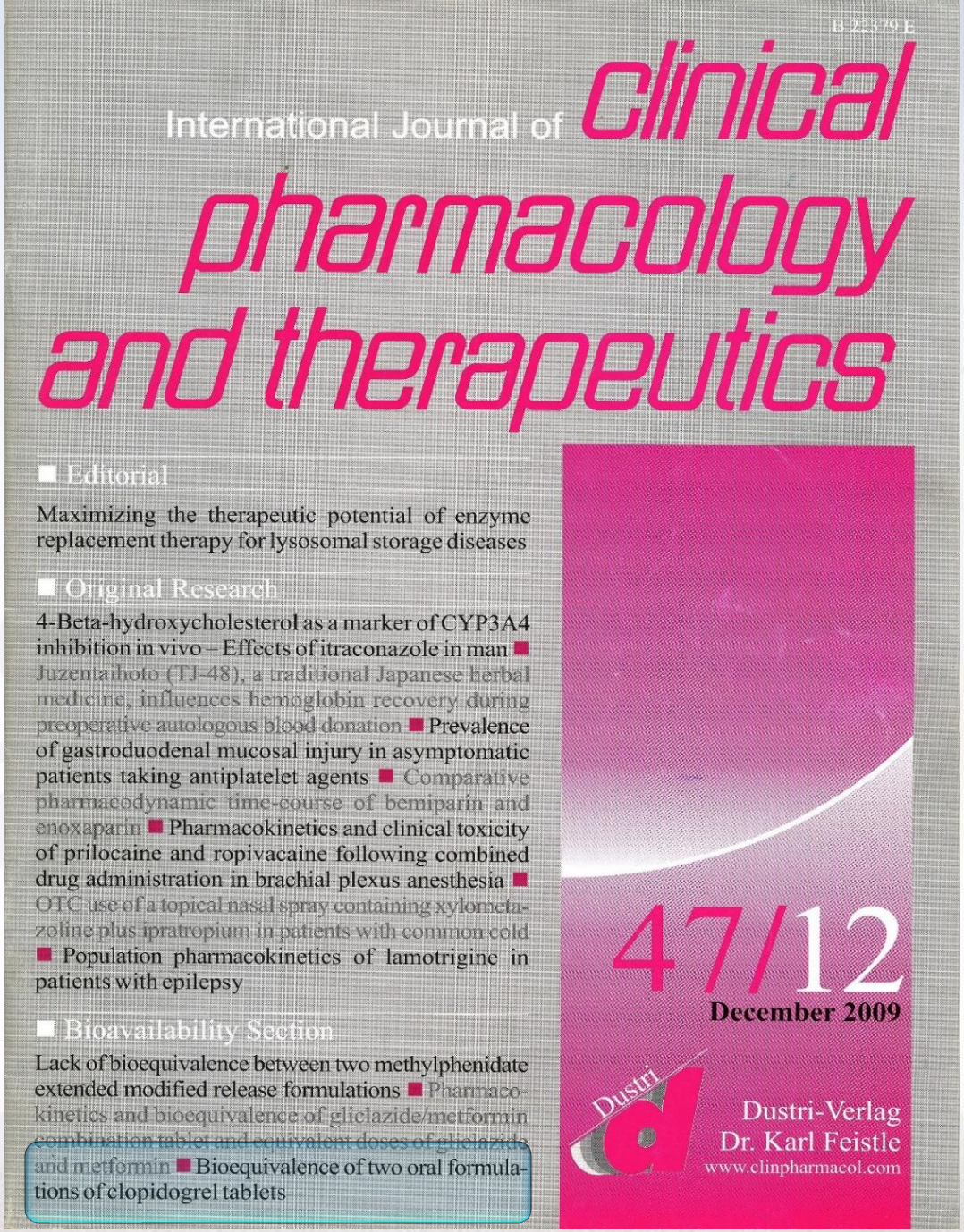
Abstract

A randomized, two-way, crossover, bioequivalence study in 32 fasting, healthy, male volunteers was conducted to compare two brands of clopidogrel 75 mg tablets, Thrombo (EIPICO, Egypt) as test and Plavix (Sanofi Pharma/Bristol-Myers Squibb, Paris, France) as reference. The study was performed in a Pharmaceutical Research Unit (PRU) using HPLC/ MS-MS. Arithmetic means for clopidogrel test versus reference formulation, respectively were for Cmax (4.39 +/- 2.58 vs. 4.30 +/- 2.65) ng/ml, AUC0-t (11.98 +/- 9.82 vs. 12.01 +/- 9.46) ng.h/ml, AUC0- yen (12.43 +/- 9.94 vs. 12.49 +/- 9.58) ng.h/ml, t1/2 (6.06 +/- 3.87 vs. 5.87 +/- 2.47) h and the medians for tmax (1 h vs. 0.75 h). Arithmetic means for clopidogrel carboxylic acid metabolite were Cmax (3.75 +/- 1.19 vs. 3.51 +/- 0.97) microg/ml AUC0-t (9.18 +/- 2.36 vs. 9.17 +/- 2.06) microg.h/ml, AUC0- yen (9.72 +/- 2.4 vs. 9.80 +/- 2.21) microg.h/ml , and t1/2 (6.43 +/- 3.52 vs. 6.33 +/- 1.71) h for test versus reference formulation respectively and there was no difference in the medians for tmax (0.75 h). The parametric 90% confidence intervals for the mean of the difference between log-transformed values were within the accepted range for bioequivalence of 80 - 125% as proposed by the US-FDA , namely for clopidogrel (90.66% - 109.66%), (90.63% - 109.73%), and (93.19% - 115.37%) for AUC0-t, AUC0- yen, and Cmax, respectively and also for clopidogrel carboxylic acid metabolite (94.90 - 104.19) , (94.04 - 103.86) and (96.47 - 114.79) for AUC0-t , AUC0- yen, and Cmax, respectively. Thus there was no significant difference between these values and therefore the two products can be considered bioequivalent.



✓ Conclusion

The results indicate that the test drug (Thrombo) is bioequivalent to the reference drug and that the two formulations can be prescribed interchangeably.

cally relevant differences in regard to safety and efficacy.

The study revealed that the 90% confidence intervals for AUC_{0-t}, $AUC_{0-\infty}$, and C_{max} (90.66% – 109.66%, 90.63% – 109.73%, and 93.19% – 115.37%, respectively) are all well within the acceptable range for bioequivalence of 80% – 125% as proposed by US-FDA.

These results were confirmed by the Schuirmann's two one-sided t-tests, which indicated that the lower and upper limits of the calculated t-value were greater than the critical t value for the three parameters for clopidogrel (Table 3) and for clopidogrel carboxylic metabolite (Table 4). Therefore, the two formulations can be considered bioequivalent in regard to the extent and rate of absorption.

Conclusion

The results indicate that the test drug (Thrombo®) is bioequivalent to the reference drug (Plavix®) and that the two formulations can be prescribed interchangeably.

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Clopidogrel 75 mg

Maintains the flow
with trusted efficacy

Prevent the sudden stops

EIPICO

Thank You