Antiagregació - Anticoagulació en pacients tractats amb Anticoagulació Oral crònica: Estratègia en relació al risc tromboembòlic / hemorràgic

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IDIBELL. Hospital Universitari de Bellvitge

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Disclosures

- **Consultant:**
  - **Abbott, Boston, Hexacath, J&J, Biosensors, Terumo, Sant Jude.**
  - **Lilly, Astra Zeneca, Daiichi Sankyo, Sanofi.**

OBJECTIUS DEL TRACTAMENT

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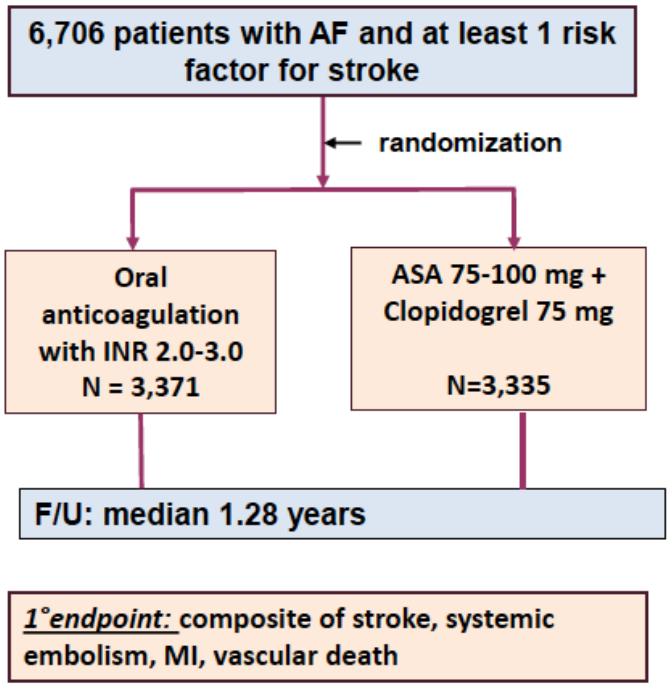
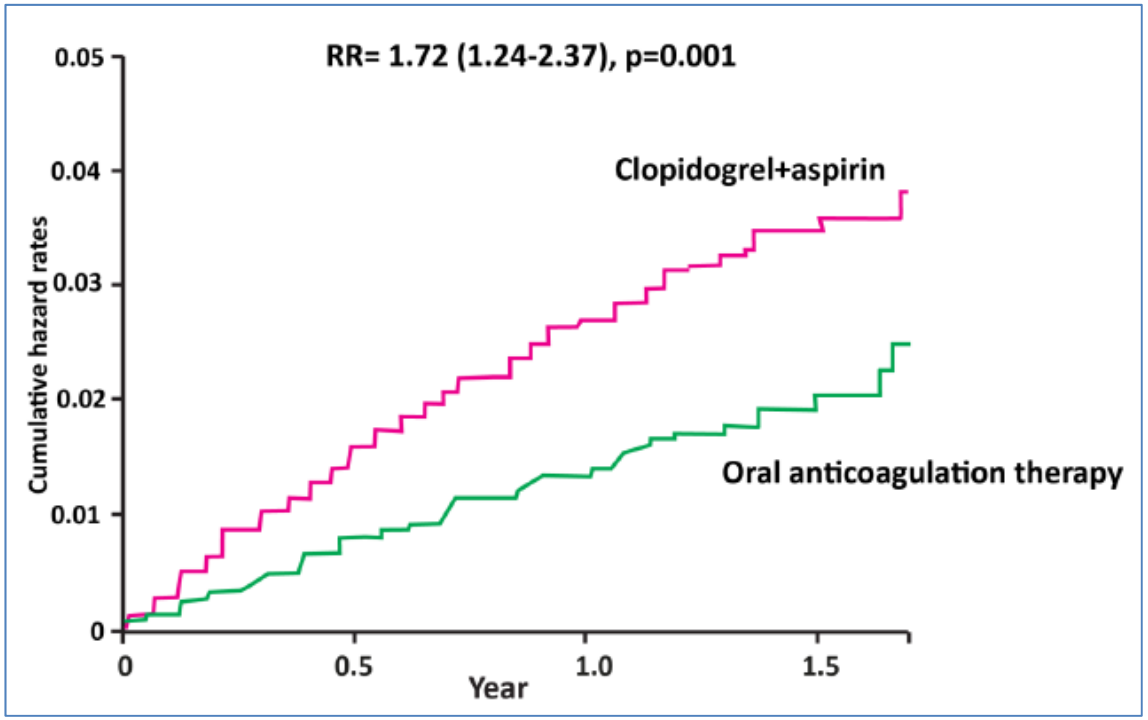
EFICACIA		SEGURETAT
Evitar problemes isquèmics: - Mort - IAM - Trombosi stent	**Evitar problemes embòlics:** - AVC - Embòlia perifèrica	**Evitar Sagnats**

Eficàcia: Prevenció embòlica: ACTIVE W





Conclusion

Oral anticoagulation therapy is superior to clopidogrel plus aspirin for prevention of vascular events in patients with atrial fibrillation at high risk of stroke, especially in those already taking oral anticoagulation therapy.

Connolly S on behalf of ACTIVE W investigators. *Lancet* 2006; 367 (9526): 1903.

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European Heart Journal
doi:10.1093/eurheartj/ehq278

Guidelines for the management of atria fibrillation

**The Task Force for the Management of Atrial Fibrillati
European Society of Cardiology (ESC)**

$CHADS_2$

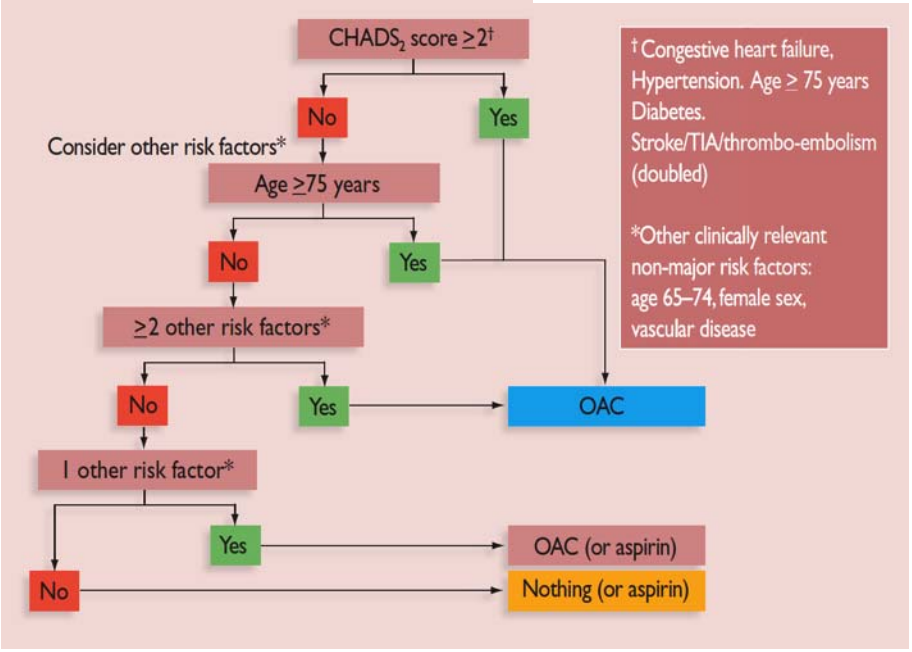
Initial	Risk Factor	Value
C	Cardiac Failure	1
H	Hypertension	1
A	Age ≥ 75	1
D	Diabetes	1
S_2	Stroke	2

CHA_2DS_2VASc

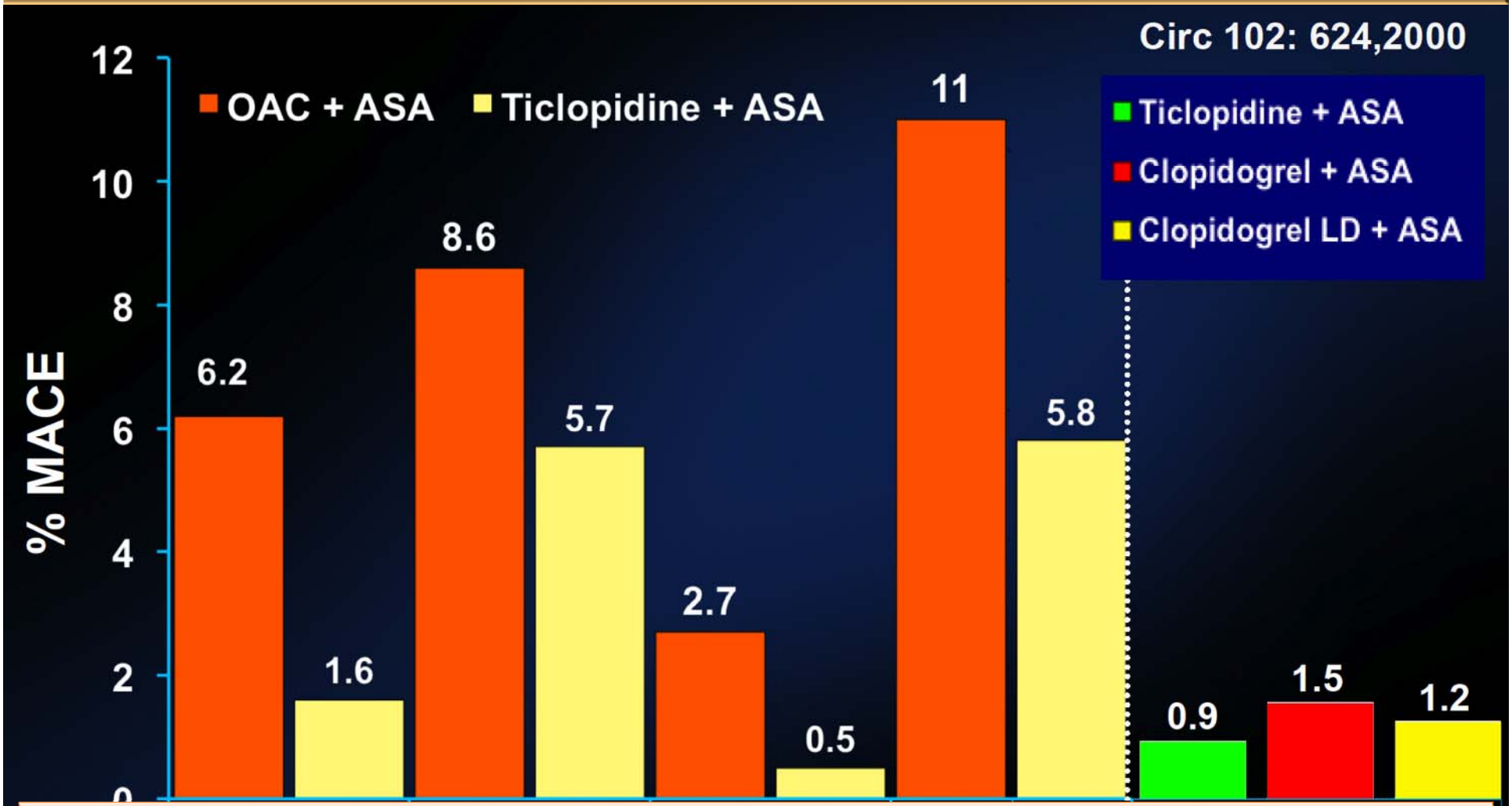
Initial	Risk Factor	Value
C	Cardiac Failure	1
H	Hypertension	1
A_2	Age ≥ 75	2
D	Diabetes	1
S_2	Stroke	2
V	Vascular disease	1
A	Age 65-74	1
Sc	Sex Category	1

Table 9 Approach to thromboprophylaxis in patients with AF

Risk category	CHA_2DS_2-VASc score	Recommended antithrombotic therapy
One 'major' risk factor or ≥2 'clinically relevant non-major' risk factors	≥ 2	OAC[a]
One 'clinically relevant non-major' risk factor	1	Either OAC[a] or aspirin 75–325 mg daily. Preferred: OAC rather than aspirin.
No risk factors	0	Either aspirin 75–325 mg daily or no antithrombotic therapy. Preferred: no antithrombotic therapy rather than aspirin.



Eficàcia: Esdeveniments CV



Per a prevenir la trombosi del stent i els esdeveniments cardíacs majors, la Doble Terapia Antiplaquetaria és superior a l'Anticoagulació Oral amb ASA.

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OBJECTIUS DEL TRACTAMENT

EFICACIA		SEGURETAT
Evitar problemes isquèmics: - Mort - IAM - Trombosi stent	**Evitar problemes embòlics:** - AVC - Embòlia perifèrica	**Evitar Sagnats**

Guidelines: No dades

Recommendations for antithrombotic therapy in AF and ACS/PCI

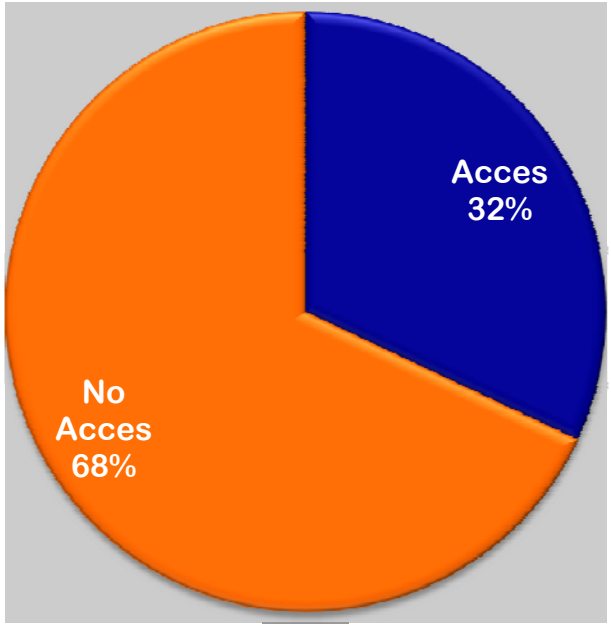
Recommendations	Class[a]	Level[b]	Ref.[c]
Following elective PCI in patients with AF with stable coronary artery disease, BMS should be considered, and drug-eluting stents avoided or strictly limited to those clinical and/or anatomical situations (e.g. long lesions, small vessels, diabetes, etc.), where a significant benefit is expected when compared with BMS.	IIa	C	
Following elective PCI, triple therapy (VKA, aspirin, clopidogrel) should be considered in the short term, followed by more long-term therapy (up to 1 year) with VKA plus clopidogrel 75 mg daily (or, alternatively, aspirin 75–100 mg daily, plus gastric protection with PPIs, H_2 antagonists, or antacids).	IIa	C	
Following elective PCI, clopidogrel should be considered in combination with VKA plus aspirin for a minimum of 1 month after implantation of a BMS, but longer with a drug-eluting stent (at least 3 months for a sirolimus-eluting stent and at least 6 months for a paclitaxel-eluting stent); following which VKA and clopidogrel 75 mg daily (or, alternatively, aspirin 75–100 mg daily, plus gastric protection with either PPIs, H_2 antagonists, or antacids) should be considered, if required.	IIa	C	
Following an ACS with or without PCI in patients with AF, triple therapy (VKA, aspirin, clopidogrel) should be considered in the short term (3–6 months), or longer in selected patients at low bleeding risk, followed by long-term therapy with VKA plus clopidogrel 75 mg daily (or, alternatively, aspirin 75–100 mg daily, plus gastric protection with PPIs, H_2 antagonists, or antacids).	IIa	C	
In anticoagulated patients at very high risk of thrombo-embolism, uninterrupted therapy with VKA as the preferred strategy and radial access used as the first choice even during therapeutic anticoagulation (INR 2–3).	IIa	C	
In patients with stable vascular disease (e.g. >1 year, with no acute events), VKA monotherapy may be considered, and concomitant antiplatelet therapy should not be prescribed in the absence of a subsequent cardiovascular event.	IIb	C	

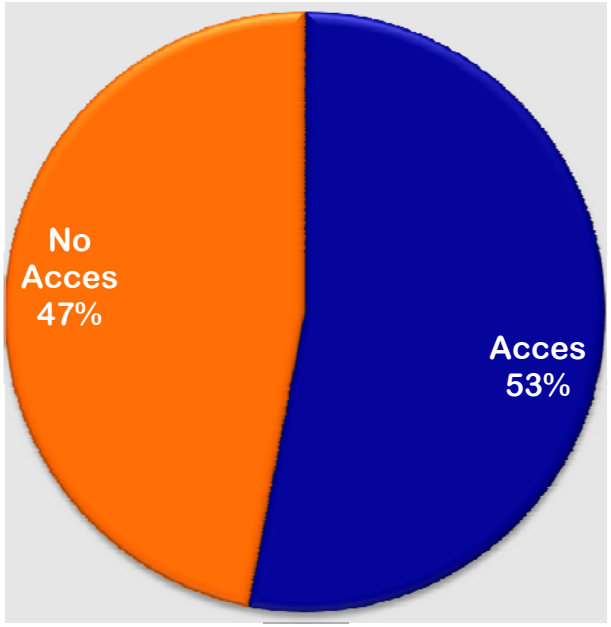
Totes les recomanacions actuals son mesures que poden ser considerades, sense cap nivell d'evidència:
NO HI HA DADES OBJECTIVES DEL QUE S'HA DE FER.

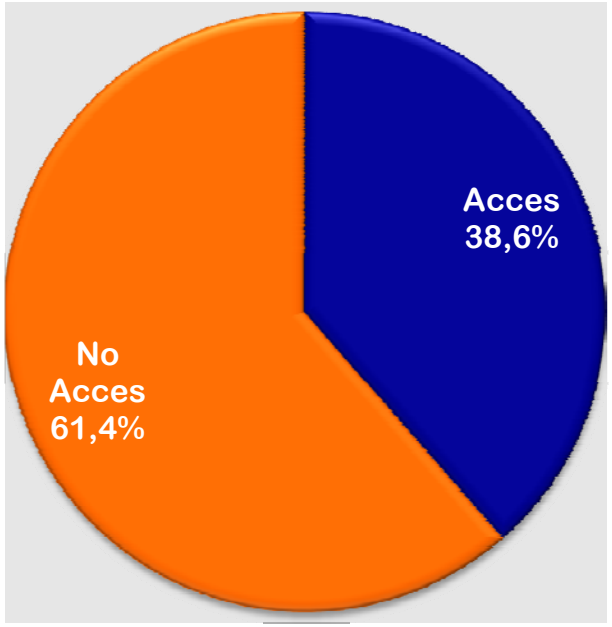
Eur Heart J 2011; doi: 10.1093/eurheartj/ehq278. www.escardio.org/guidelines

IMPORTANCIA DEL SAGNAT

Localització del sagnat







RIVAL TRIAL	ACC-NCDR	POOLED ANALYSIS
7.021	1.522.935	17.393 (Horizons, Acuity, Replace 2)
Sagnat 0.8%	Sagnat 2%	Sagnat 5.3%
Jolly S. *Lancet* 2011	Marso S. *JACC* 2010	Verheugt FW. *JACC Interv* 2011

Malgrat diferents definicions de sagnat, és important el sagnat fora del punt de punció

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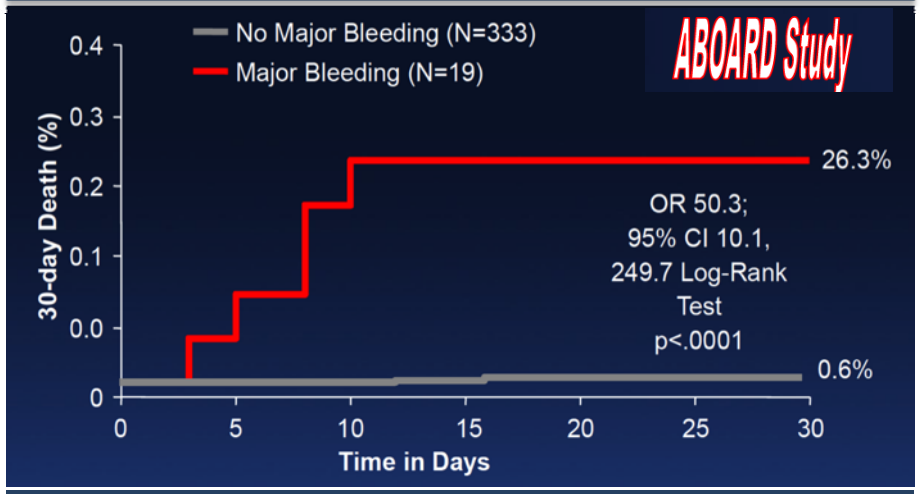
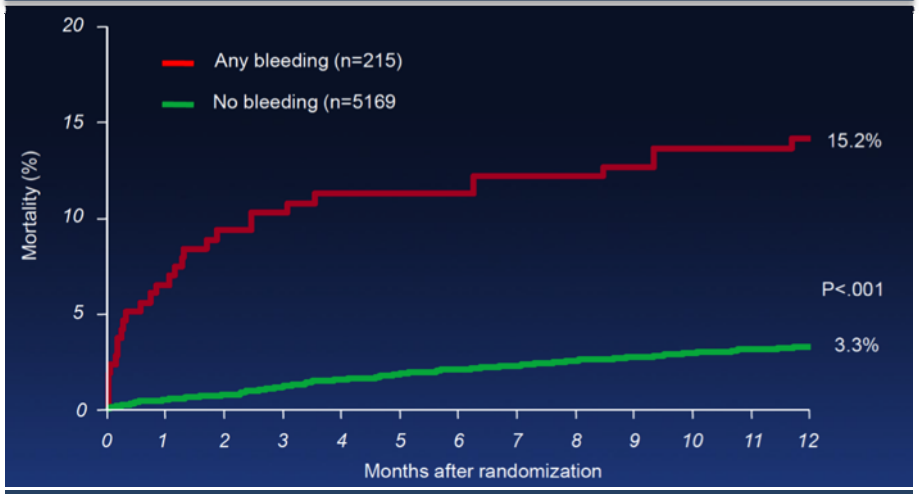
Trascendència del Sagnat

- Sagnat Major (escala STEEPLE): 5,4%.
- Transfusió 4,5%
- Localització sagnat:
  - Ocult 36,8%
  - Gastrointestinal 21%



Cayla et al, on behalf of ABOARD Study. *Heart* 2011; 97: 887.

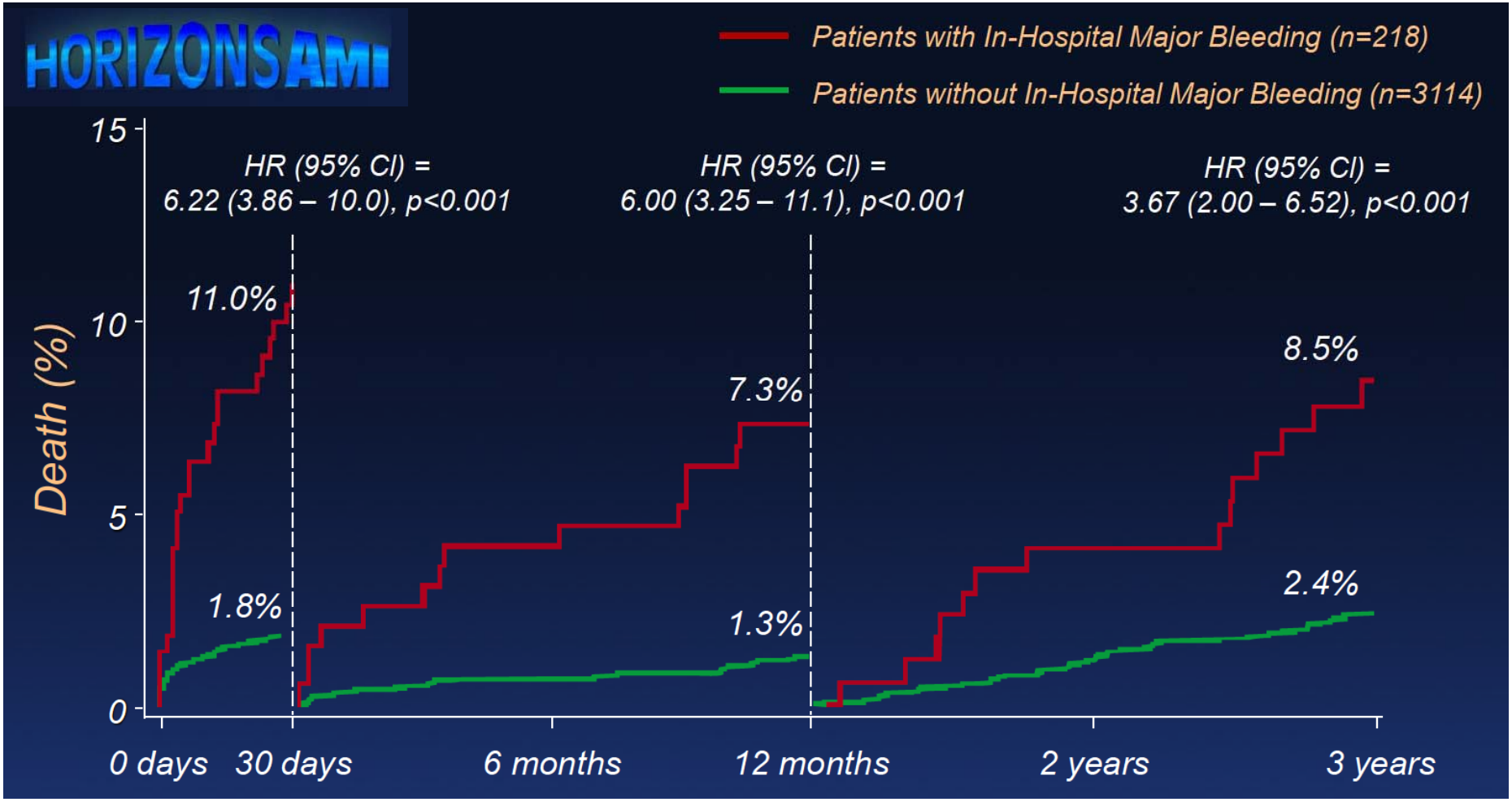
- Meta-analysis of 5384 PCI patients from 4 randomized trials
- K-M estimates of 1 year mortality with/without any TIMI bleeding



Ndrepepa G et al. *JACC* 2008; 51(7): 690.

Sagnat i Pronòstic a llarg termini

Landmark analysis of mortality: < 1 month, >1 month and < 1 year, and > 1 year



Suh LW on behalf of HORIZONS AMI. *J Am Coll Cardiol* 2011; 58: 1752.

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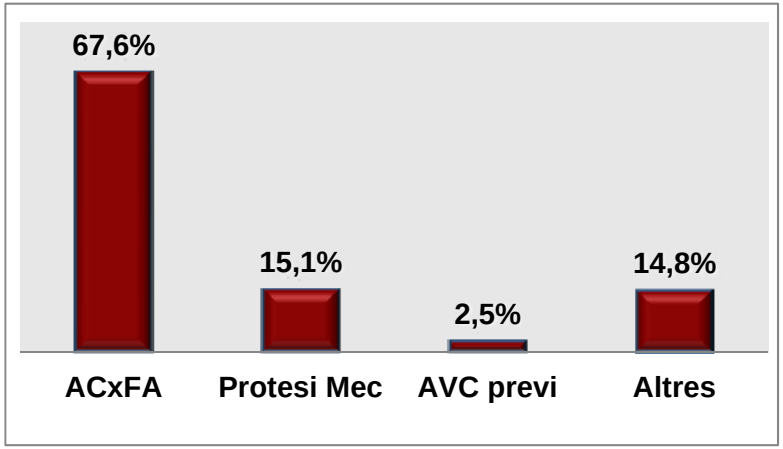
REGISTRES I METANÀLISI

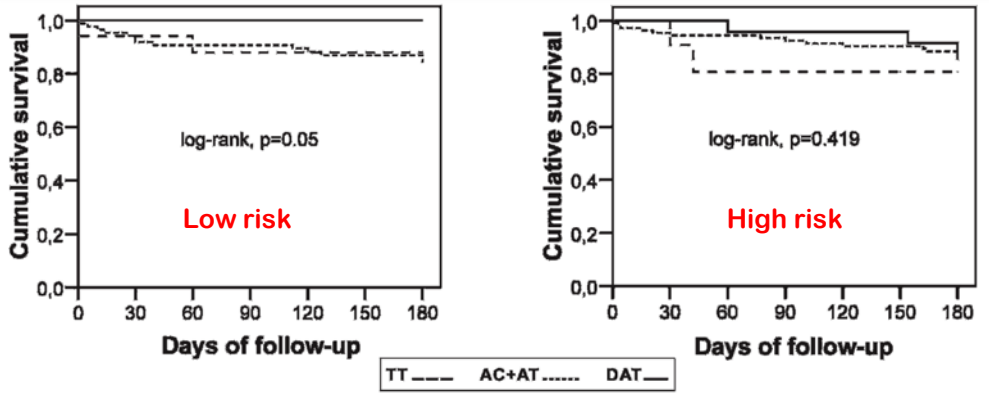
Therapeutic strategies after coronary stenting in chronically anticoagulated patients: the MUSICA study

A Sambola,[1] I Ferreira-González,[1,11] J Angel,[1] F Alfonso,[2] J Maristany,[3] O Rodríguez,[4] H Bueno,[5] J R López-Minguez,[6] J Zueco,[7] F Fernández-Avilés,[5] A San Román,[8] B Prendergast,[9] V Mainar,[10] D García-Dorado,[1] P Tornos[1]

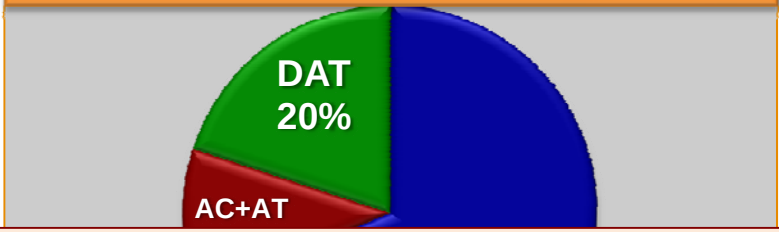
- **Registre prospectiu.**
- **n= 405 pacients**



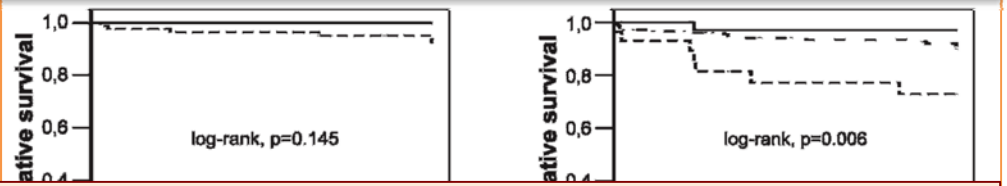
Seguretat: Sagnat amb caiguda Hb 4 d/dl, transfusió, IC o retroperitoneal.



Tipus tractament:



Eficàcia: Supervivència lliure esdeveniments CV: stent trombosis, IAM, TVR, AVC, embolia, mort CV.



Conclusions: In patients receiving OAT, TT was the most commonly used regimen after PCI-S. DAT was associated with the lowest rate of bleeding events and a similar efficacy to TT in patients at low thromboembolic risk. TT should probably be restricted to patients at moderate-high thromboembolic risk.

Sambola A et al. *Heart* 2009; 95: 1483.

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Canadian Journal of Cardiology 29 (2013) 213–218

Clinical Research

Antithrombotic Therapy After Coronary Stenting in Patients With Nonvalvular Atrial Fibrillation

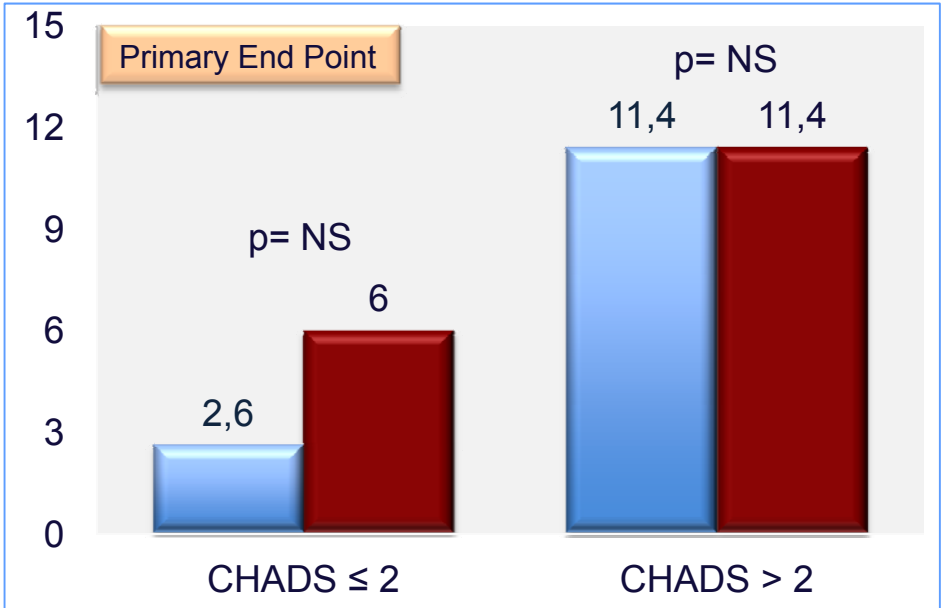
Kay W. Ho, MBBS,[a,b] Joan Ivanov, PhD,[a,c] Xavier Freixa, MD,[a] Christopher B. Overgaard, MD,[a]

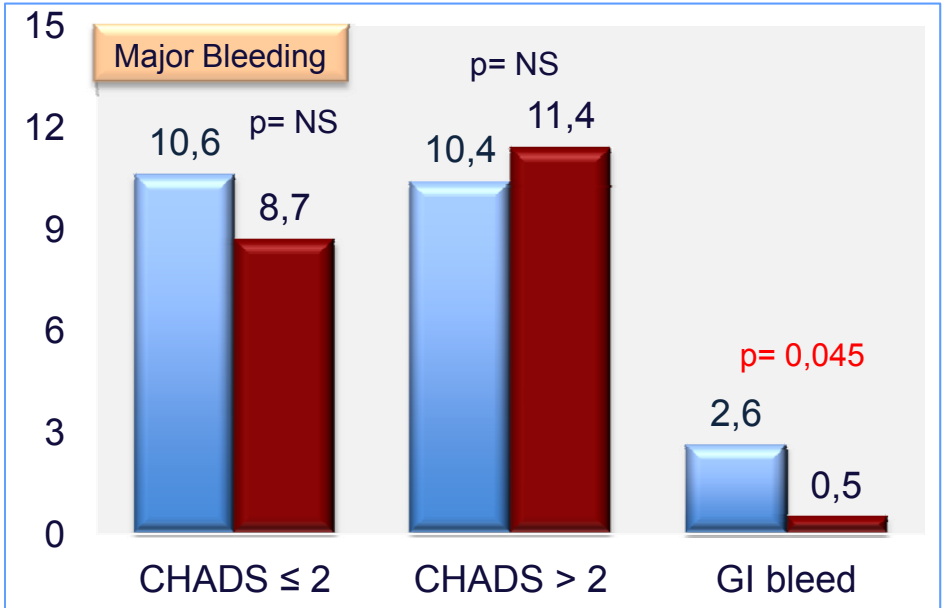
Methods:

- **Single centre, retrospective study.**
- **1º endpoint: Composite death, ischemic stroke or TIA.**
- **2º endpoint: Bleeding, transfusion rates.**

Results:

- **n= 602 patients.**
- **FU: 5-6 months.**





Conclusions: ...TT was associated with 5-fold increase in gastrointestinal bleeding vs DAPT. Net clinical benefit calculations suggest benefits of TT in patients with $CHADS_2$ > 2. Stratification with $CHADS_2$ might be useful to determine the optimal antithrombotic therapy post PCI.

Ho KW et al. *Canadian J Cardiol* 2013; 29: 213.

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LESS IS MORE

Risk of Bleeding With Single, Dual, or Triple Therapy With Warfarin, Aspirin, and Clopidog in Patients With Atrial Fibrillation

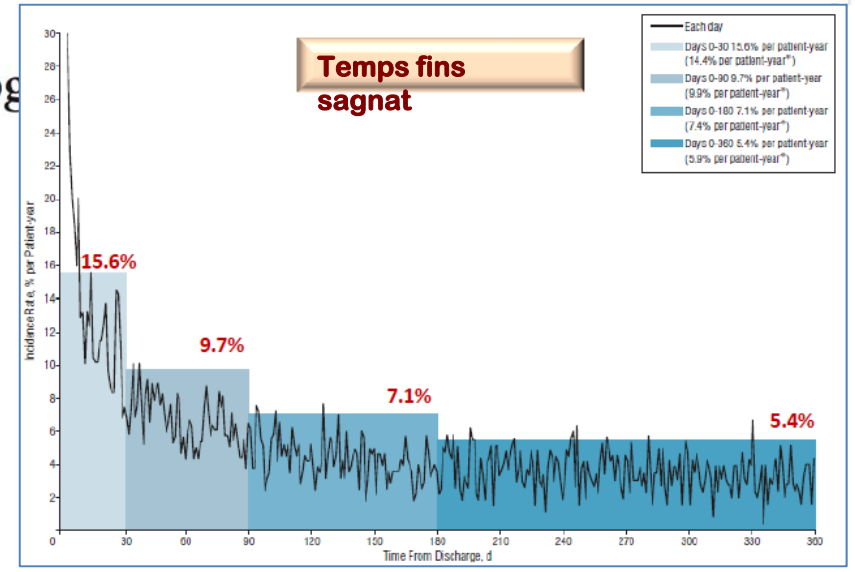
Morten L. Hansen, MD, PhD; Rikke Sørensen, MD; Mette T. Clausen, MSc Pharm;

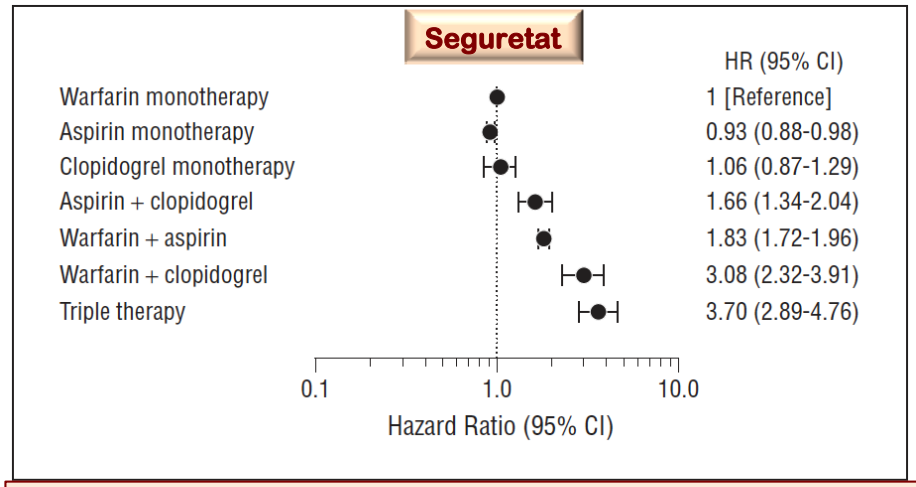
Mètode:

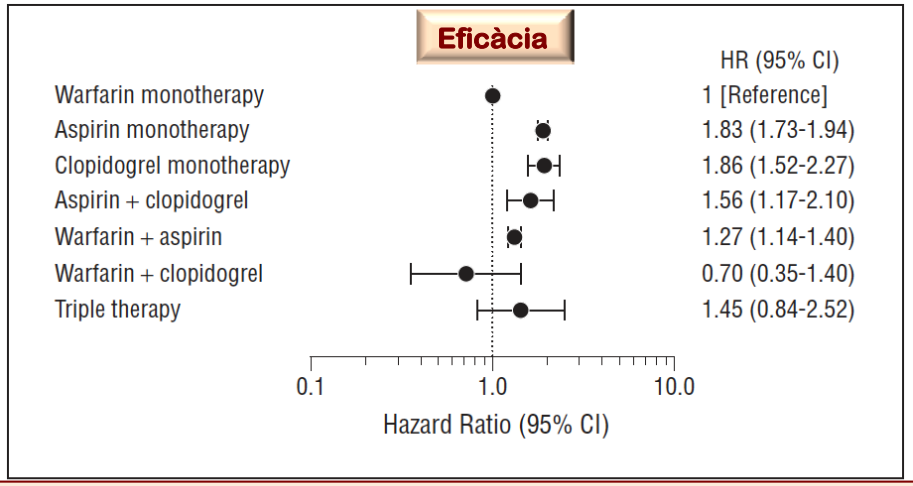
- **Registre danés que identifica altes de pacients en FA, entre 1997 i 2006.**

Resultats:

- **Pacients: 82.854.**
- **Seguiment: 3.3 a.**
- **Sagnats: 11,4%.**







Conclusions: **In patients with AF, all combinations of warfarin, aspirin and clopidogrel are associated with increased risk of nonfatal and fatal bleeding. Dual warfarin and clopidogrel therapy and Triple Therapy carried a more than 3-fold higher risk than did warfarin monotherapy.**

Hansen M et al. *Arch Intern Med*. 2010; 170(16): 1433.

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Bleeding After Initiation of Multiple Antithrombotic Drugs, Including Triple Therapy, in Atrial Fibrillation Patients Following Myocardial Infarction and Coronary Intervention

A Nationwide Cohort Study

Morten Lamberts, MD; Jonas Bjerring Olesen, MD; Martin Huth Ruwald, MD;

Mètode:

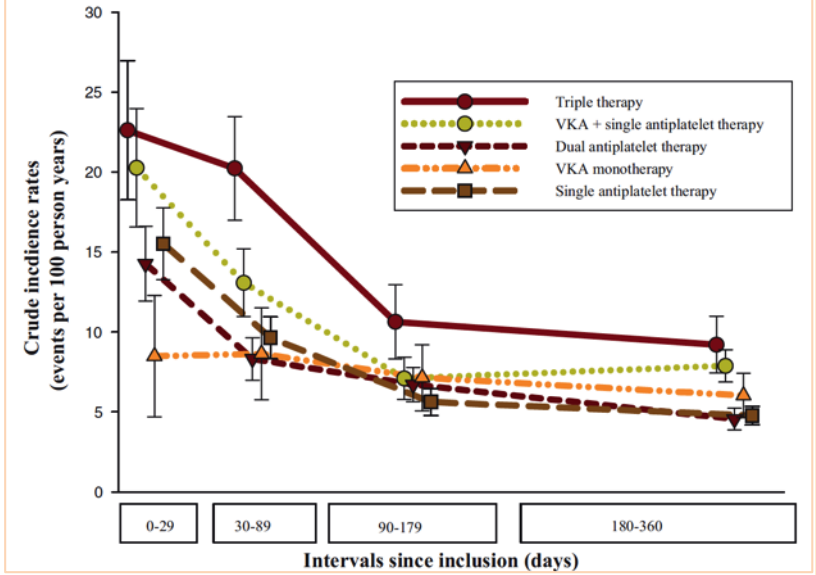
- **11480 pacients amb IAM + PCI en ACxFA.**

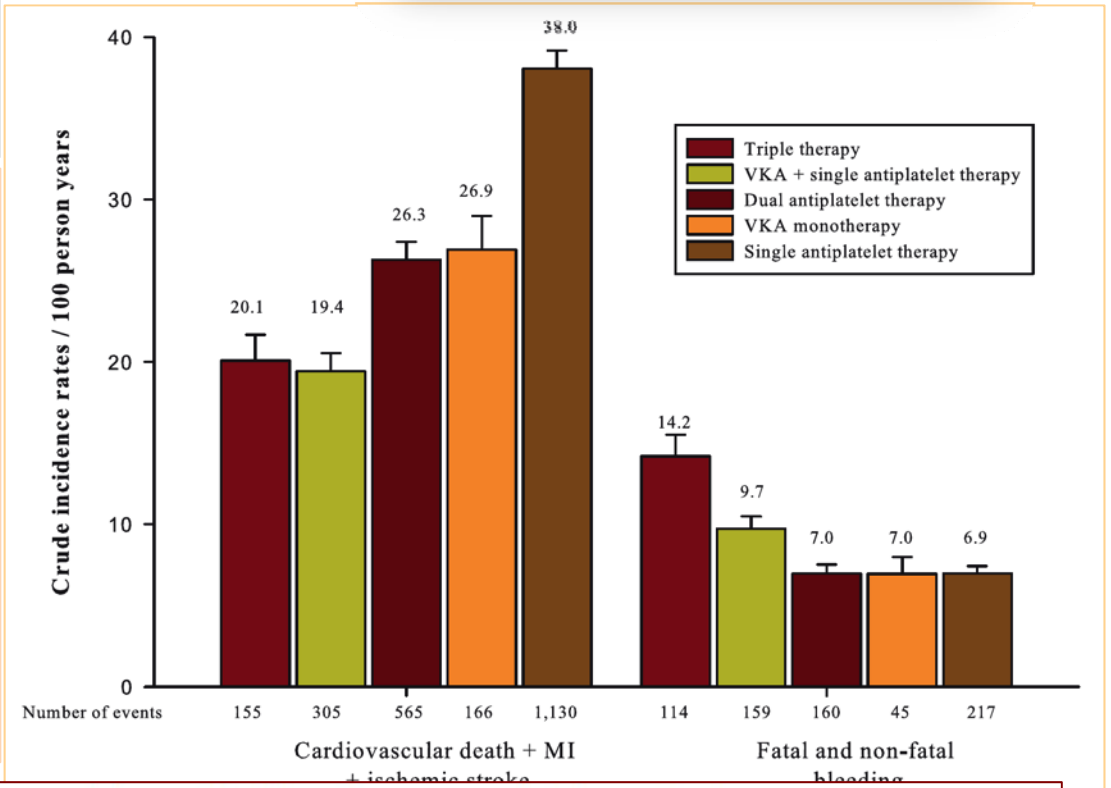
Objectiu:

- **Risc de sagnat.**
- **Temps d'aparició del sagnat.**

Table 2. Distribution and Type of Nonfatal and Fatal Bleedings

	Nonfatal Bleeding, n (%)	Fatal Bleeding, n (%)
Intracranial	38 (5.8)	36 (48.0)
Gastrointestinal	221 (33.8)	34 (45.3)
Respiratory	109 (16.7)	1 (1.3)
Urogenital	120 (18.4)	0 (0.0)
Anemia caused by bleeding	165 (25.3)	4 (5.3)
Total bleeding events	653	75





Conclusions—High risk of bleeding is immediately evident with TT after myocardial infarction/percutaneous coronary intervention in patients with atrial fibrillation. A continually elevated risk associated with TT indicates no safe therapeutic window, and TT should only be prescribed after thorough bleeding risk assessment of patients. **(*Circulation*. 2012;126:1185-1193.)**

Lamberts et al. *Circulation* 2012; 126: 1185.

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Canadian Journal of Cardiology 29 (2013) 204–212

Systematic Review/Meta-analysis

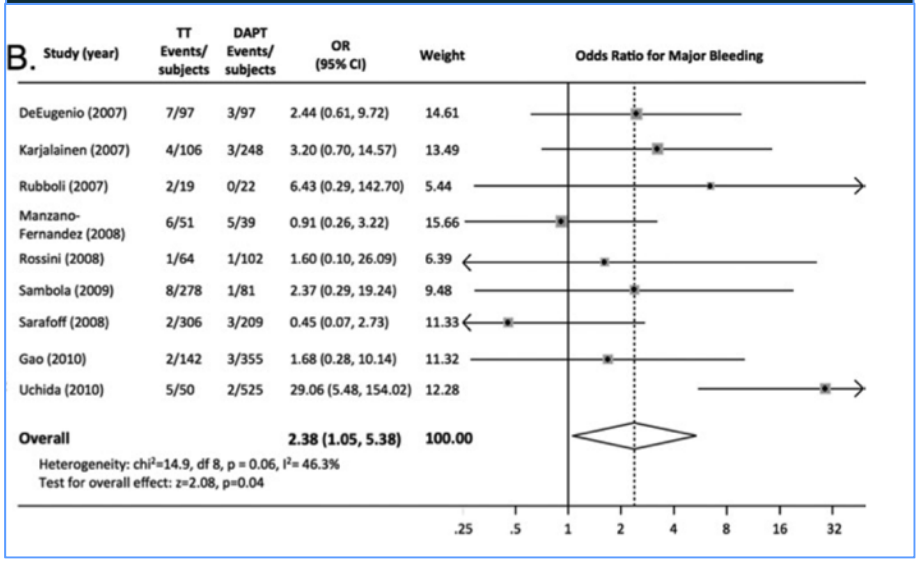
Risk of Bleeding on Triple Antithrombotic Therapy After Percutaneous Coronary Intervention/Stenting: A Systematic Review and Meta-analysis

Jason G. Andrade, MD,[a,b] Marc W. Deyell, MD,[a] Clarence Khoo, MD,[a] May Lee, MSc,[c] Karin Humphries, DSc,[a] and John A. Cairns, MD[a]

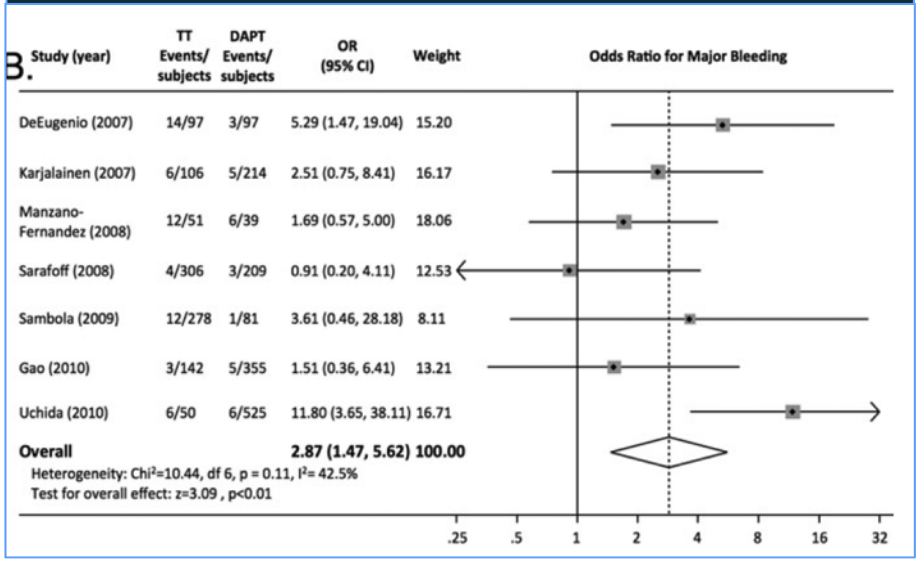
Table 2. Pooled estimates of bleeding outcomes on triple therapy after PCI

Time period	Any bleeding, % (95% CI)	Major bleeding, % (95% CI)
In-hospital*	—	1.59 (0.43-4.01)
30 Days†	8.28 (5.62-10.94)	2.38 (0.98-3.77)
6 Months‡	11.92 (5.46-18.38)	4.55 (0.56-8.53)

Increment de sagnat a 30 dies



Increment de sagnat a 6 mesos



Conclusions: This systematic review and meta-analysis of reports of triple therapy with a vitamin K antagonist, aspirin, and clopidogrel after PCI-S provides precise and valid bleeding risk data. Based on existing observational studies the rates of major and any bleeding associated with TT are clinically important and significantly greater than those reported with DAPT.

Andrade JG et al. *Can J Cardiol* 2013: 29: 204.

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ESTUDI ALEATORIZAT

Diseny

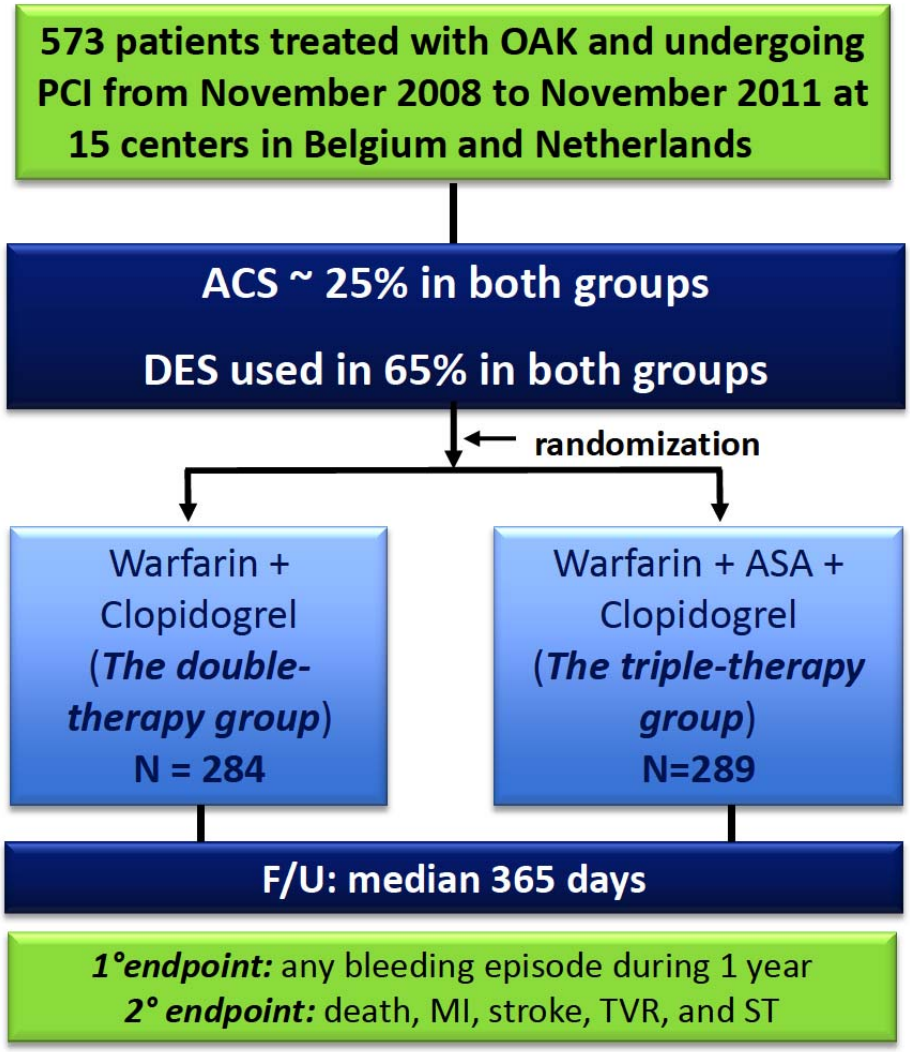
Use of clopidogrel with or without aspirin in patients taking oral anticoagulant therapy and undergoing percutaneous coronary intervention: an open-label, randomised, controlled trial

Willem J M Dewilde, Tom Oirbans, Freek W A Verheugt, Johannes C Kelder, Bart J G L De Smet, Jean-Paul Herrman, Tom Adriaenssen, 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 investig

Design:
Randomized, placebo-controlled, open-label, multi-center.

Objective:
To compare the safety and efficacy of Clopidogrel alone with Clopidogrel + ASA in patients taking OAC and undergoing PCI.

	Double therapy (n=279)	Triple therapy (n=284)
(Continued from previous column)		
Indication for oral anticoagulation		
Atrial fibrillation/atrial flutter	164/236 (69%)	162/234 (69%)
Mechanical valve	24/236 (10%)	25/234 (11%)
Other (eg, apical aneurysm, pulmonary embolus, PAD, EF <30%)	48/236 (20%)	47/234 (20%)
Acute coronary syndrome at baseline		
Yes	69 (25%)	86 (30%)



Dewilde W et al for the WOEST investigators. *Lancet* 2013; 381: 1107.

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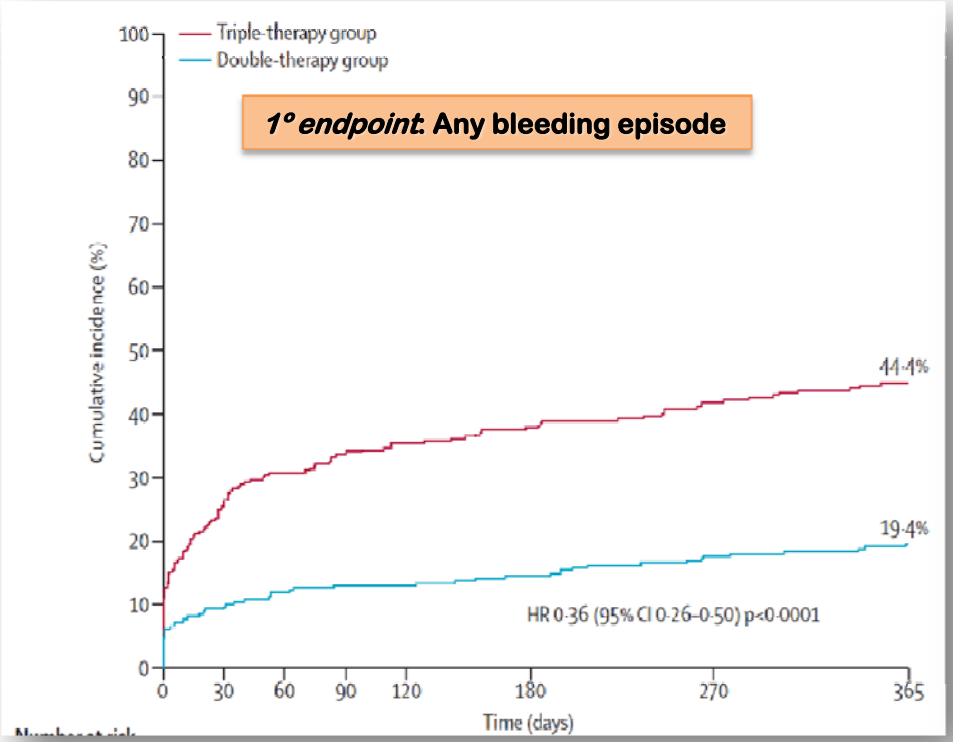
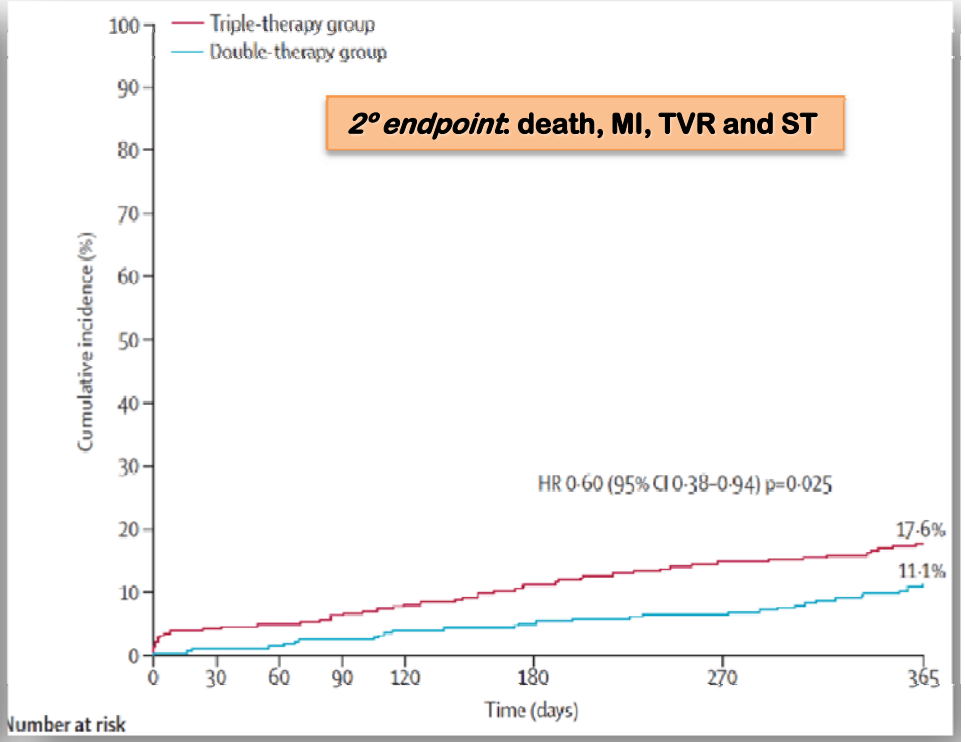
Resultats:

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





Dewilde W et al for the WOEST investigators. *Lancet* 2013; 381: 1107.

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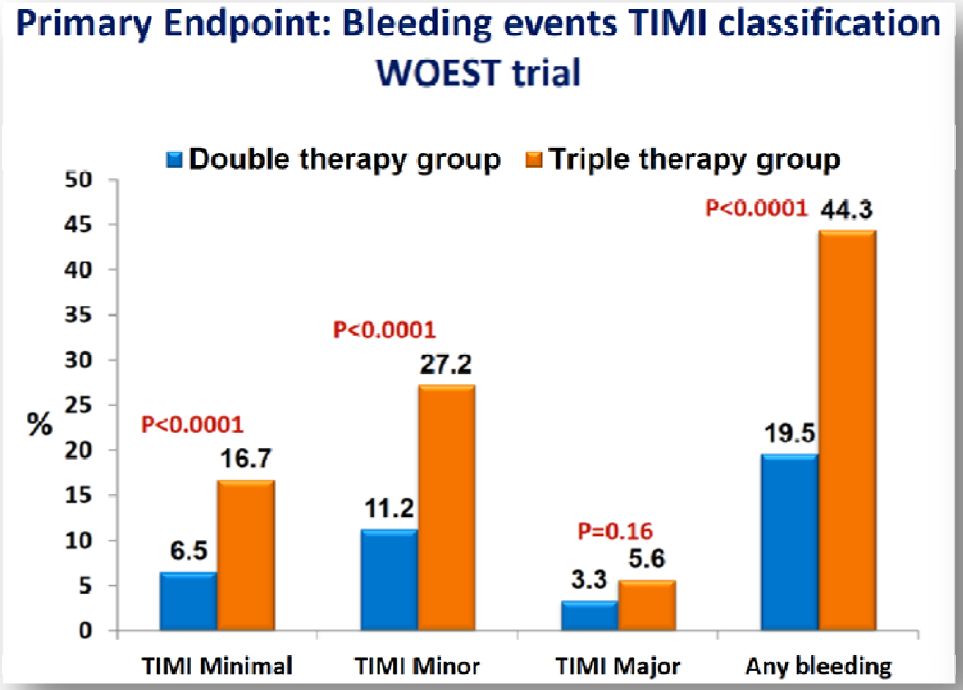
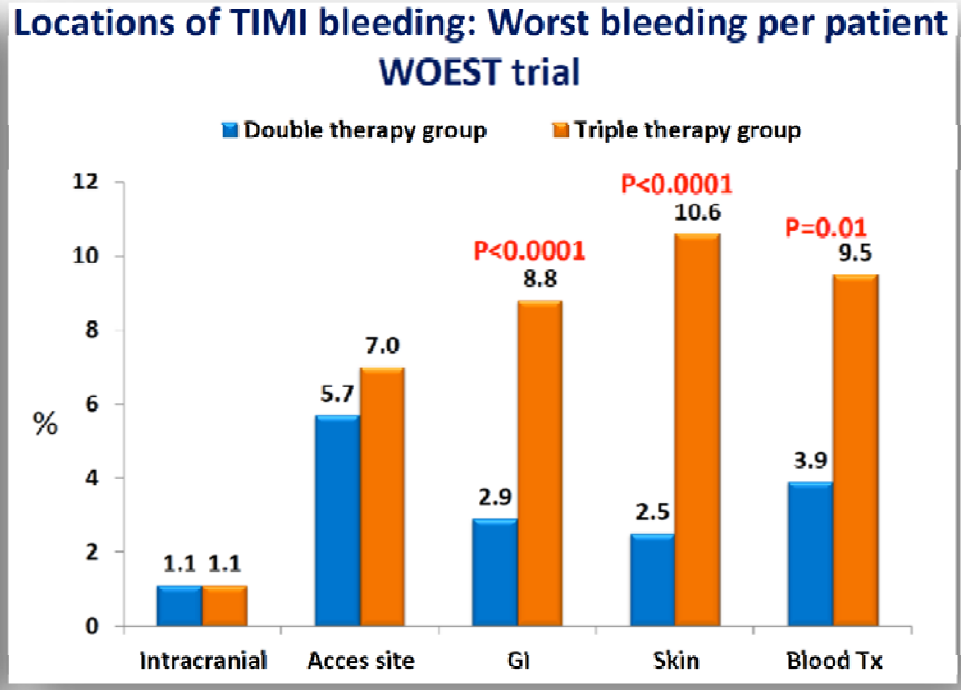
Anàlisi Sagnats

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





Interpretation Use of clopiogrel without aspirin was associated with a significant reduction in bleeding complications and no increase in the rate of thrombotic events.

Dewilde W et al for the WOEST investigators. *Lancet* 2013; 381: 1107.

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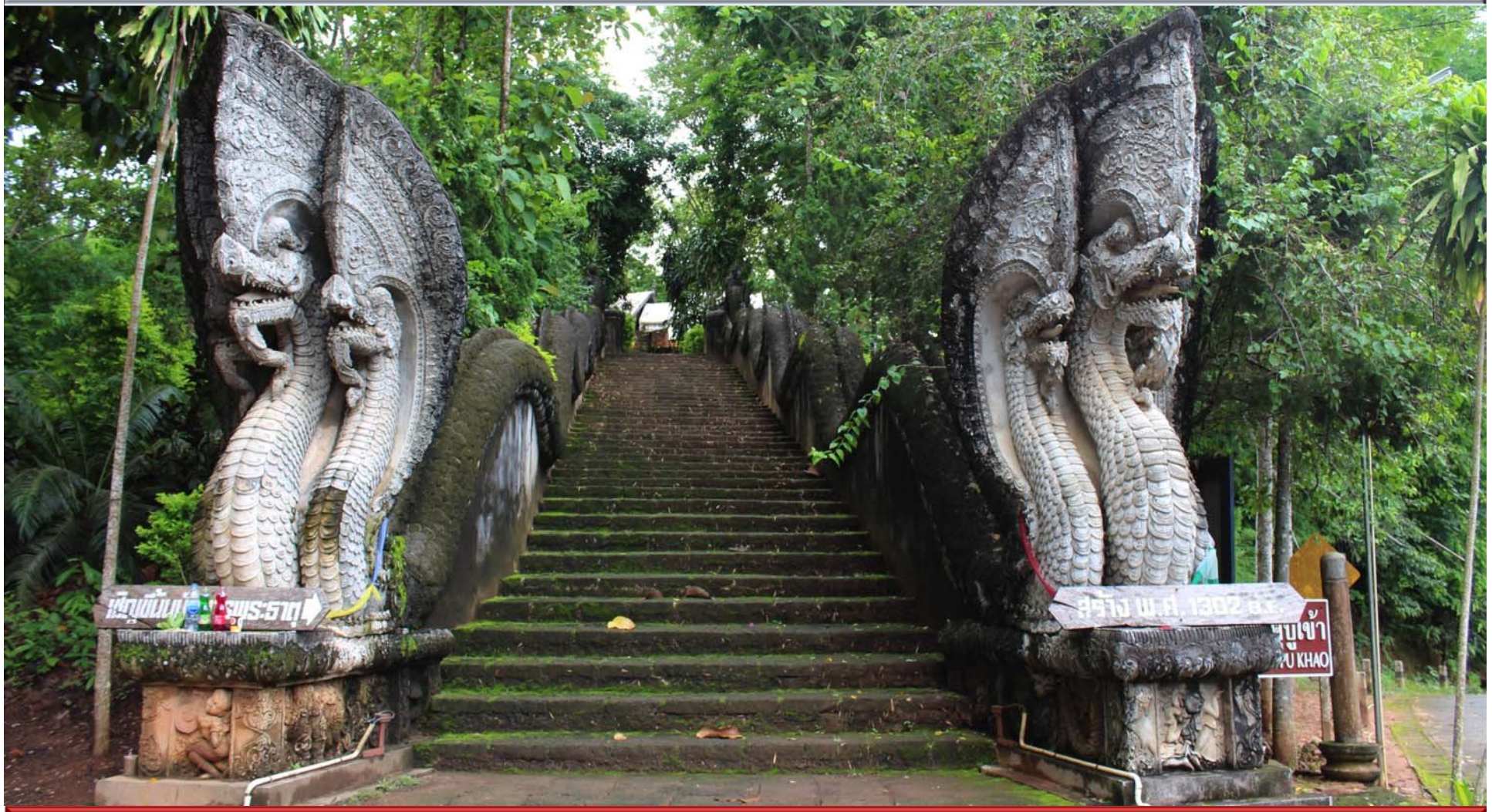
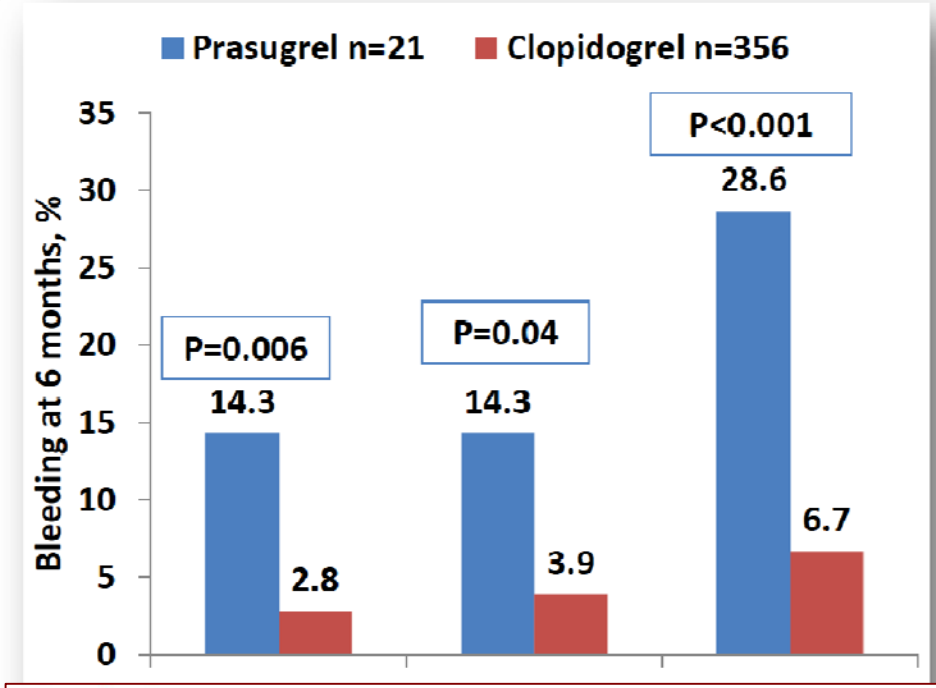
NOUS FÀRMACS:

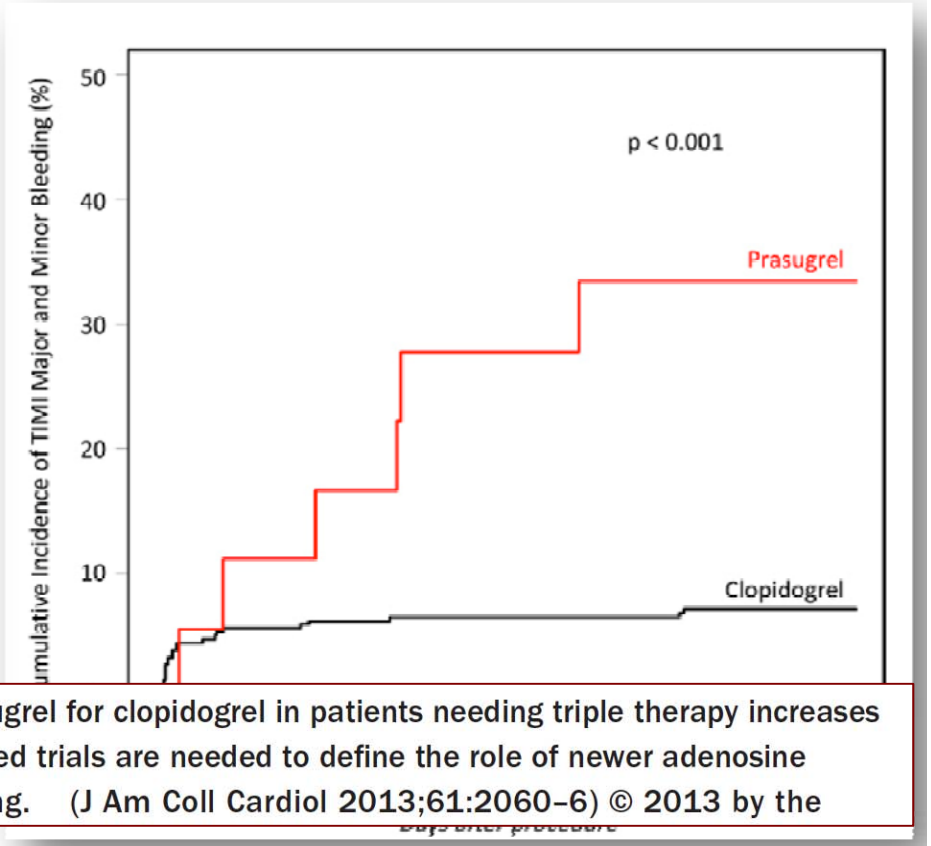


CME

Triple Therapy With Aspirin, Prasugrel, and Vitamin K Antagonists in Patients With Drug-Eluting Stent Implantation and an Indication for Oral Anticoagulation

- Serie de 477 pacients en 2 centres Alemania, amb indicació de ACO i implantació de DES.
- Tractament: ASA + Antag Vit K + Clopidogrel/Prasugrel.
- 1 End Point: Sagnat a 6 mesos.





Conclusions These findings suggest that substitution of prasugrel for clopidogrel in patients needing triple therapy increases the risk of bleeding. However, specific randomized trials are needed to define the role of newer adenosine diphosphate receptor antagonists in this setting. (J Am Coll Cardiol 2013;61:2060–6) © 2013 by the

Sarafoff N et al. *J Am Coll Cardiol* 2013; 61: 2060.

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The NEW ENGLAND JOURNAL of MEDICINE
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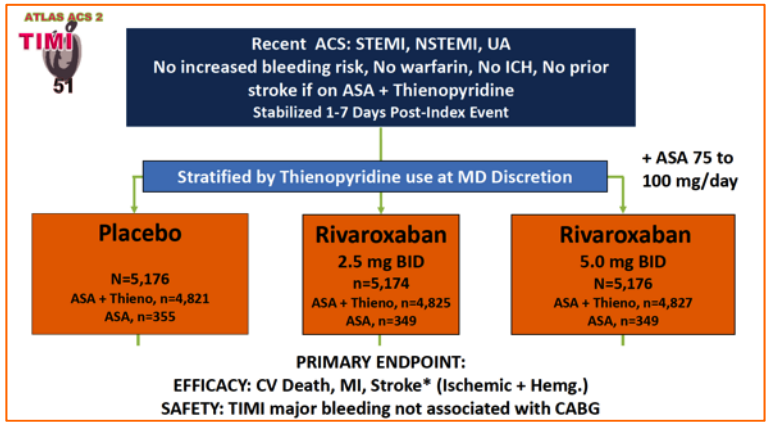
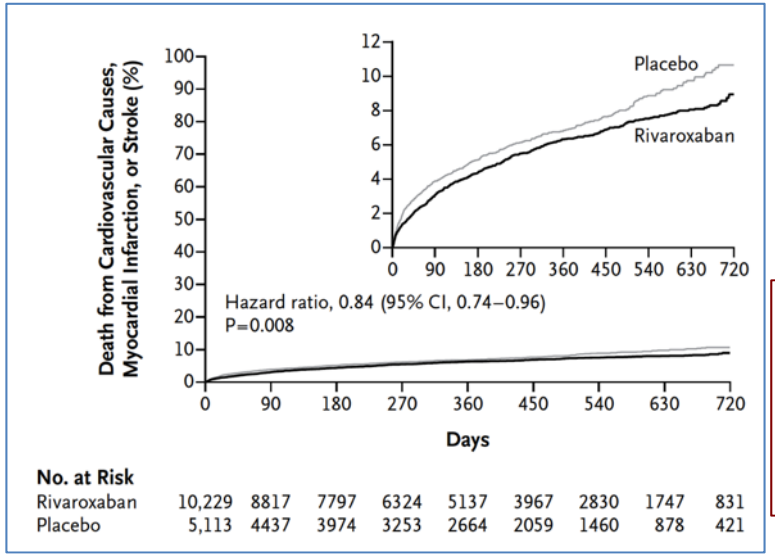
Rivaroxaban in Patients with a Recent Acute Coronary Syndrome

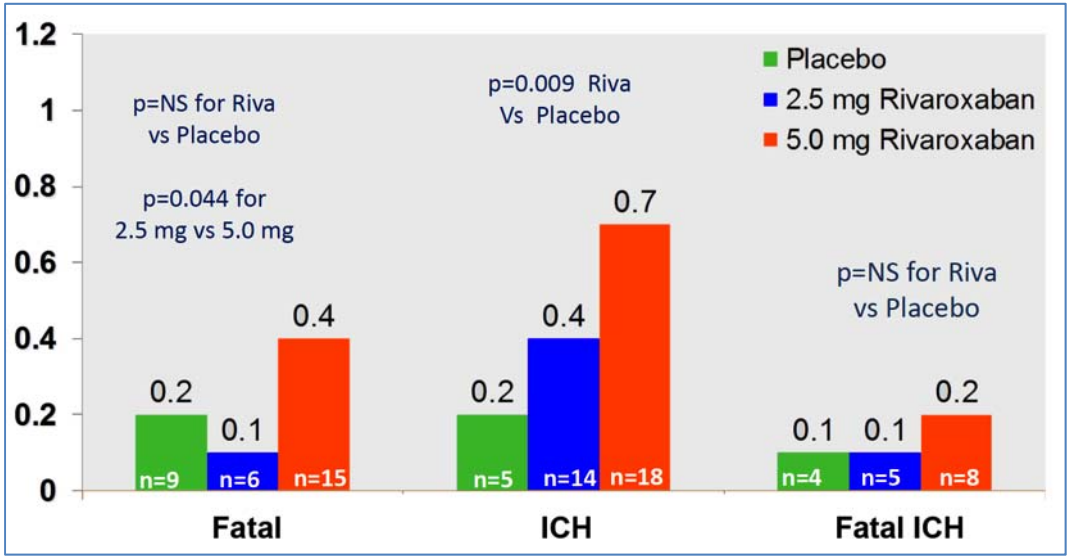




Non CABG TIMI major Bleeding

Analysis	Placebo	2.5 mg Rivaroxaban	5.0 mg Rivaroxaban
2 Yr KM Estimate	0.6%	1.8% HR 3.46	2.4% HR 4.47

p<0.001 compared to placebo for both Riva doses



CONCLUSIONS

In patients with a recent acute coronary syndrome, rivaroxaban reduced the risk of the composite end point of death from cardiovascular causes, myocardial infarction, or stroke. Rivaroxaban increased the risk of major bleeding and intracranial hemorrhage but not the risk of fatal bleeding. (Funded by Johnson & Johnson and Bayer Healthcare; ATLAS ACS 2–TIMI 51 ClinicalTrials.gov number, NCT00809965.)

Mega JL on behalf of ATLAS TIMI 51; *N Eng J Med* 2012; 366: 9.

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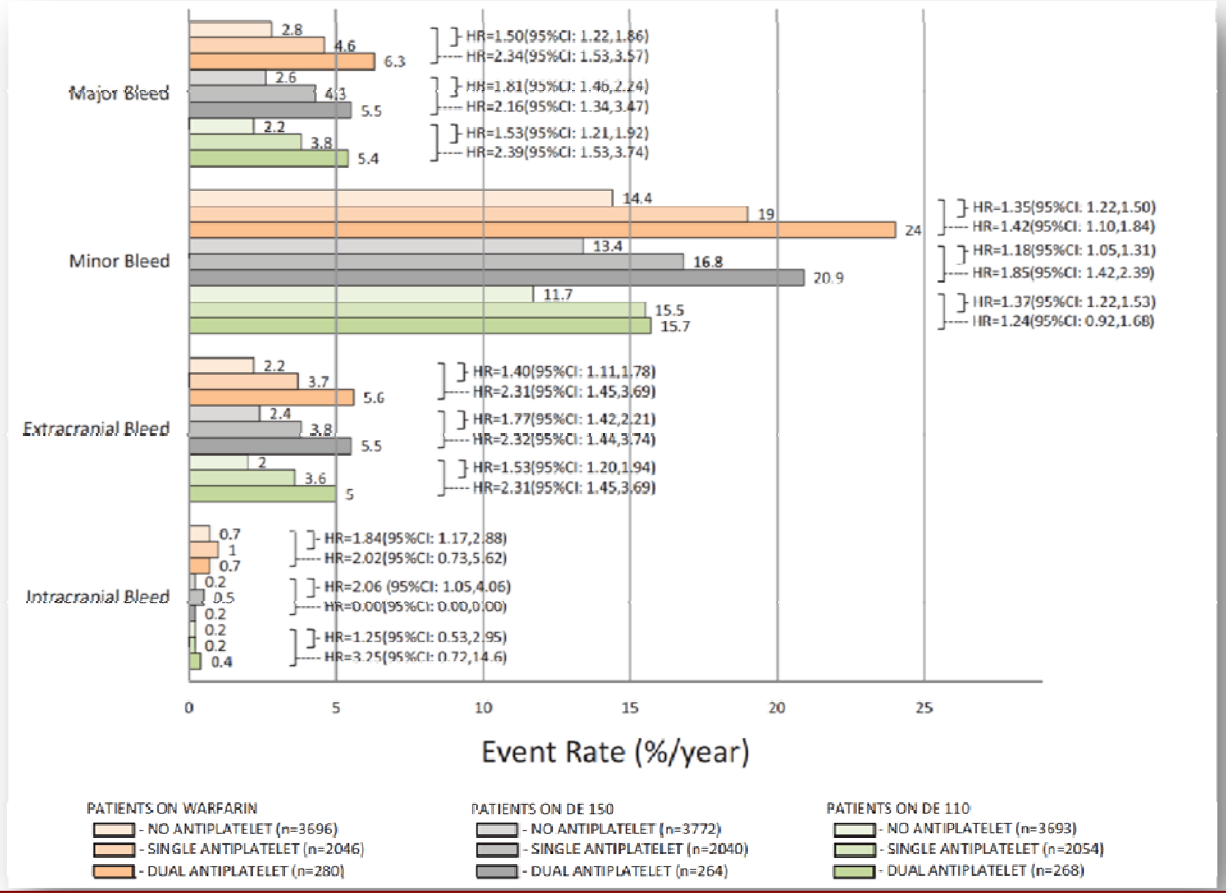
Concomitant Use of Antiplatelet Therapy with Dabigatran or Warfarin in the Randomized Evaluation of Long-Term Anticoagulation Therapy (RE-LY) Trial

Antonio L. Dans, MD, MSc; Stuart J. Connolly, MD; Lars Wallentin, MD, PhD; Sean Yang, MSc; Juliet Nakamya, PhD; Martina Brueckmann, MD; Michael Ezekowitz, MBChB, DPhil; Jonas Oldgren, MD, PhD; John W. Eikelboom, MD; Paul A. Reilly, PhD; Salim Yusuf, DPhil, FRCPC, FRSC

- Subestudi de l'estudi RE-LY.
- 6952 pacients amb TAP.

Objectiu:

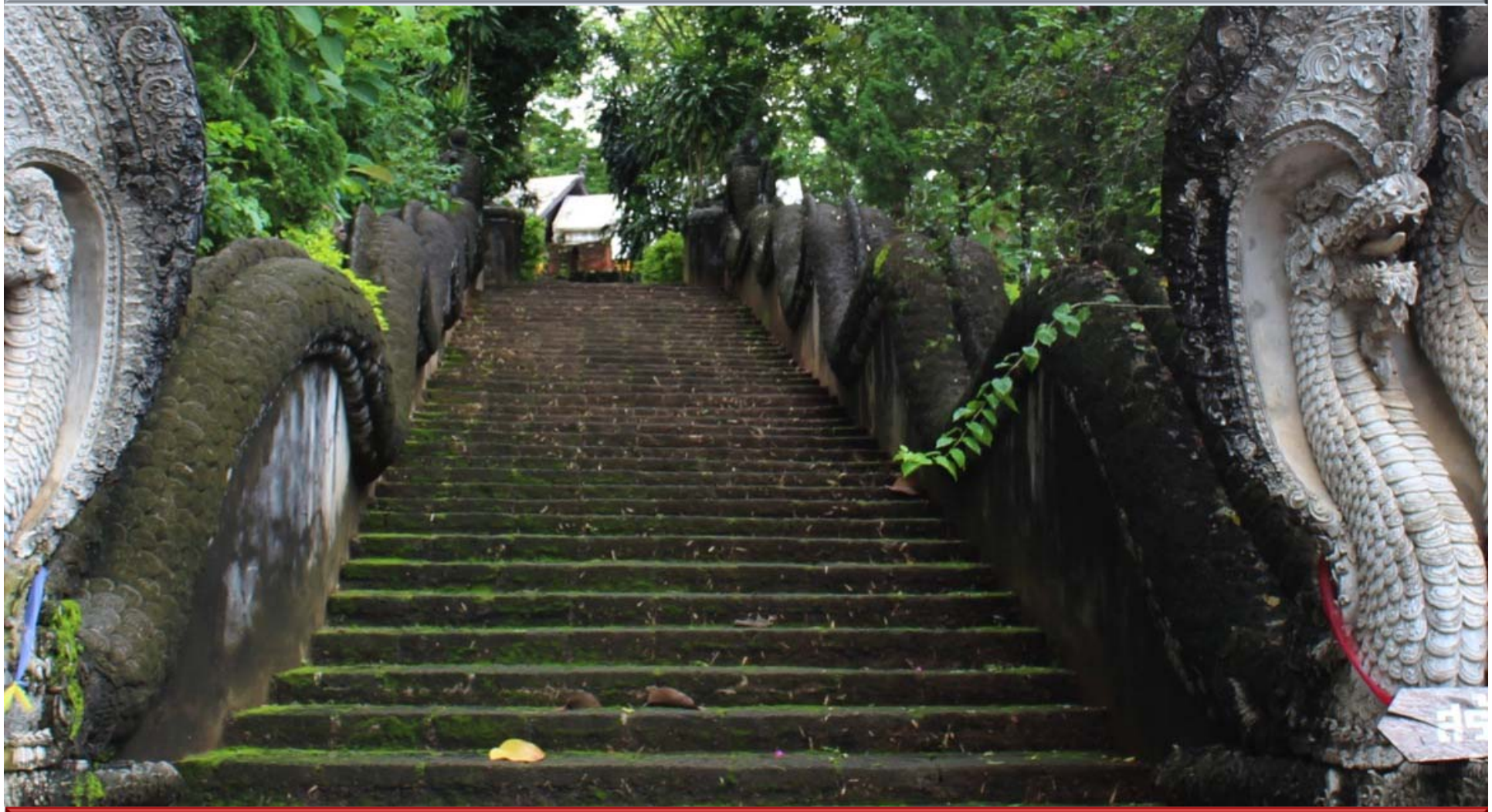
- Anàlisi del sagnat.
- Comparació entre grups.



Conclusions—Concomitant antiplatelet drugs appeared to increase the risk for major bleeding in RE-LY without affecting the advantages of dabigatran over warfarin. Choosing between dabigatran etexilate 110 mg BID and dabigatran etexilate 150 mg BID requires a careful assessment of characteristics that influence the balance between benefit and harm.

Dans AL et al. *Circulation* 2013; 127: 634.

FUTUR:



ESTUDIS EN CURS

Estudi	ISAR TRIPLE	MUSICA 2	PIONEER AF-PCI
n	600	304	2100
Tipus	Aleatorizat	Aleatorizat	Aleatorizat
Pacients	CAD + NVAF	CAD + NVAF	CAD + NVAF - AVC
Indicació	Indicació ACO + Implantació DES	Implantació Stent	Implantació Stent
Branques	TT 6 setmanes	ASA + Clopi + ACO	Riva + Clopi
	TT 6 mesos	ASA + Clopi	Riva + Clopi + ASA
			War + Clopi + ASA
1 End Point	9 mesos: Mort, IAM, ST, AVC, Sagnat major	12 mesos: Mort, IAM, ST, AVC, Embolia sistèmica.	12 mesos: Sagnat Major /menor (TIMI)
2 End Point	Cadascun separats	Sagnat Major / Menor	Mort, IAM, ST, AVC

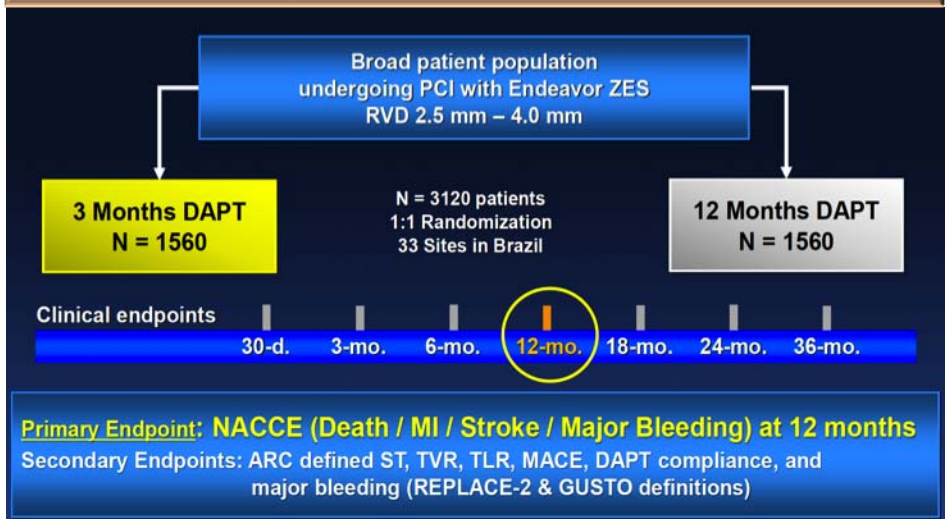
Original Investigation

Three vs Twelve Months of Dual Antiplatelet Therapy After Zotarolimus-Eluting Stents

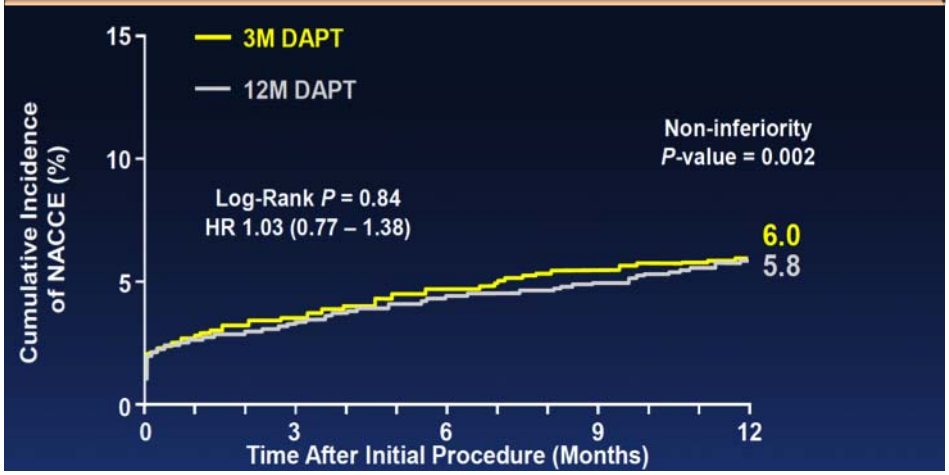
The OPTIMIZE Randomized Trial

Fausto Feres, MD, PhD; Ricardo A. Costa, MD, PhD; Alexandre Abizaid, MD, PhD; Martin B. Leon, MD; J. Antônio Marin-Neto, MD, PhD; Roberto V. Botelho, MD, PhD; Spencer B. King III, MD; Manuela Negoita, MD; Minglei Liu, PhD; J. Eduardo T. de Paula, MD; José A. Mangione, MD, PhD; George X. Meireles, MD, PhD; Hélio J. Castello Jr, MD, MSc; Eduardo L. Nicolela Jr, MD; Marco A. Perin, MD, PhD; Fernando S. Devito, MD, PhD; André Labrunie, MD, PhD; Décio Salvadori Jr, MD, PhD; Marcos Gusmão, MD; Rodolfo Staico, MD, PhD; J. Ribamar Costa Jr, MD, PhD; Juliana P. de Castro, PhD; Andrea S. Abizaid, MD, PhD; Deepak L. Bhatt, MD, MPH; for the OPTIMIZE Trial Investigators

Study Design



Primary End Point: NACCE at 1 year (All-Cause Death, MI, Stroke, Major Bleeding)



CONCLUSIONS AND RELEVANCE In patients with stable coronary artery disease or low-risk ACS treated with zotarolimus-eluting stents, 3 months of dual antiplatelet therapy was noninferior to 12 months for NACCE, without significantly increasing the risk of stent thrombosis.

Feres F for the OPTIMIZE Investigators. *JAMA* 2013; online before print (31/10/2013)

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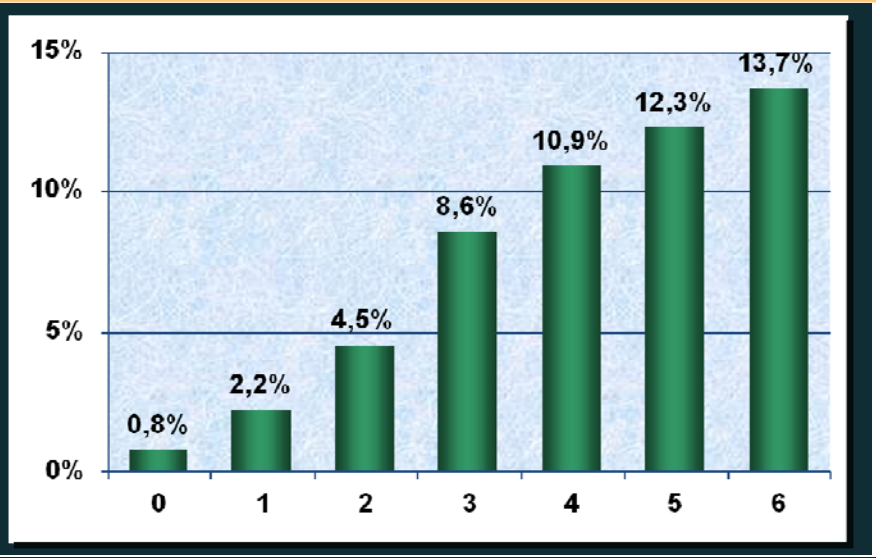
PROPOSTES ACTUACIÓ:

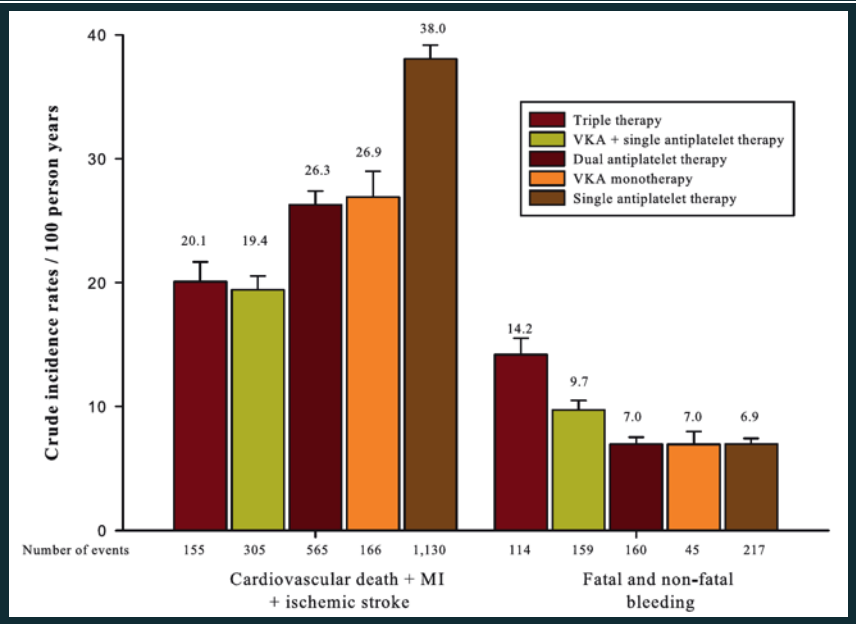
Avaluació Benefici / Risc

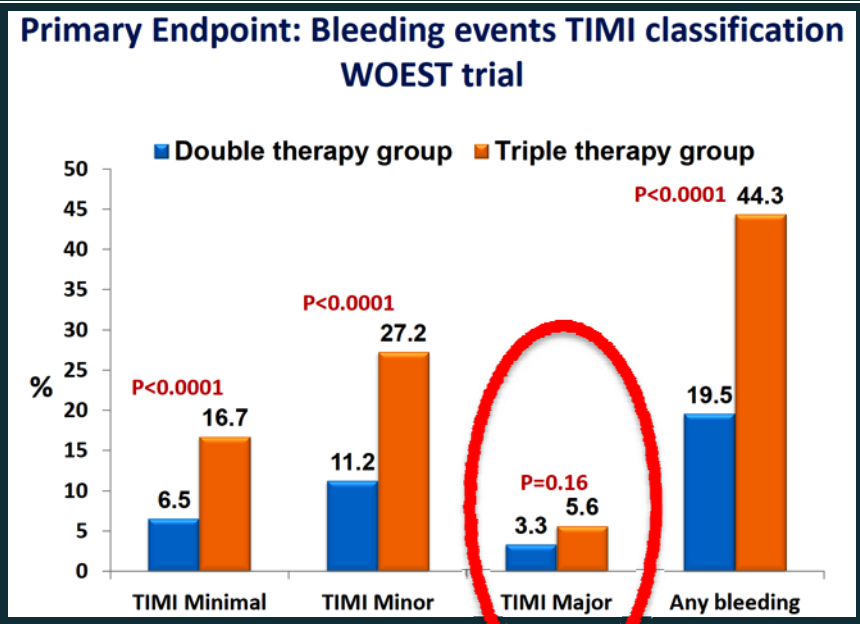
BENEFICI

$CHADS_2$ Score	Valor
Congestive Heart Failure	+1
Hypertension	+1
Age > 75 y	+1
Diabetes Mellitus	+1
Stroke or History of Cerebral Ischemia	+2



RISC





Gage, B. F. et al. *JAMA* 2001;285:2864.
Lamberts et al. *Circulation* 2012; 126: 1185.
Dewilde W et al. *Lancet* 2013; 381: 1107.

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Bleeding Risk Scores in AF

HAS-BLED	
Hypertension[4]	1
Abnormal Renal[5] or Liver function[6]	1 1
Stroke	1
Bleeding	1
Labile INR[8]	1
Elderly (>65 yrs)	1
Drugs[9] or Alcohol	1 1

1. Hemoglobin <13 g/dl men; <12 g/dl women
2. Estimated glomerular filtration rate <30 ml/min or dialysis-dependent
3. Diagnosed hypertension
4. Systolic blood pressure >160 mmHg
5. Presence of chronic dialysis or renal transplantation or serum creatinine ≥200 mmol/L
6. Chronic hepatic disease (eg cirrhosis) or biochemical evidence of significant hepatic derangement (eg bilirubin 2 x upper limit of normal, in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphatase >3 x upper limit normal, etc.)
8. Unstable/high INRs or poor time in therapeutic range (eg <60%)
9. Concomitant use of drugs, such as antiplatelet agents, non-steroidal anti-inflammatory drugs, or alcohol abuse etc.
10. Cirrhosis, two-fold or greater elevation of AST or APT, or albumin <3.6 g/dl
11. Platelets <75,000, use of antiplatelet therapy (eg daily aspirin) or NSAID therapy; or blood dyscrasia
12. Prior hospitalization for bleeding
13. Most recent hematocrit <30 or hemoglobin <10 g/dl
14. CYP2C9*2 and/or CYP2C9*3
15. Alzheimer's dementia, Parkinson's disease, schizophrenia, or any condition predisposing to repeated falls

Apostolakis S et al. *J Am Coll Cardiol* 2012; 60: 861.

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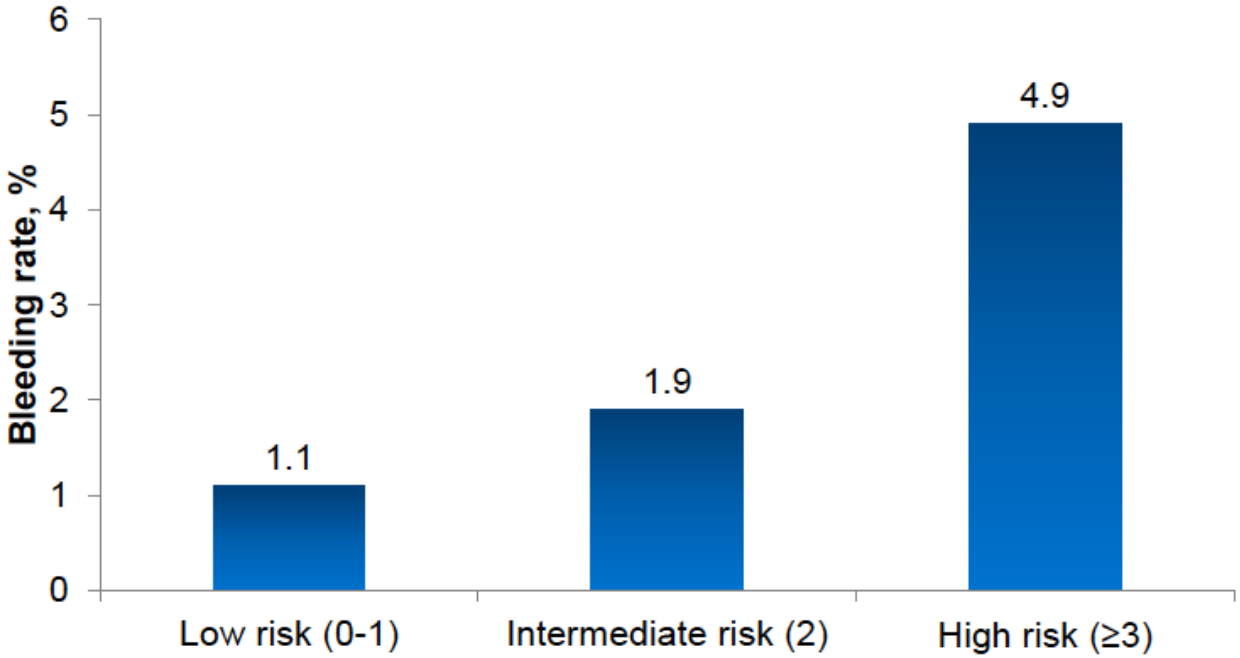
Importància

HAS-BLED	
Hypertension[4]	1
Abnormal Renal[5] or Liver function[6]	1 1
Stroke	1
Bleeding	1
Labile INR[8]	1
Elderly (>65 yrs)	1
Drugs[9] or Alcohol	1 1



Pisters R et al. Chest 2010; 138: 1093.

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PAUTA ACTUAL

CHADS2

Objectiu

HAS-BLED

Tipus Stent

Tractament

Comentaris

Moltes gràcies per l'atenció

jagomezh@bellvitgehospital.cat

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