FA E CAD: QUALE GESTIONE NEL GRANDE ANZIANO ?

Claudio Moretti
Cardiologia Universitaria – Città della Salute e della Scienza di Torino

POLLENZO, 3 Marzo 2018

CASO CLINICO_anamnesi

R.I., sesso maschile, 87 anni.

- Arteriopatia polidistrettuale.
- I.R.C. eGFR 33

- 1993 CABG (AMIS-DA, SVGseq MO1, MO2,IVP
- 2007 PCI + DES su SVG

- Dal 2016 FA permanente in TAO

CASO CLINICO_presentazione I

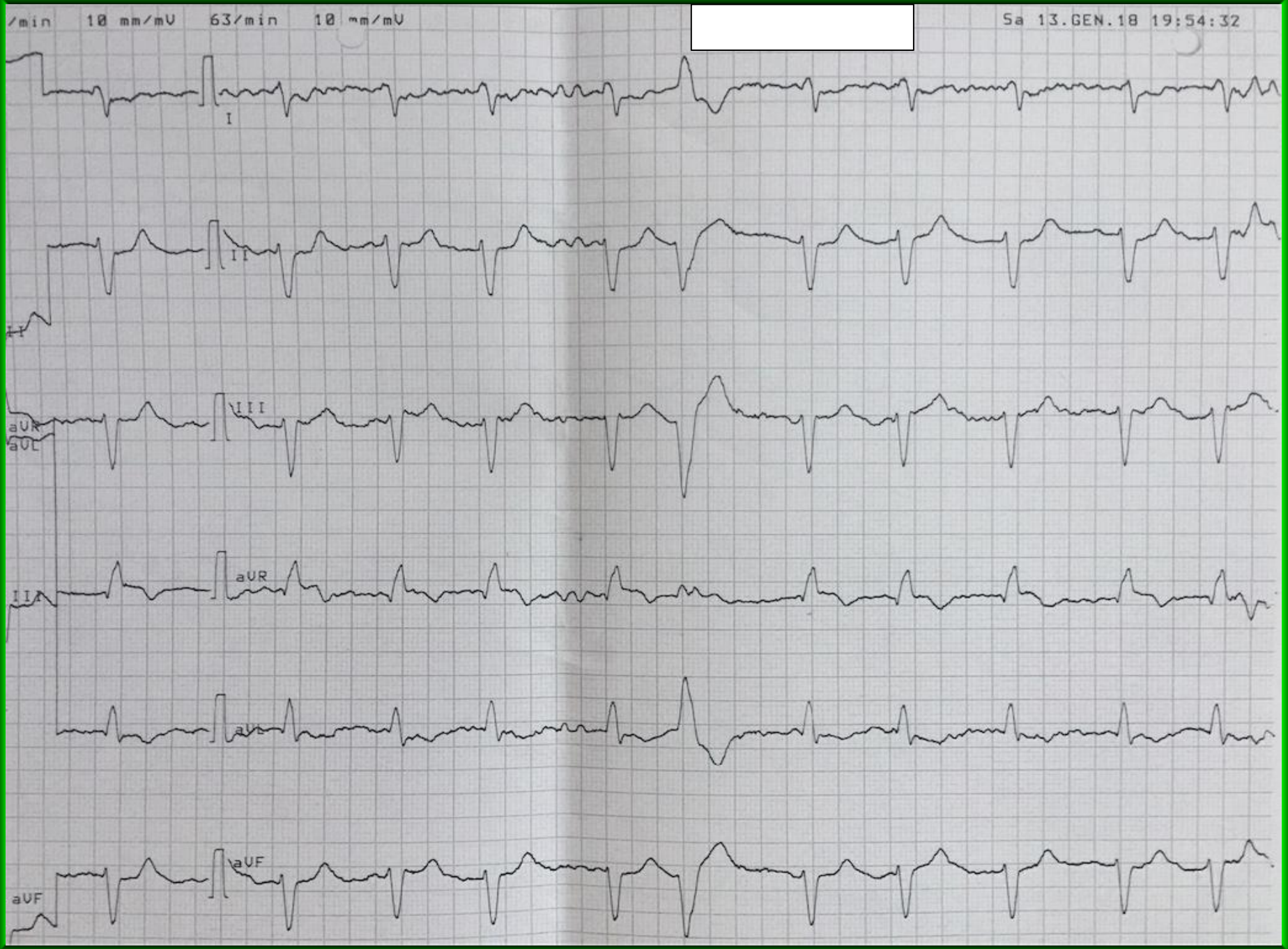
13.1.2018

"Riferito dolore toracico da 3-4 gg alleviato da nitrati s.l.
Alle 1930 *dolore toracico più intenso. Trasportato PS Molinette"*

Alle 1950 in P.S. Molinette:

Angor 4/10. PAOD 90/60 mmHg Fc 60 SatO2 in AA 91%

ECG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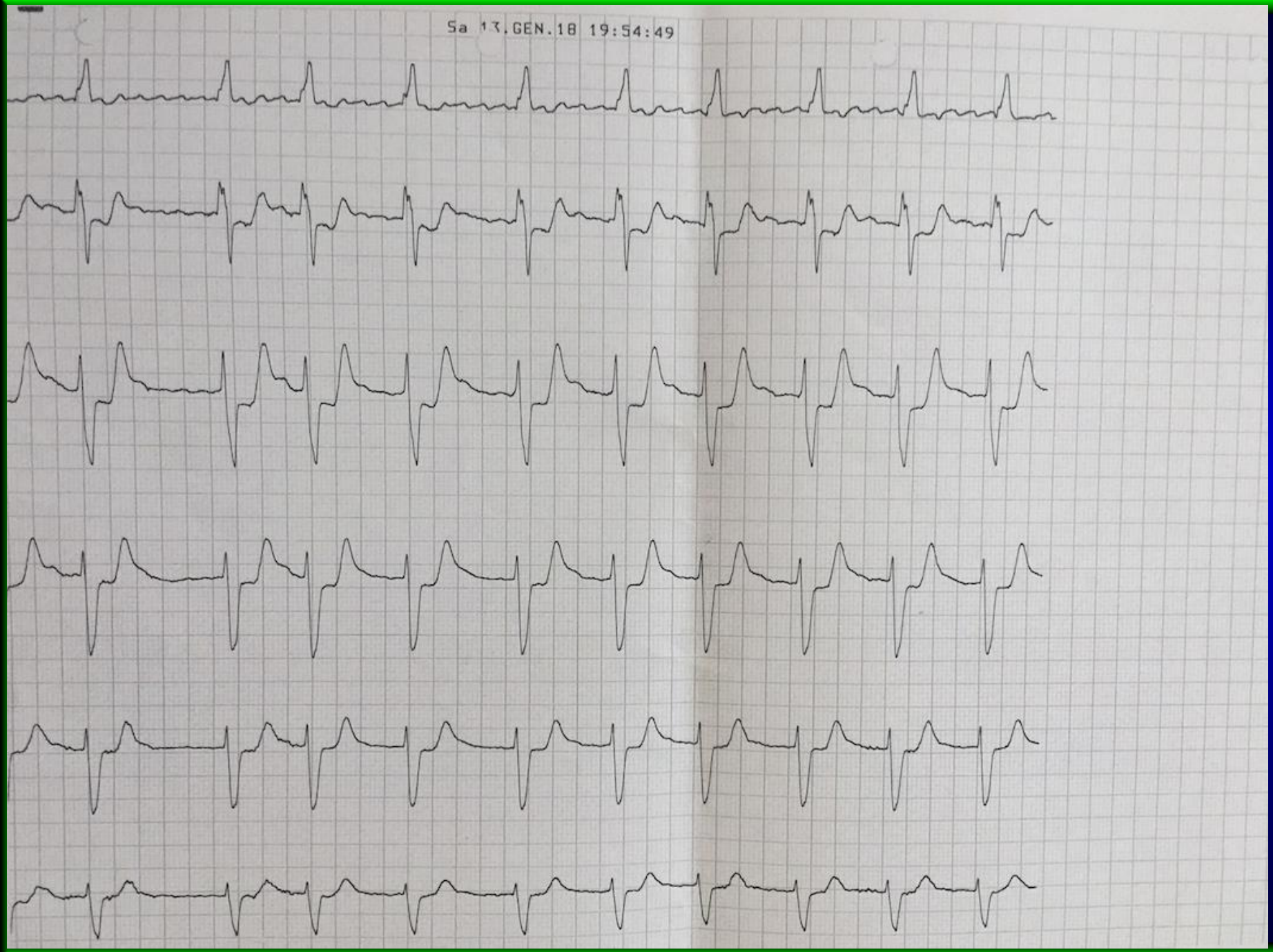
I
II
III
aVR
aVL
aVF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CASO CLINICO_presentazione II

13.1.2018

"Riferito dolore toracico da 3-4 gg alleviato da nitrati s.l.
Alle 1930 *dolore toracico più intenso. Trasportato PS Molinette"*

Alle 1950 in P.S. Molinette:

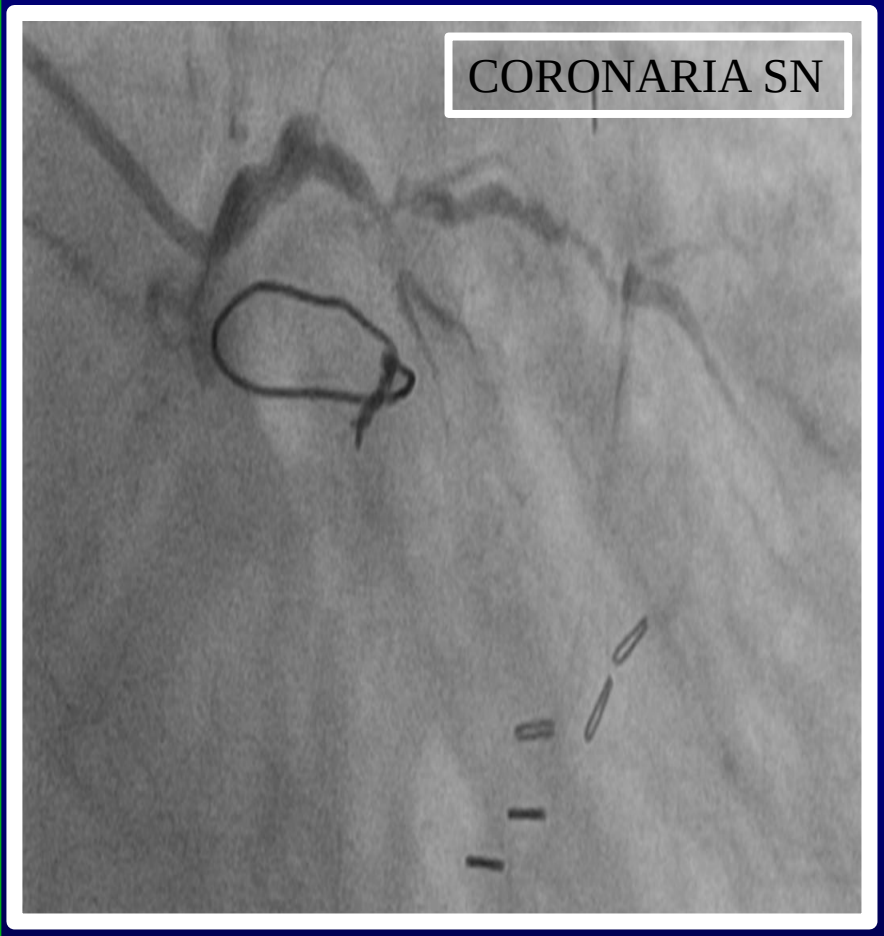
Angor 4/10. PAOD 90/60 mmHg Fc 60 SatO2 in AA 91%

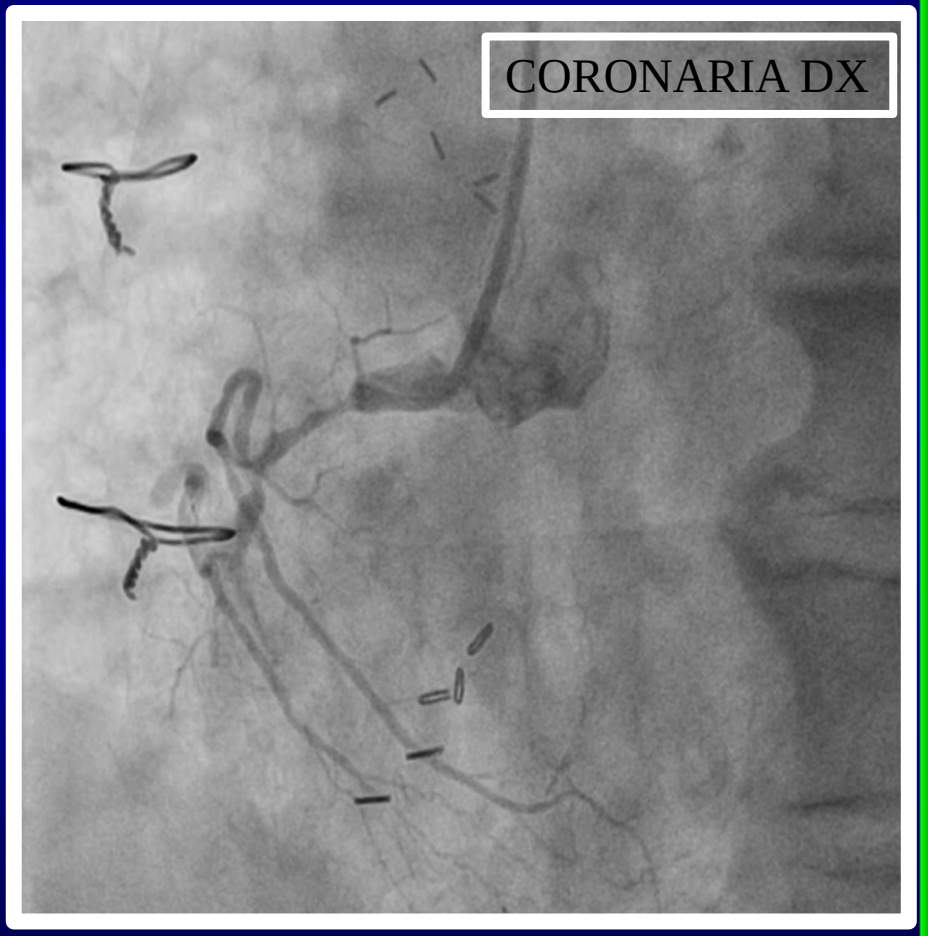
Ecoscopia: EF 25%. IM moderata
Esami: Hb 14,3, Trop 992, creat 2,0 mg/dL

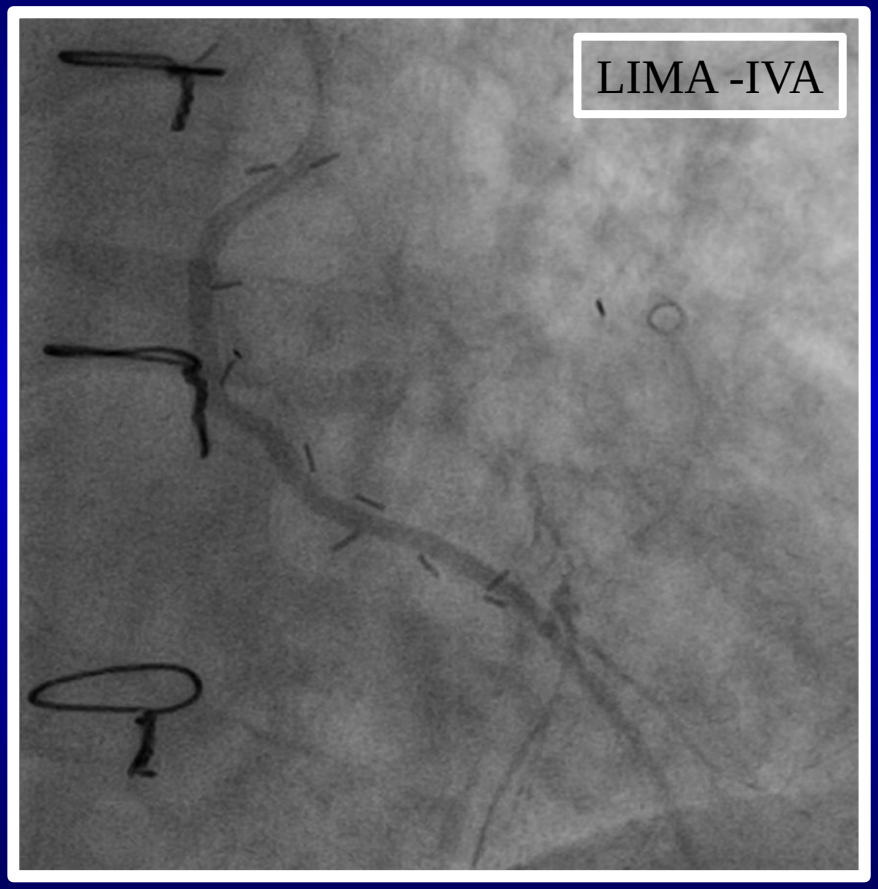
TX "on board": Coumadin INR 2.4

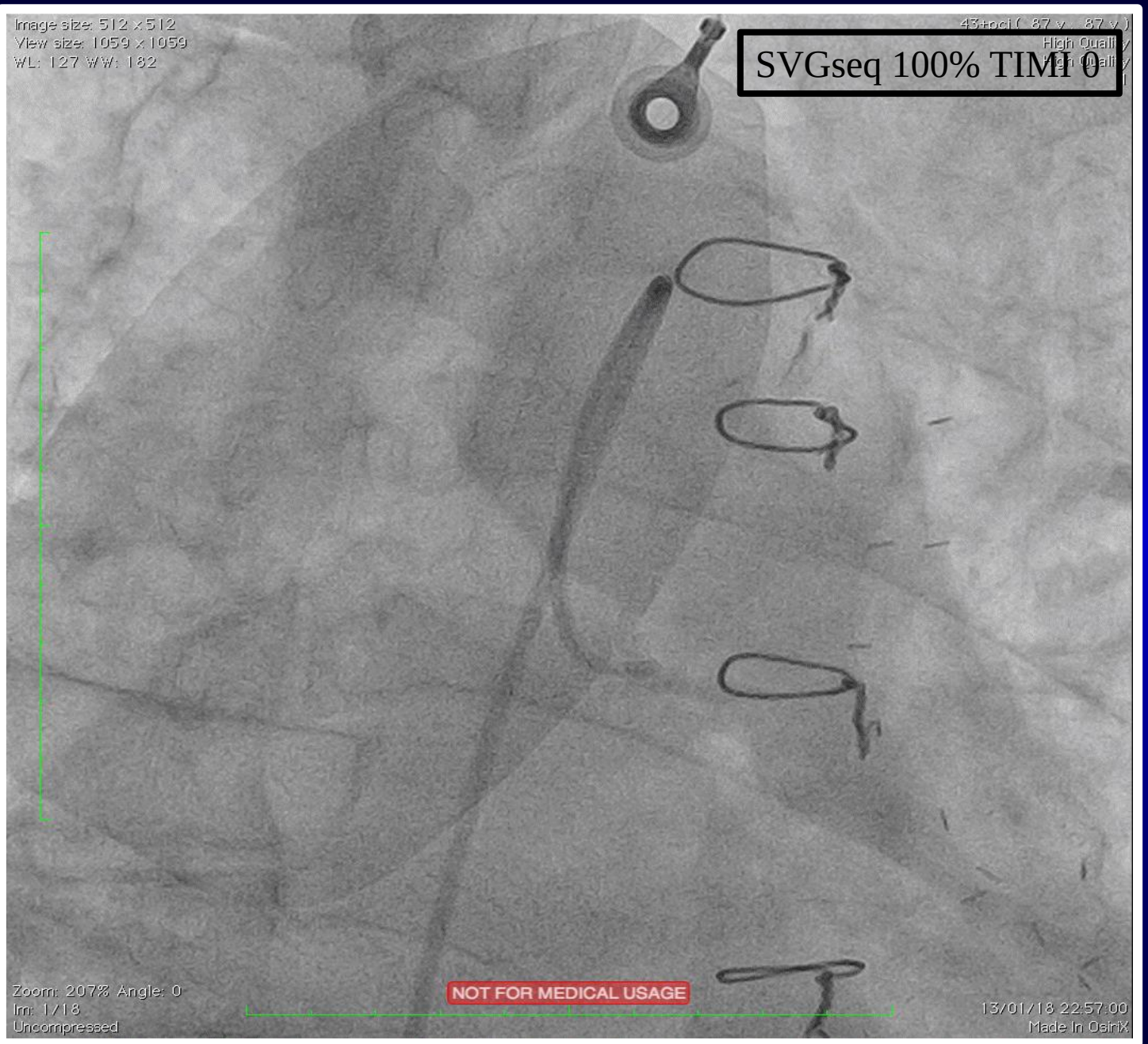
Alle 2030 in sala emodinamica

5.2017 – STEMI INFERIORE / PPCI + BIOFREEDOM






LIMA -IVA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NOT FOR MEDICAL USAGE
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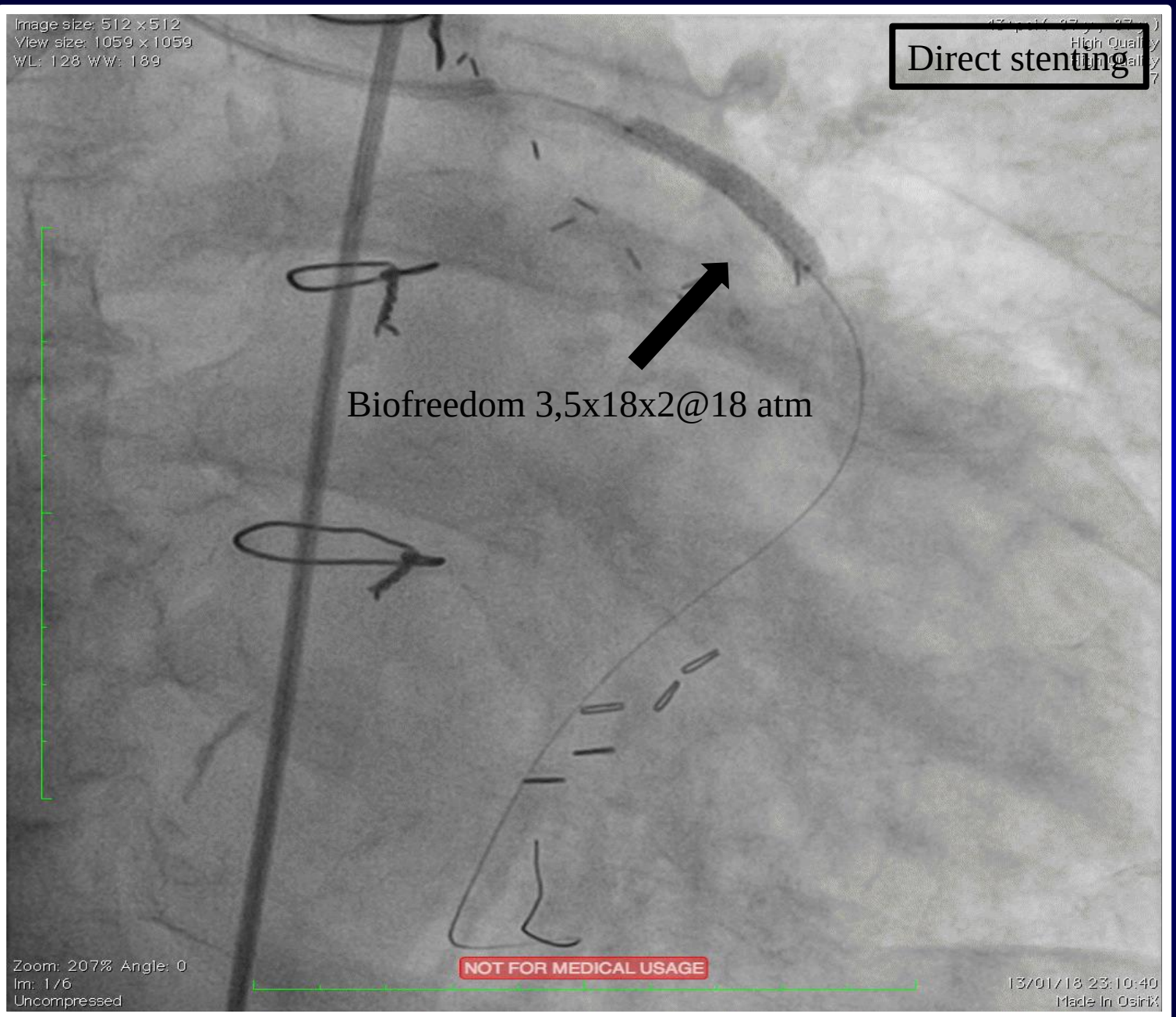
Made In OsiriX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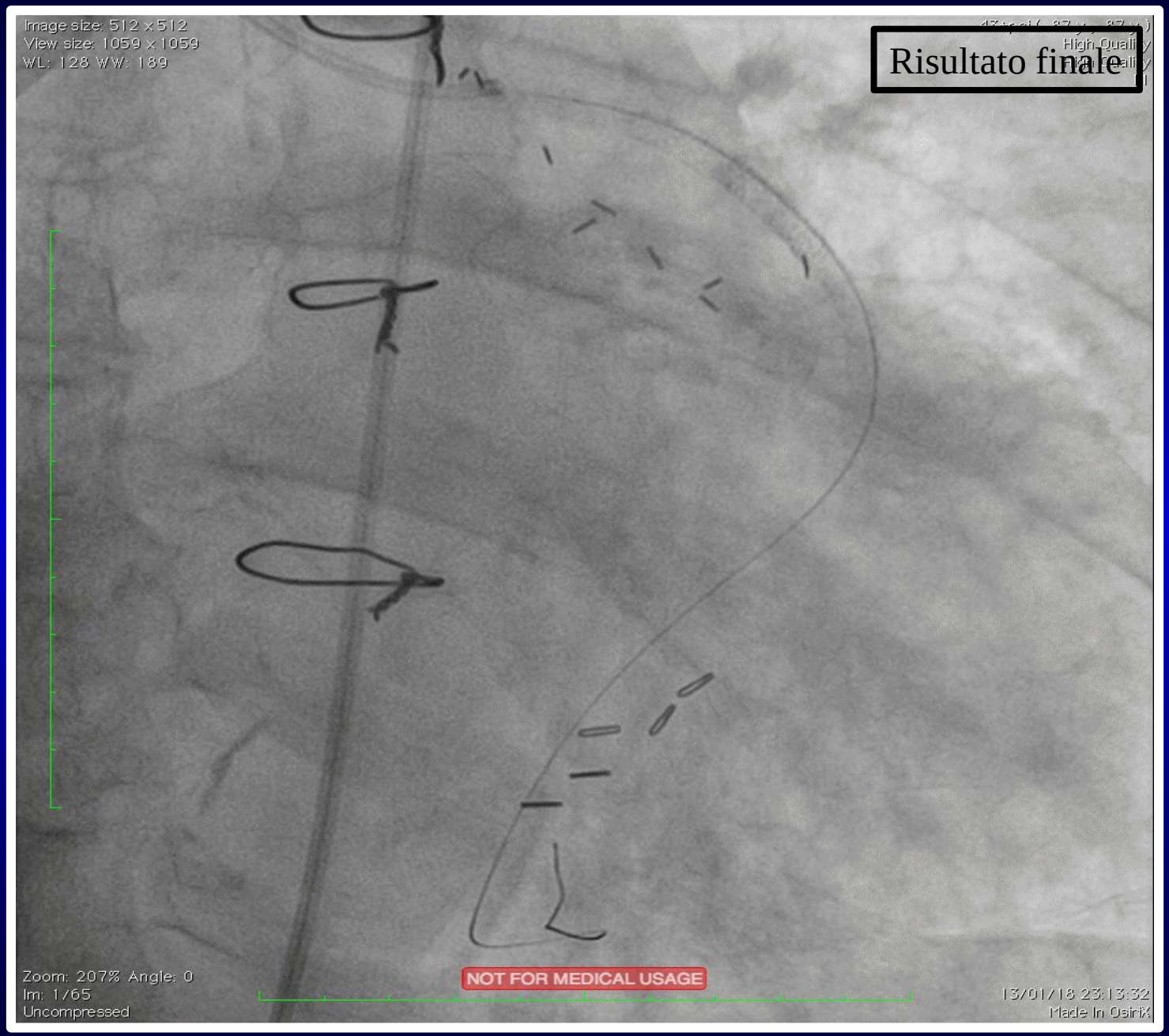
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Made In OsiriX

POSITION PAPER

G Ital Cardiol 2016;17(1):64-79

Documento di posizione della Società Italiana di Cardiologia Interventistica (SICI-GISE): terapia antitrombotica nel paziente anziano con sindrome coronarica acuta

Giuseppe Tarantini[1], Sergio Berti[2], Leonardo De Luca[3], Stefano De Servi[4], Luca Favero[5], Marco Ferlini[4], Alessio La Manna[6], Alfredo Marchese[7], Ciro Mauro[8], Alberto Menozzi[9], Marco Mojoli[1], Valeria Paradies[7], Ferdinando Varbella[10], Giuseppe Musumeci[11]

[1]Dipartimento di Scienze Cardiologiche, Toraciche e Vascolari, Università degli Studi, Padova

[2]U.O. Cardiologia Diagnostica ed Interventistica, Fondazione Toscana "G. Monasterio", Ospedale del Cuore, Massa

[3]Dipartimento di Scienze Cardiovascolari, European Hospital, Roma

[4]S.C. Cardiologia, Fondazione IRCCS Policlinico San Matteo, Pavia

[5]Dipartimento Cardiovascolare, Ospedale Ca' Foncello, Treviso

[6]Dipartimento Cardiovascolare, Università degli Studi, Catania

[7]U.O.C. Cardiologia Interventistica, Anthea Hospital, GVM Care & Research, Bari

[8]Dipartimento di Cardiologia, Ospedale Cardarelli, Napoli

[9]U.O. Cardiologia, Azienda Ospedaliero-Universitaria, Parma

[10]Divisione di Cardiologia, Ospedali degli Infermi, Rivoli (TO)

[11]Dipartimento Cardiovascolare, A.O. Papa Giovanni XXIII, Bergamo

IL GRANDE ANZIANO: principi metodologici

- L'età anagrafica di per sé non costituisce e non deve costituire un motivo sufficiente per condizionare una qualsivoglia scelta clinica.

- Valutare l'età biologica, le comorbilità, lo stato cognitivo e fiunzionale e la fragilità del paziente.

- I pazienti grandi anziani sono stati praticamente esclusi dai grandi RCT: attenzione all'estensione delle conclusioni. Operare attento bilancio tra rischio ischemico ed emorragico, valutare preferenze del paziente.

- Utilizzare specifiche valutazioni a punteggio per evitare valutazioni soggettive ed arbitrarie.

THE STORM (acute coronary Syndrome in paTients end Of life and Risk assesMent) study

Claudio Moretti,[1] Giorgio Quadri,[1] Fabrizio D'Ascenzo,[1] Maurizio Bertaina,[1] Federico Giusto,[1] Sebastiano Marra,[1] Corrado Moiraghi,[2] Luca Scaglione,[3] Mauro Torchio,[3] Giuseppe Montrucchio,[2] Mario Bo,[2] Massimo Porta,[2] Paolo Cavallo Perin,[2] Carlo Marinone,[3] Franco Riccardini,[2] Javaid Iqbal,[4] Pierluigi Omedè,[1] Serena Bergerone,[1] Franco Veglio,[2] Fiorenzo Gaita[1]

GENERAL CRITERIA OF END-STAGE ILLNESS
1) Weight loss > 10% in last 6 months
2) General physical decline
3) Serum albumin < 25 g/l
4) Reducing performance status (Karnovsky score < 50%)
HEART DISEASE SPECIFIC CRITERIA
1) The Surprise Question (to be asked of a health care provider familiar with the patient): "Would you be surprised if the patients died in the next 6 to 12 months?"
2) New York Heart Association (NHYA). Stage III or IV heart failure
3) Repeated hospital admissions within the last year
4) Difficult physical or psychological symptoms despite optimised tolerated therapy
GSF Positive status: at least one general criterion and two heart disease specific criteria.

Moretti C, *et al*. *Emerg Med J* 2016;**33**:10–16.

THE STORM (acute coronary Syndrome in paTients end Of life and Risk assesMent) study

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GENERAL CRITERIA OF END-STAGE ILLNESS

CONCLUSIONS

A sizeable proportion of patients with ACS have a positive GSF score. GSF could represent a powerful and accurate tool to predict 3-month and 1-year non-cardiovascular adverse events and guide management in patients with ACS. These results need to be externally validated on a larger sample size (eg, multicentre studies) and finally by randomised trials.

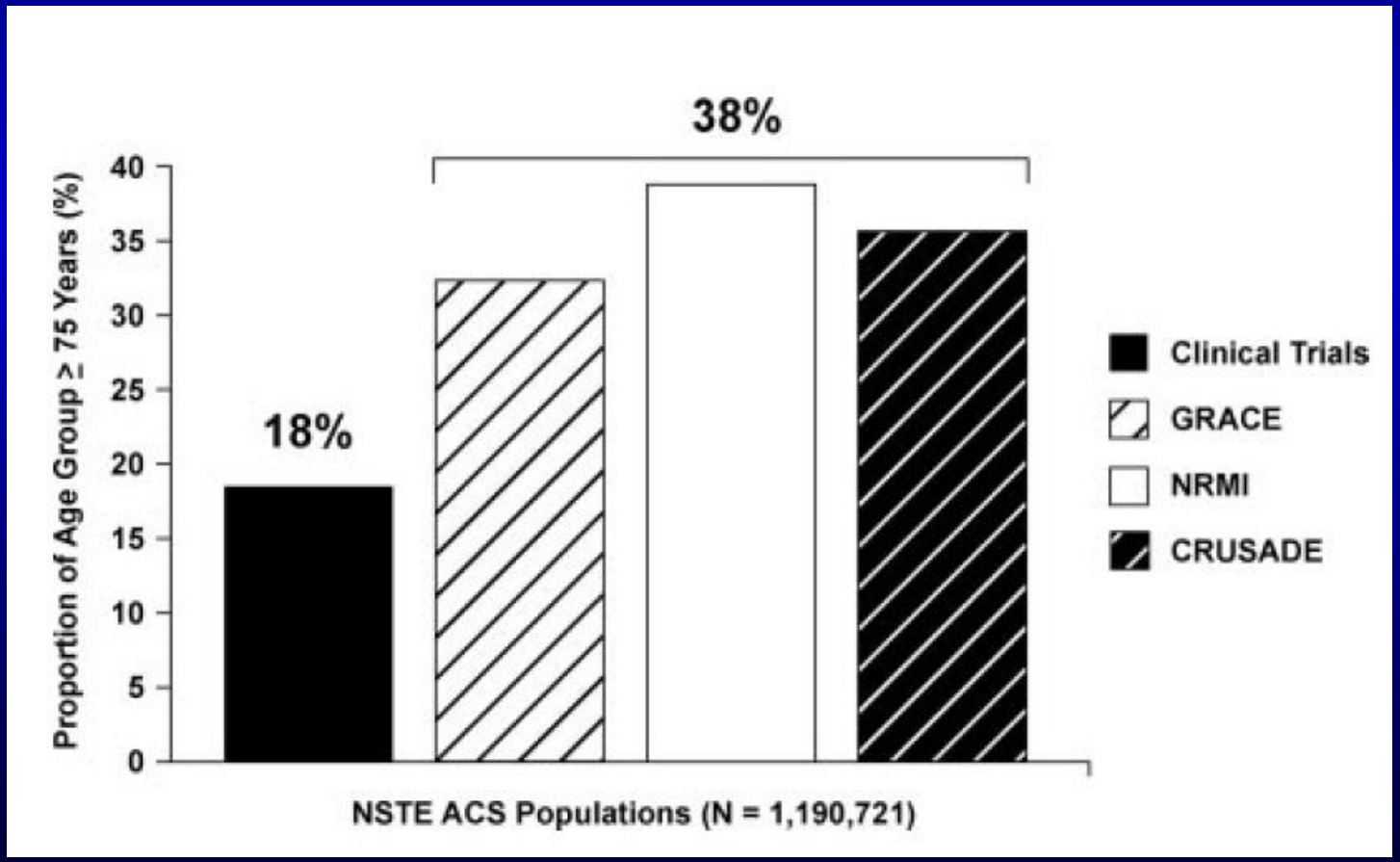
at least one general criterion and two heart disease specific criteria.

Moretti C, *et al*. *Emerg Med J* 2016;**33**:10–16.

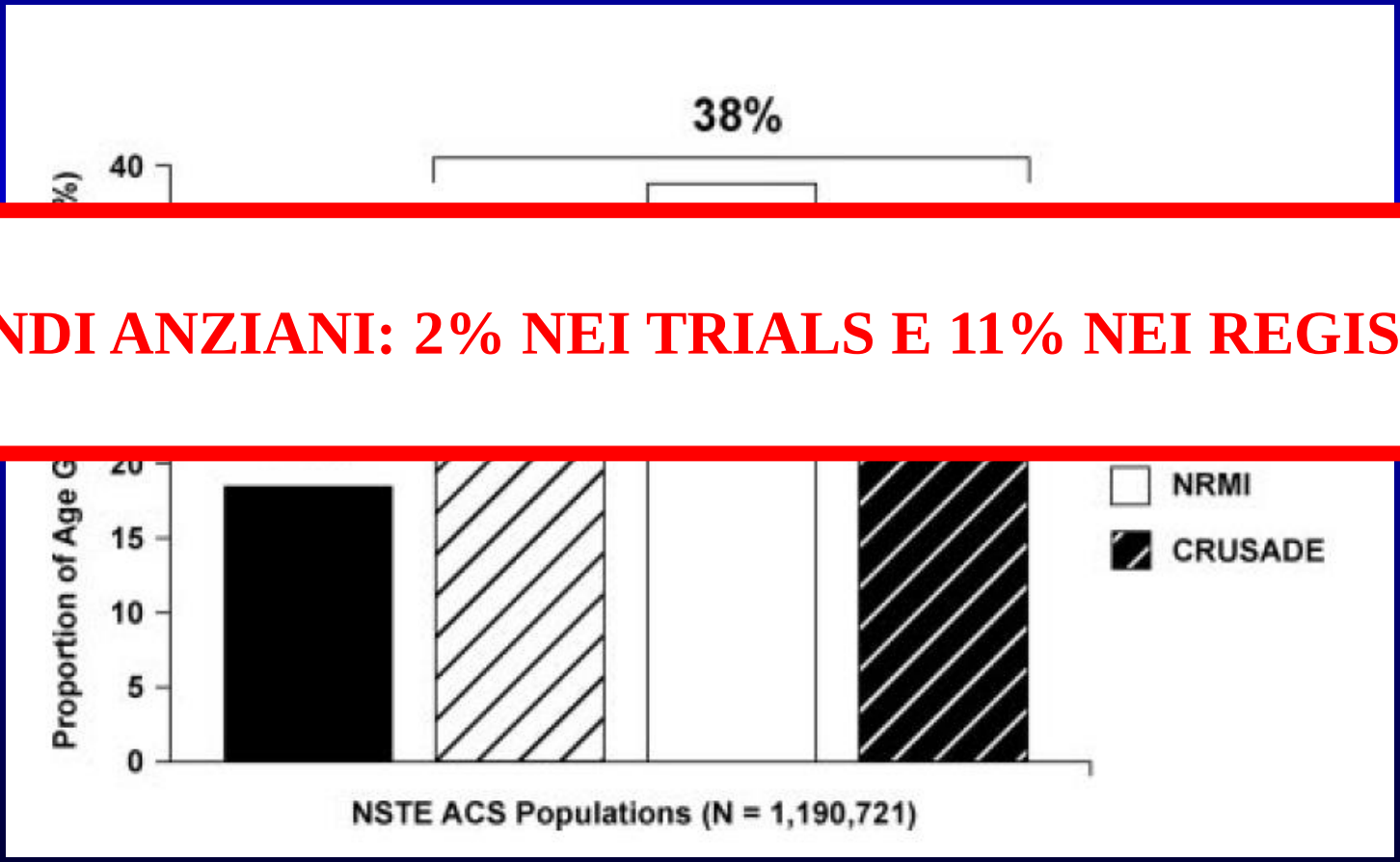
Raccomandazione

- Nei pazienti con età >85 anni, clopidogrel dovrebbe essere considerato l'inibitore del recettore $P2Y_{12}$ di scelta, sulla base dell'elevato rischio emorragico generalmente presente in tali pazienti.
- In casi selezionati, in cui rischio ischemico possa considerarsi molto elevato e il rischio emorragico accettabile, potrà essere considerato l'uso di ticagrelor (in particolare nel paziente STEMI). Al momento, le evidenze disponibili sconsigliano l'impiego di prasugrel in questa categoria di pazienti.
- Si sconsiglia l'utilizzo degli inibitori GPIIb/IIIa, salvo in caso di bailout.
- Si raccomanda l'utilizzo di bivalirudina o in alternativa di ENF come anticoagulante nel paziente con STEMI e di fondaparinux (con uso di ENF durante eventuale PCI) nel paziente con UA/NSTEMI.

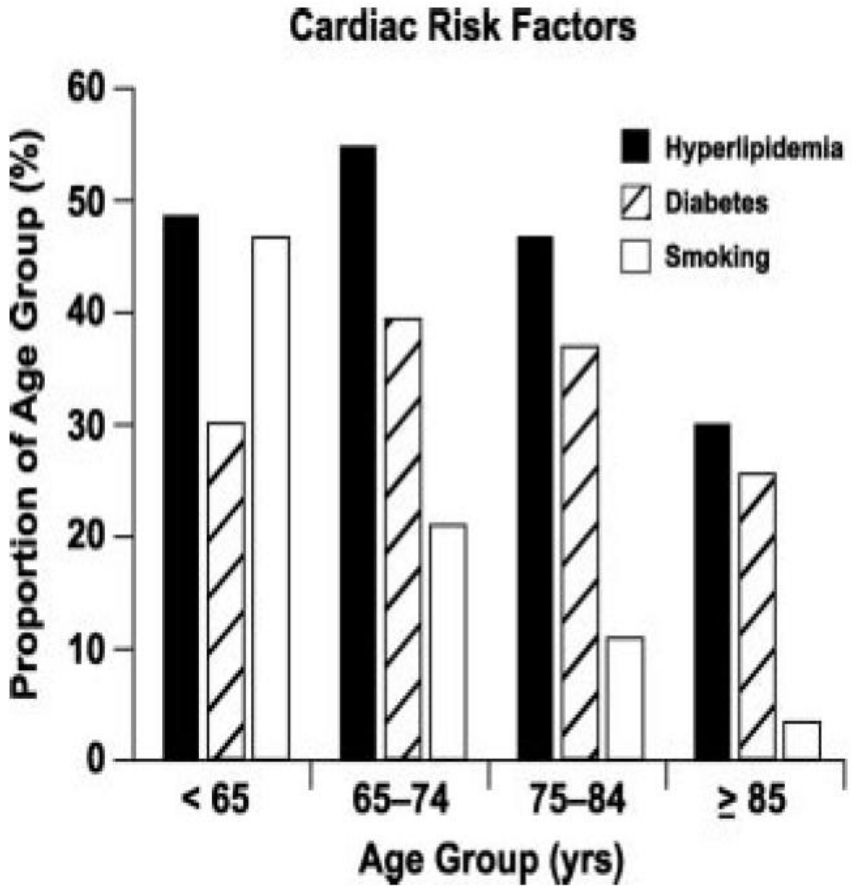
PAZIENTI > 75 AA IN TRIALS E REGISTRI



PAZIENTI > 75 AA IN TRIALS E REGISTRI



GRANDI ANZIANI: 2% NEI TRIALS E 11% NEI REGISTRI


Cardiac Risk Factors
Proportion of Age Group (%)
60
50
40
30
20
10
0
Hyperlipidemia
Diabetes
Smoking
< 65
65–74
75–84
≥ 85
Age Group (yrs)

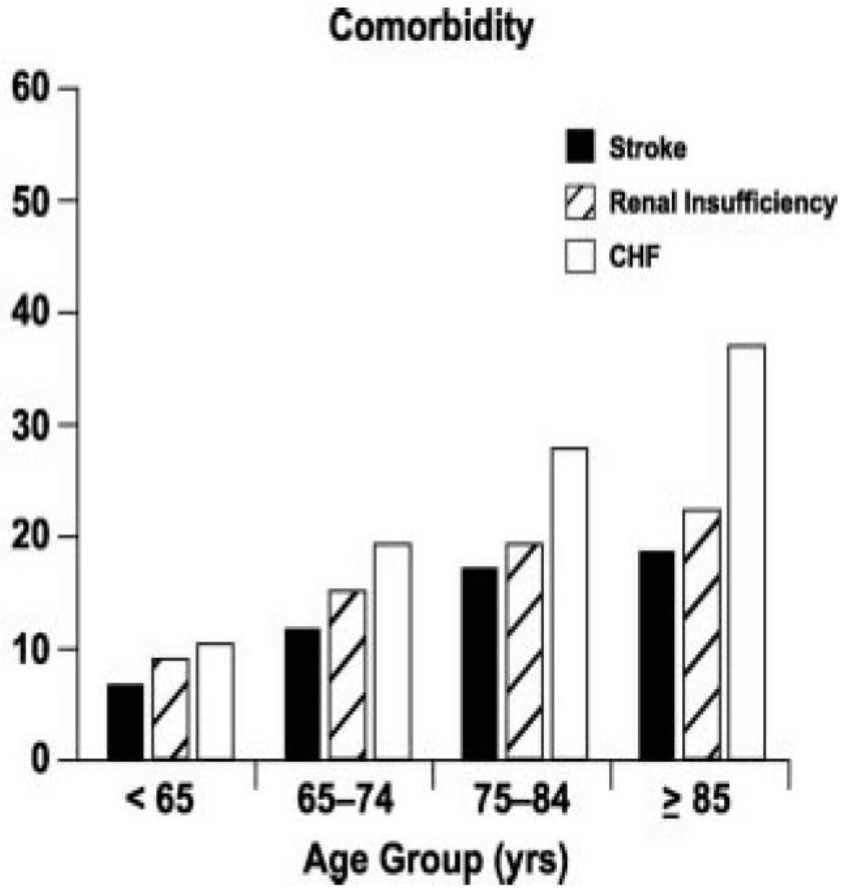

Comorbidity
60
50
40
30
20
10
0
Stroke
Renal Insufficiency
CHF
< 65
65–74
75–84
≥ 85
Age Group (yrs)

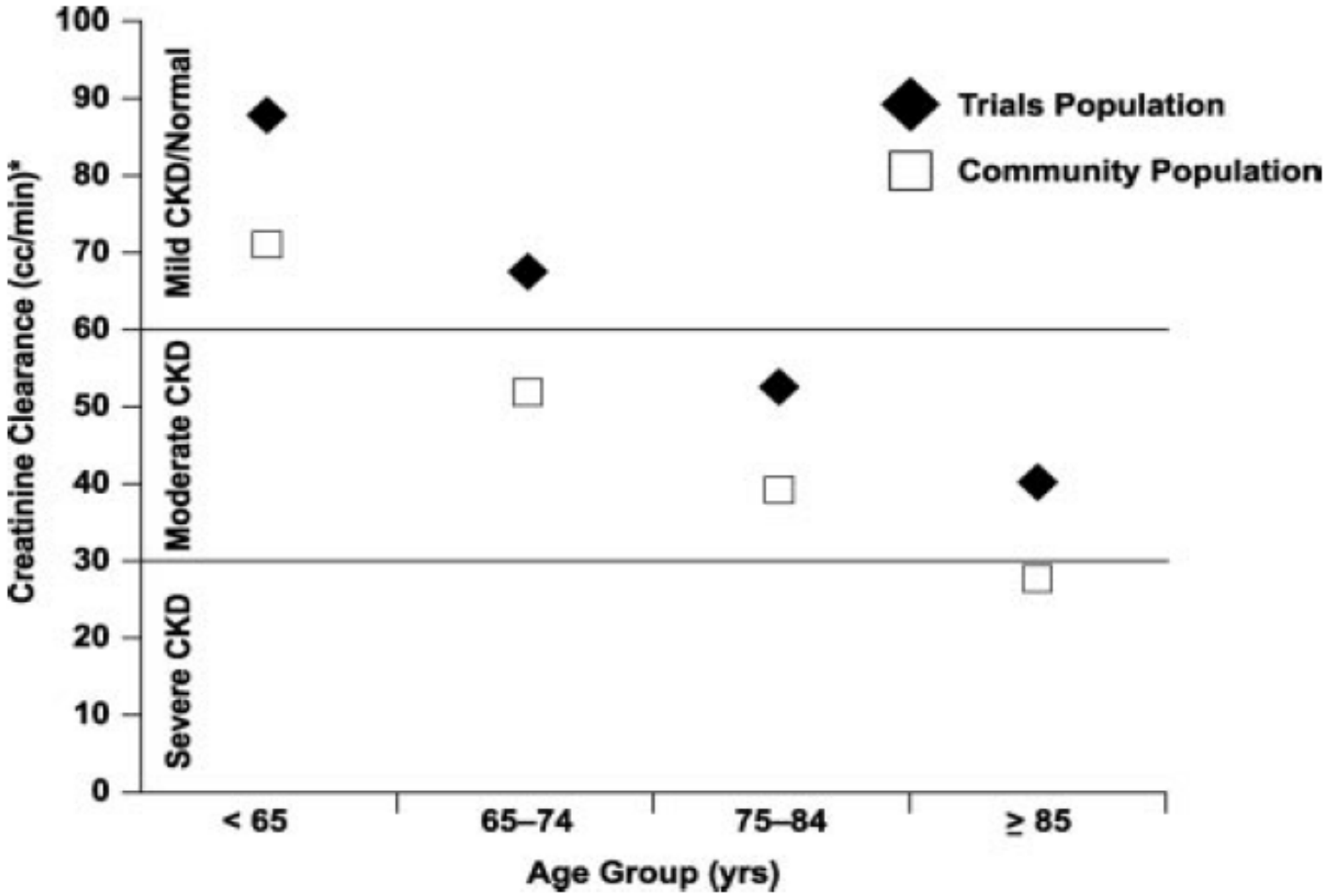
TABLE 3. Selected Baseline Characteristics of Trial (VIGOUR) and Community (CRUSADE) Populations by Age Subgroup

	Age Group			
Population	<65 y	65–74 y	75–84 y	≥85 y
Age group				
Trials	49	33	16	2
Community	42	23	24	11
Female				
Trials	28	38	48	57
Community	31	39	48	62
Hypertension				
Trials	47	58	59	57
Community	62	73	75	73
Hyperlipidemia				
Trials	44	41	32	21
Community	49	53	45	28
Diabetes mellitus				
Trials	17	25	25	20
Community	30	39	36	25
Current smoker				
Trials	41	16	7	3
Community	46	22	10	4
Body mass index, kg/m^2				
Trials	28±5	27±4	26±4	25±4
Community	30±8	29±6	27±6	25±5
CHF				
Trials	6	10	16	22
Community	10	19	26	36

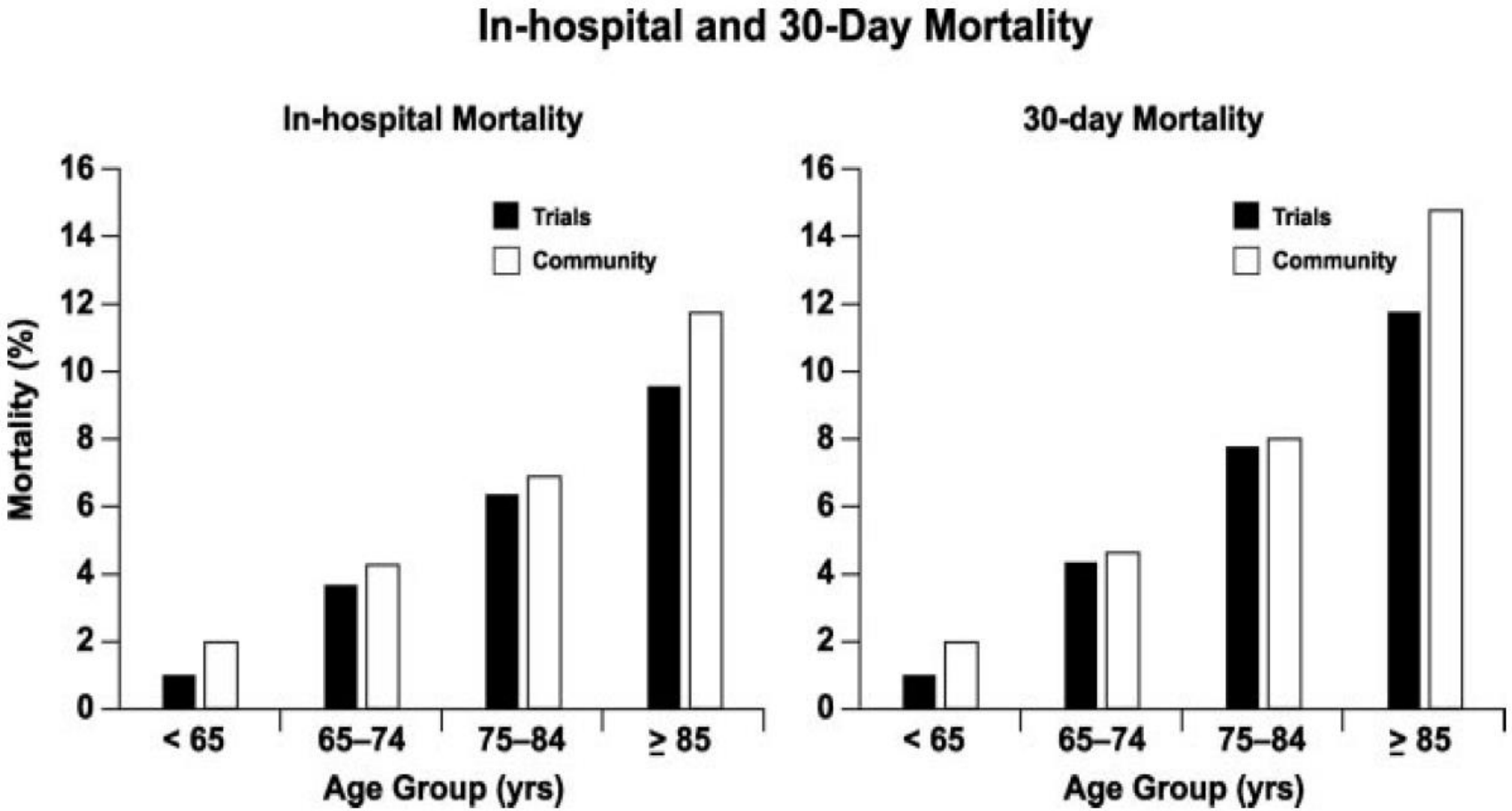
TABLE 3. Selected Baseline Characteristics of Trial (VIGOUR) and Community (CRUSADE) Populations by Age Subgroup

Population	Age Group			
	<65 y	65–74 y	75–84 y	≥85 y
Prior stroke				
Trials	3	6	9	8
Community	6	11	17	18
Prior MI				
Trials	27	35	37	41
Community	27	33	35	35
ST depression				
Trials	44	56	61	64
Community	38	42	42	40
Heart rate, bpm				
Trials	74±14	75±15	76±15	78±16
Community	84±21	85±24	87±24	90±24
Systolic blood pressure, mm Hg				
Trials	134±21	138±22	139±23	138±24
Community	146±30	146±32	145±32	142±33
High-risk tertile, % of age group*				
Trials	9	48	76	93
Community	15	55	83	94

Creat Clearance per età



MORTALITA' (VIGOUR vs GRACE)



Comparison of Outcomes in Patients Aged <75, 75 to 84, and ≥85 Years With ST-Elevation Myocardial Infarction (from the ACTION Registry-GWTG)

Daniel E. Forman, MD[a,b,*], Anita Y. Chen, MS[c], Stephen D. Wiviott, MD[a], Tracy Y. Wang, MD, MHS[b,d], David J. Magid, MD, MPH[e,f], and Karen P. Alexander, MD[b,d]

Baseline characteristics for overall cohort with ST-elevation myocardial infarction and by age groups

Baseline Characteristics	Total Population (n = 30,188)	Age (years)			p Value for Trend
		<75 (n = 24,070)	75–84 (n = 4,273)	≥85 (n = 1,845)	
Age (years)*	60 (52–72)	57 (50–64)	79 (77–82)	88 (86–91)	<0.0001
Women	30%	25%	48%	61%	<0.0001
Caucasian	85%	84%	89%	91%	<0.0001
Body mass index (kg/m^2)*	28 (25–32)	29 (26–33)	26 (24–30)	24 (22–27)	<0.0001
Current/recent smoker	42%	50%	13%	5%	<0.0001
Previous myocardial infarction	19%	18%	21%	22%	<0.0001
Previous revascularization	23%	23%	26%	20%	0.0047
Previous hypertension†	60%	57%	73%	76%	<0.0001
Previous hyperlipidemia‡	47%	47%	51%	40%	0.4820
Previous heart failure	5%	3%	10%	17%	<0.0001
Previous peripheral artery disease	6%	5%	11%	10%	<0.0001
Previous stroke	5%	4%	10%	13%	<0.0001
Diabetes mellitus	22%	22%	27%	20%	0.0031
Creatinine clearance (ml/min)*§	84 (60–111)	93 (73–118)	51 (39–65)	34 (25–45)	<0.0001
Brain natriuretic peptide (pg/ml)*	181 (46–555)	115 (31–365)	401 (151–923)	602 (243–1,390)	<0.0001
Initial systolic blood pressure (mm Hg)*	138 (117–157)	138 (118–158)	136 (114–157)	133 (110–155)	<0.0001
Initial heart rate (beats/min)*	78 (65–93)	78 (65–92)	78 (64–94)	81 (66–98)	0.843
Initial hematocrit (%)*	43 (39–46)	43 (40–46)	40 (36–43)	38 (35–42)	<0.0001
Left bundle branch block on presentation	4%	3%	9%		
Door-to-electrocardiogram time (min)*	7 (3–14)	6 (3–13)	8 (4–16)		
Symptom onset to presentation time (hours)*‖	1.70 (0.98–3.60)	1.63 (0.97–3.42)	1.93 (1.02–4.05)	2.20 (1.05–4.97)	<0.0001

(Am J Cardiol 2010;106:1382–1388)

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In-hospital procedures overall and by age

Procedures	Total Population (n = 30,188)	Age (years)			p Value for Trend
		<75 (n = 24,070)	75–84 (n = 4,273)	≥85 (n = 1,845)	
Cardiac catheterization*	92%	93%	90%	79%	<0.0001
Percutaneous coronary intervention†	85%	88%	78%	69%	<0.0001
Coronary artery bypass grafting†	8%	8%	9%	3%	0.298
Assessment of left ventricular ejection fraction	89%	90%	87%	81%	<0.0001

Reasons of contraindications to reperfusion overall and by age*

Contraindications to reperfusion	Total Population (n = 30,188)	Age (years)			p Value for Trend
		<75 (n = 24,070)	75–84 (n = 4,273)	≥85 (n = 1,845)	
Total contraindications	17% (5,078)	13% (3,239)	25% (1,067)	42% (772)	<0.0001
Reason for contraindication					
Absolute or relative†	9% (465)	8% (269)	11% (120)	10% (76)	
Symptom, timing, or electrocardiographic factors	31% (1,582)	34% (1,089)	30% (319)	23% (174)	
Coronary anatomy factors	30% (1,505)	35% (1,123)	27% (293)	12% (89)	
Patient preferences	13% (639)	4% (129)	15% (162)	45% (348)	
Other	17% (865)	19% (620)	16% (170)	10% (75)	

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Unadjusted in-hospital outcomes* overall and by age

In-Hospital Outcome	Total population (n = 30,188)	Age (years)			p Value for Trend
		<75 (n = 24,070)	75–84 (n = 4,273)	≥85 (n = 1,845)	
Mortality	6%	4%	12%	19%	<0.0001
Major bleeding†	12%	10%	18%	16%	<0.0001
Heart failure	6%	5%	11%	15%	<0.0001
Stroke	0.8%	0.6%	1.5%	1.7%	<0.0001

La mortalità raddoppia ad ogni decade !

2017 ESC focused update on dual antiplatelet therapy in coronary artery disease developed in collaboration with EACTS

STRATEGIE PER EVITARE I SANGUINAMENTI

- Assess ischaemic and bleeding risks using validated risk predictors (e.g. CHA_2DS_2-VASc, ABC, HAS-BLED) with a focus on modifiable risk factors.
- Keep triple therapy duration as short as possible; dual therapy after PCI (oral anticoagulant and clopidogrel) to be considered instead of triple therapy.
- Consider the use of NOACs instead of VKA.
- Consider a target INR in the lower part of the recommended target range and maximize time in therapeutic range (i.e. > 65–70%) when VKA is used.
- Consider the lower NOAC regimen tested in approval studies and apply other NOAC regimens based on drug-specific criteria for drug accumulation.[a]
- Clopidogrel is the $P2Y_{12}$ inhibitor of choice.
- Use low-dose (≤ 100 mg daily) aspirin.
- Routine use of PPIs.

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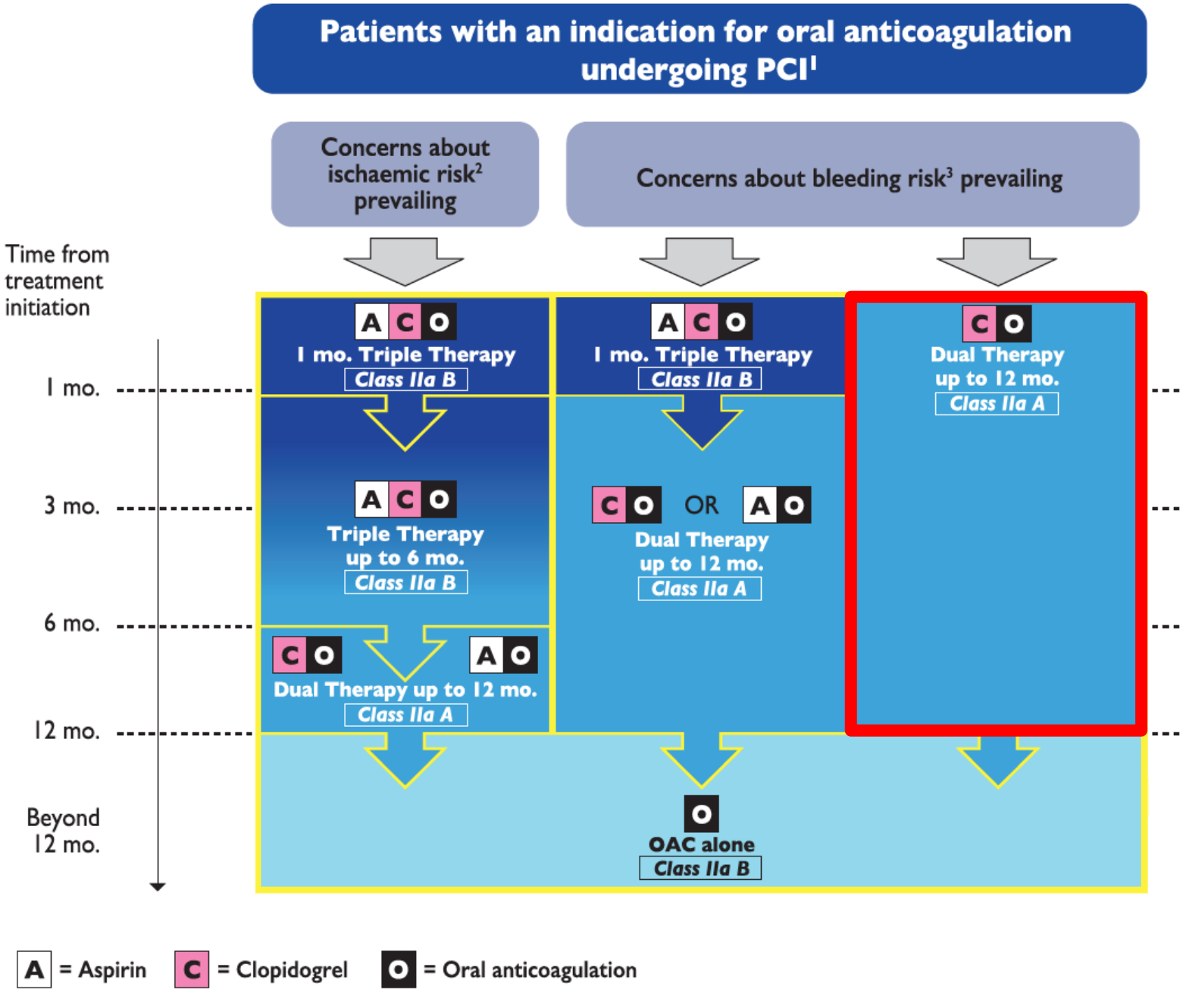

Patients with an indication for oral anticoagulation undergoing PCI[1]
Concerns about ischaemic risk[2] prevailing
Concerns about bleeding risk[3] prevailing
Time from treatment initiation
1 mo.
3 mo.
6 mo.
12 mo.
Beyond 12 mo.
A C O
1 mo. Triple Therapy
Class IIa B
A C O
1 mo. Triple Therapy
Class IIa B
C O
Dual Therapy up to 12 mo.
Class IIa A
A C O
Triple Therapy up to 6 mo.
Class IIa B
C O OR A O
Dual Therapy up to 12 mo.
Class IIa A
C O A O
Dual Therapy up to 12 mo.
Class IIa A
O
OAC alone
Class IIa B
A = Aspirin
C = Clopidogrel
O = Oral anticoagulation
©ESC 2017

Table 5 High-risk features of stent-driven recurrent 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 stent length >60 mm
• Treatment of a chronic total occlusion

Le evidenze…

WOEST

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

PIONEER AF

Dual Antithrombotic Therapy with Dabigatran after PCI in Atrial Fibrillation

Christopher P. Cannon, M.D., Deepak L. Bhatt, M.D., M.P.H., Jonas Oldgren, M.D., Ph.D., Gregory Y.H. Lip, M.D., Stephen G. Ellis, M.D., Takeshi Kimura, M.D., Michael Maeng, M.D., Ph.D., Bela Merkely, M.D., Uwe Zeymer, M.D., Savion Gropper, M.D., Ph.D., Matias Nordaby, M.D., Eva Kleine, M.Sc., Ruth Harper, Ph.D., Jenny Manassie, B.Med.Sc., James L. Januzzi, M.D., Jurrien M. ten Berg, M.D., Ph.D., P. Gabriel Steg, M.D., and Stefan H. Hohnloser, M.D., for the RE-DUAL PCI Steering Committee and Investigators*

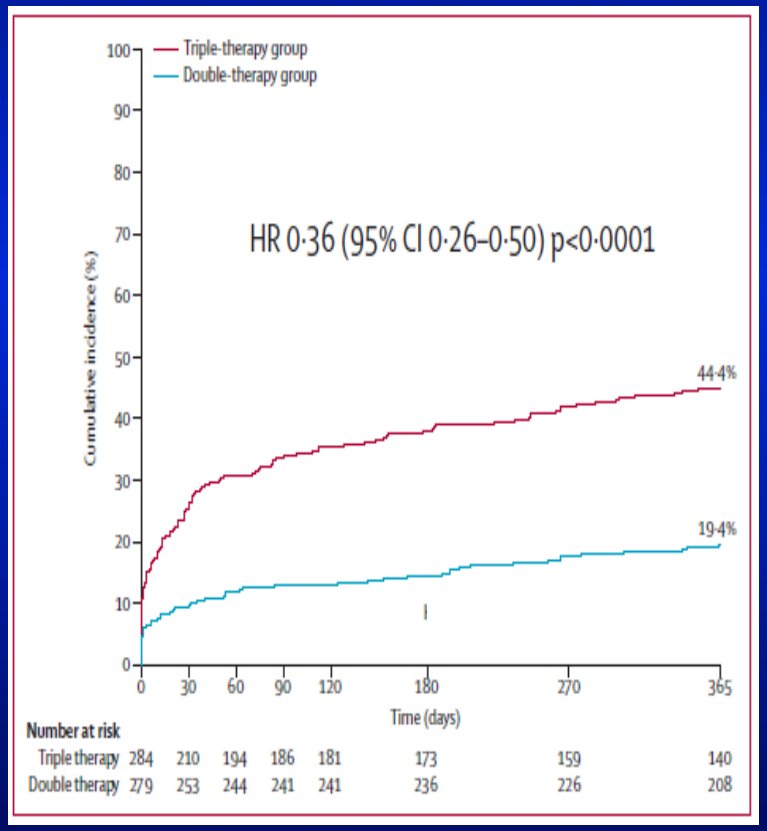
RE-DUAL PCI

Prevention of Bleeding in Patients with Atrial Fibrillation Undergoing PCI

C. Michael Gibson, M.D., Roxana Mehran, M.D., Christoph Bode, M.D., Jonathan Halperin, M.D., Freek W. Verheugt, M.D., Peter Wildgoose, Ph.D., Mary Birmingham, Pharm.D., Juliana Ianus, Ph.D., Paul Burton, M.D., Ph.D., Martin van Eickels, M.D., Serge Korjian, M.D., Yazan Daaboul, M.D., Gregory Y.H. Lip, M.D., Marc Cohen, M.D., Steen Husted, M.D., Eric D. Peterson, M.D., M.P.H., and Keith A. Fox, M.B., Ch.B.

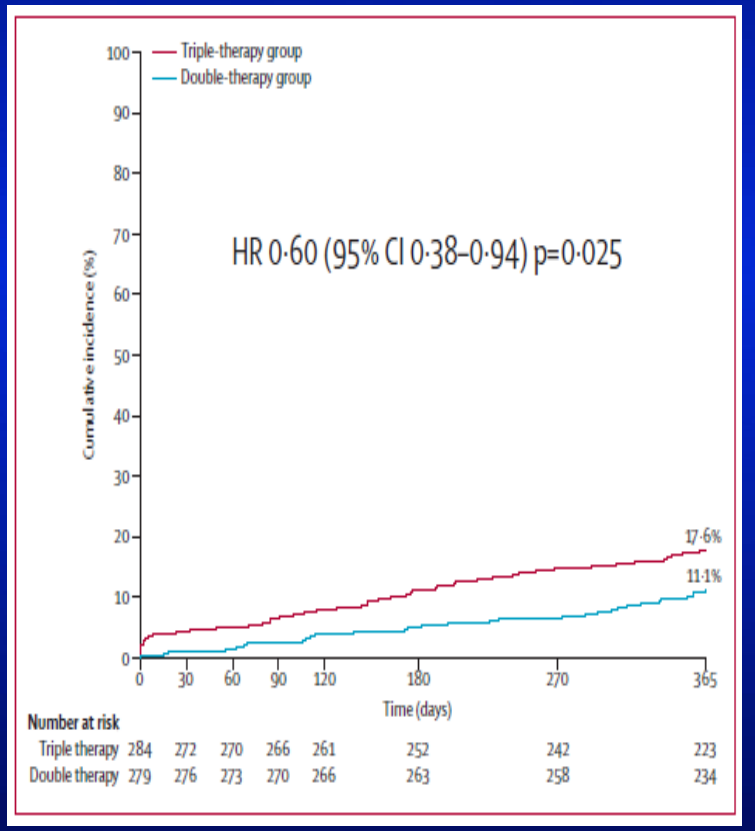
Dual vs triple therapy: the WOEST study

1° endpoint - Safety (total bleeding)

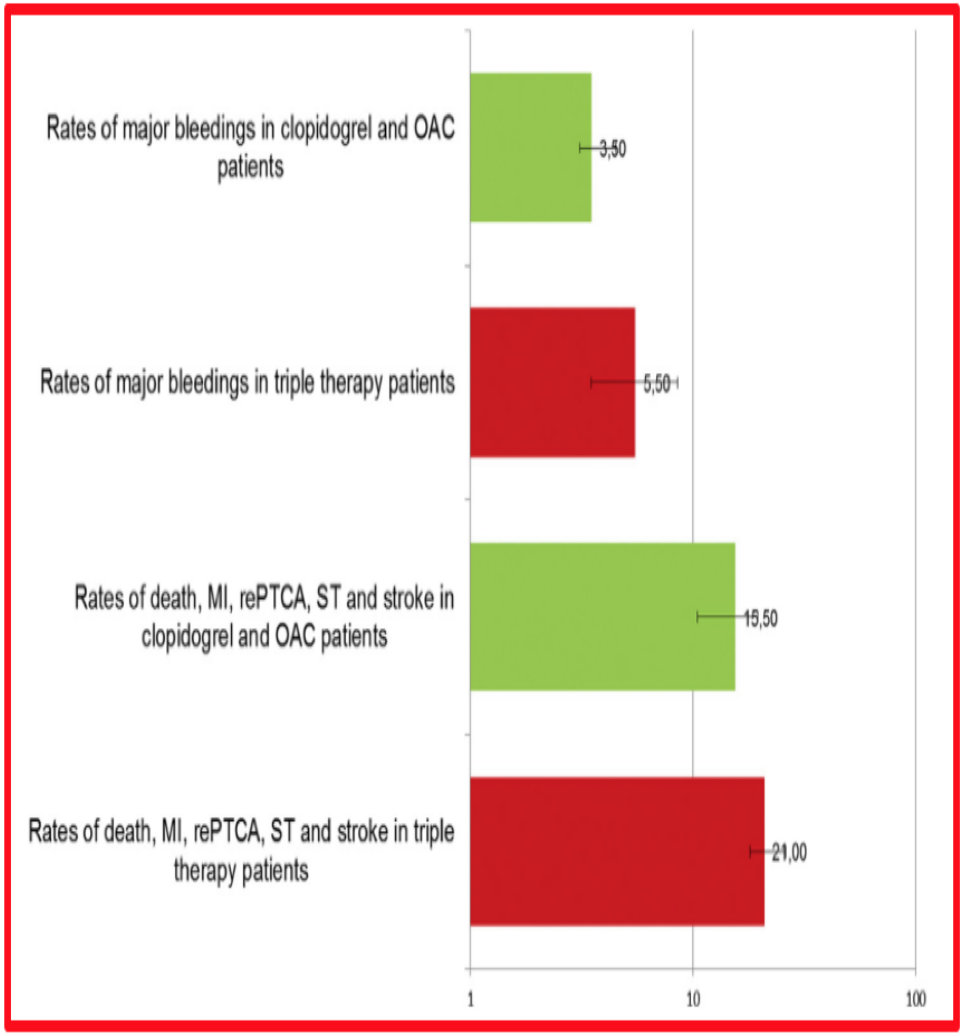


Trascinata da emorragie NON maggiori

2° endpoint - Efficacy (stroke, death, MI, re-PCI/CABG, stent thrombosis)



Trascinata da mortalità NON cardiaca

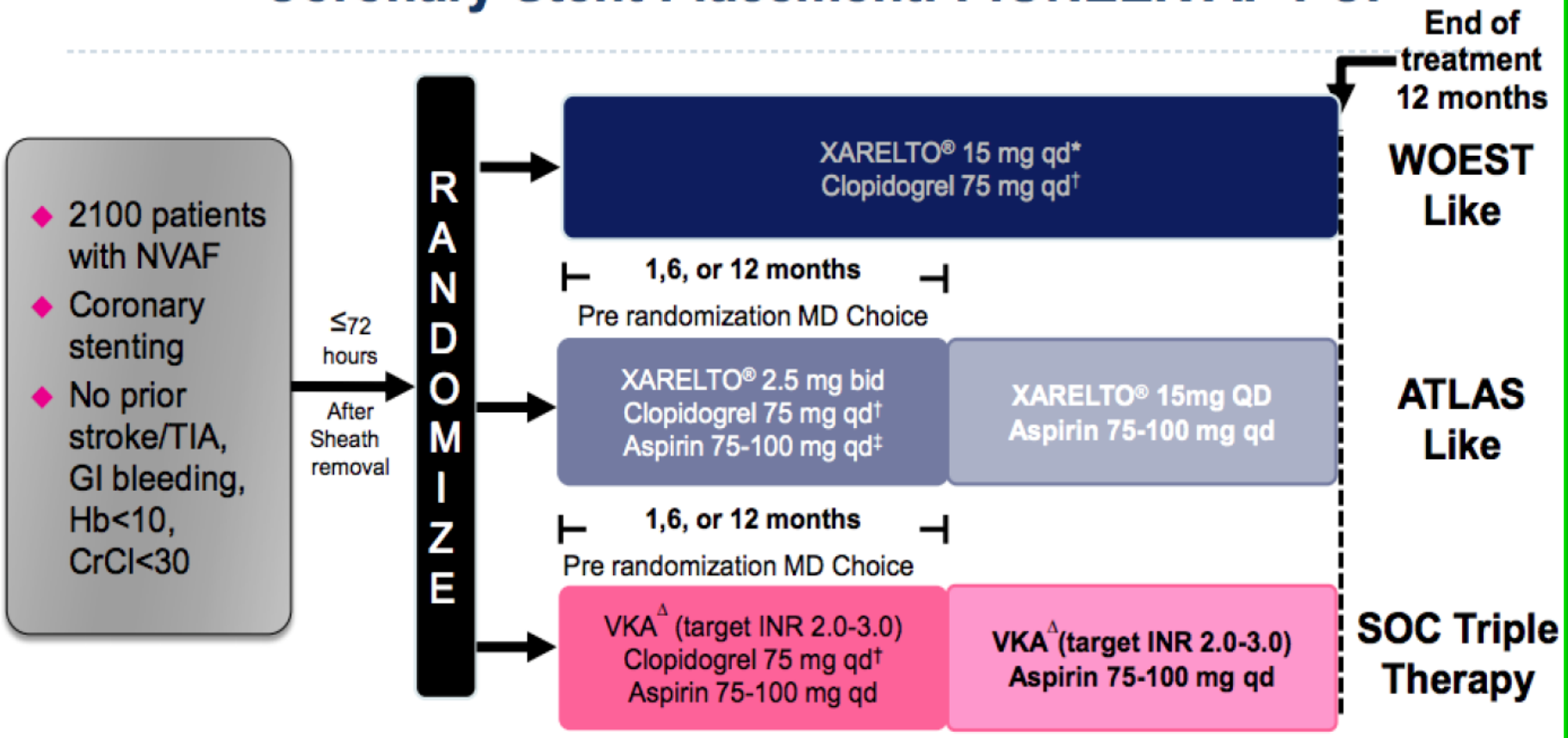


Meta-Analysis of Randomized Controlled Trials and Adjusted Observational Results of Use of Clopidogrel, Aspirin, and Oral Anticoagulants in Patients Undergoing Percutaneous Coronary Intervention

Fabrizio D'Ascenzo, MD[a], Salma Taha, MD[a,b,*], Claudio Moretti, MD[a], Pierluigi Omedè, MD[a], Walter Grossomarra, MD[a], Jonas Persson, PhD[c], Morten Lamberts, MD[d], Willem Dewilde, MD[e], Andrea Rubboli, MD[f], Sergio Fernández, PhD[g], Enrico Cerrato, MD[a], Ilaria Meynet, MD[a], Flavia Ballocca, MD[a], Umberto Barbero, MD[a], Giorgio Quadri, MD[a], Francesca Giordana, MD[a], Federico Conrotto, MD[a], Davide Capodanno, PhD[h], James DiNicolantonio, PhD[i], Sripal Bangalore, MD[j], Matthew Reed, MD[k], Pascal Meier, MD[l], Giuseppe Zoccai, MD[m], and Fiorenzo Gaita, PhD[a]

D'Ascenzo F et al. Am J Card 2015;115:1185-1193

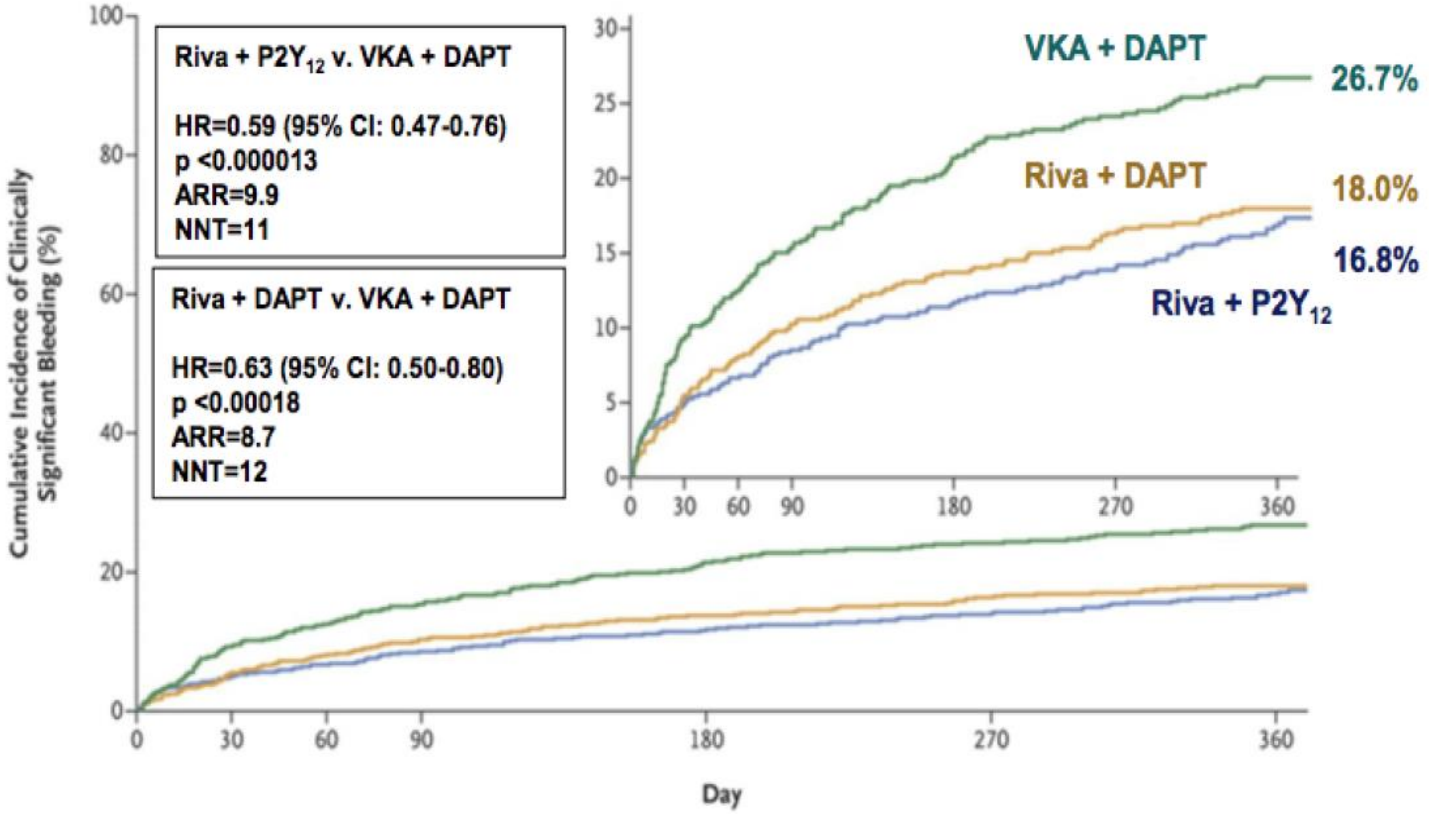
Patients With Atrial Fibrillation Undergoing Coronary Stent Placement: PIONEER AF-PCI



- Primary endpoint: TIMI major + minor + bleeding requiring medical attention
- Secondary endpoint: CV death, MI, and stroke (Ischemic, Hemorrhagic, or Uncertain Origin)

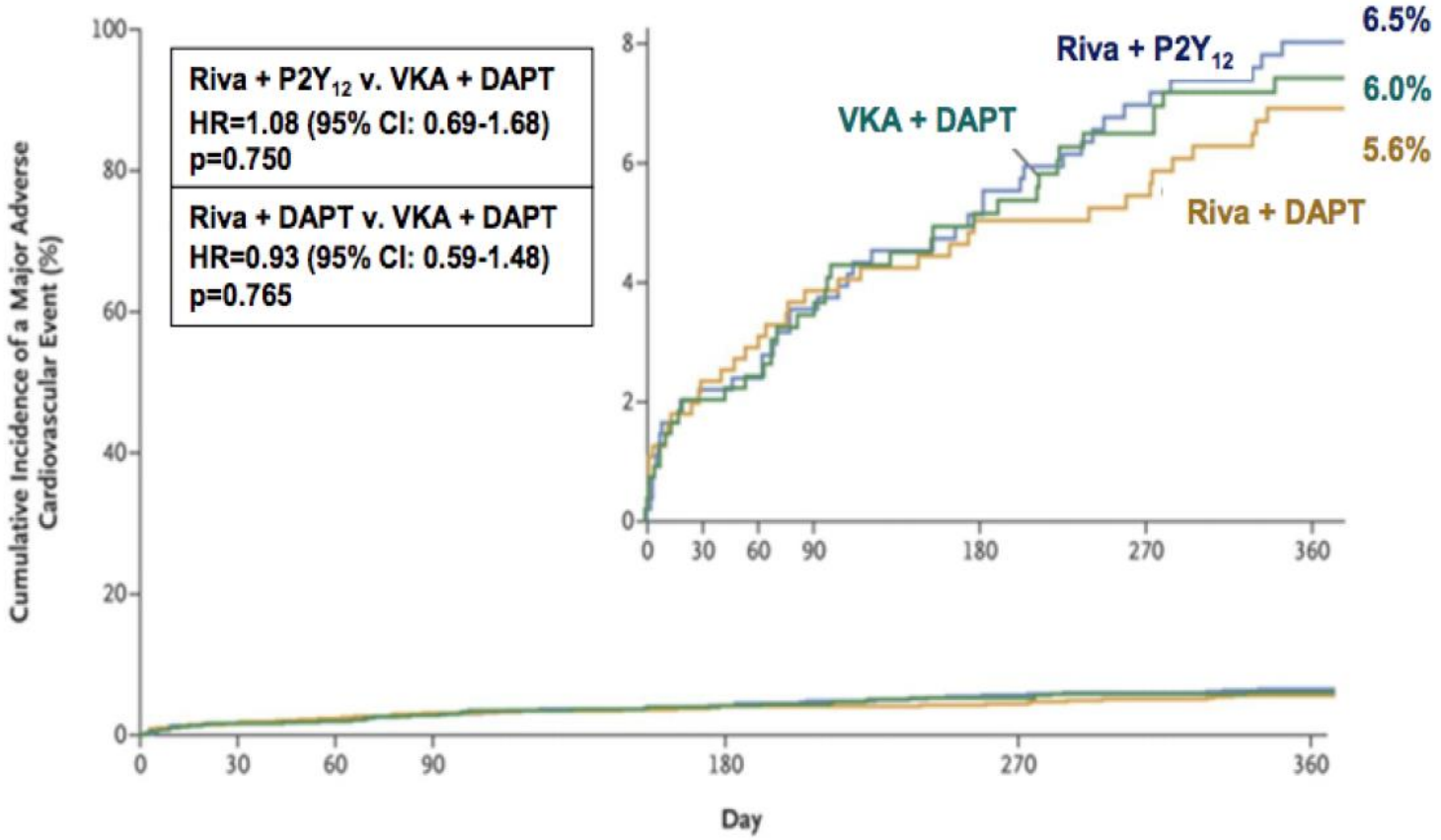
*Rivaroxaban dosed at 10 mg once daily in patients with CrCl of 30 to <50 mL/min.
†Alternative $P2Y_{12}$ inhibitors: 10 mg once-daily prasugrel or 90 mg twice-daily ticagrelor.
‡Low-dose aspirin (75–100 mg/d). Δ Open label VKA

Rivaroxaban plus DAPT or $P2Y_{12}$ reduces clinically relevant bleeding compared with standard therapy



No. at Risk							
Group 1	696	628	606	585	543	510	383
Group 2	706	636	600	579	543	509	409
Group 3	697	593	555	521	461	426	329

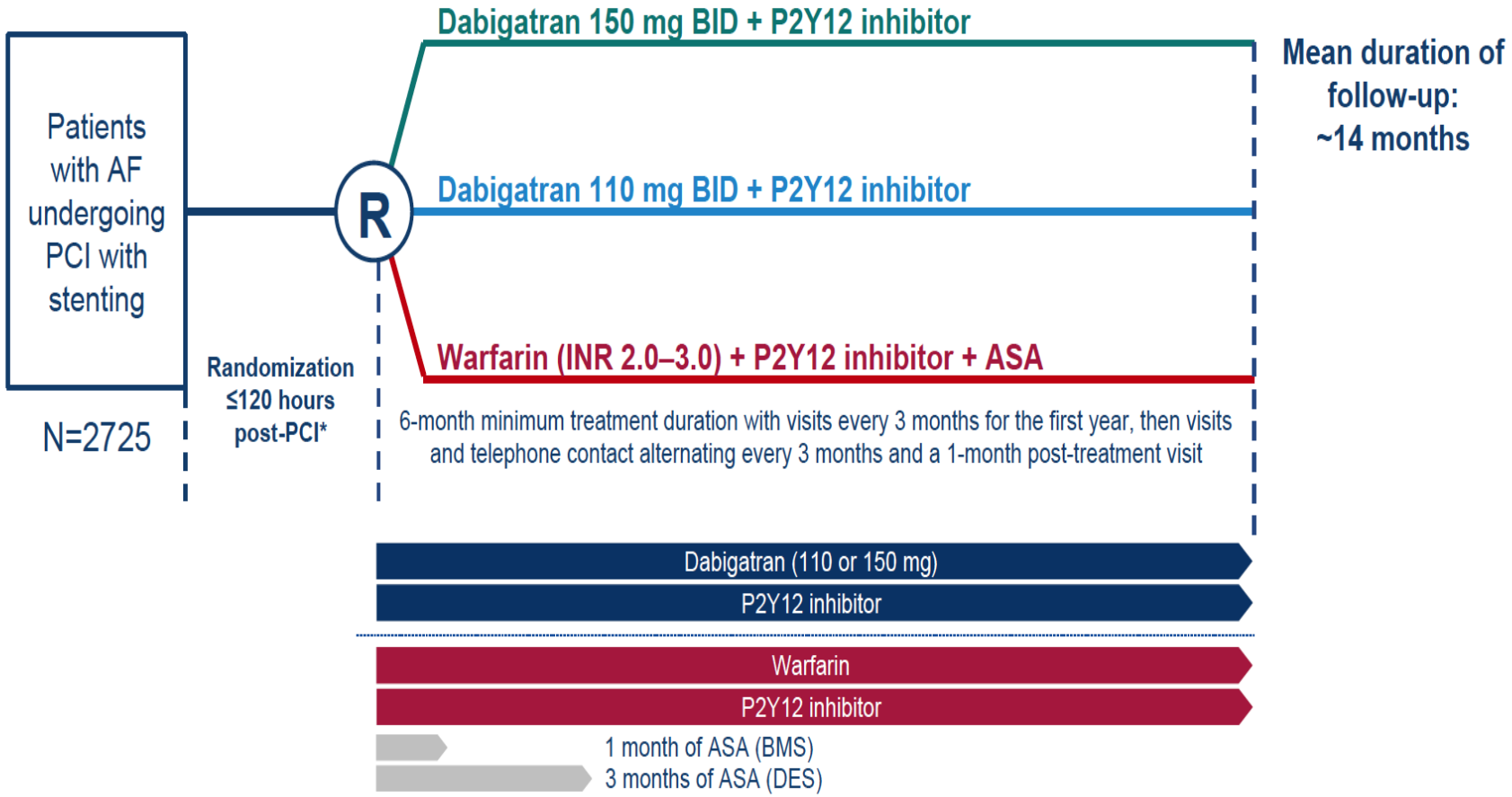
Similar incidence of MACE with rivaroxaban compared with standard therapy



No. at Risk							
Group 1	694	648	633	621	590	562	430
Group 2	704	662	640	628	596	570	457
Group 3	695	635	607	579	543	514	408

Study Design: Multicenter, randomized, open-label trial following a PROBE design

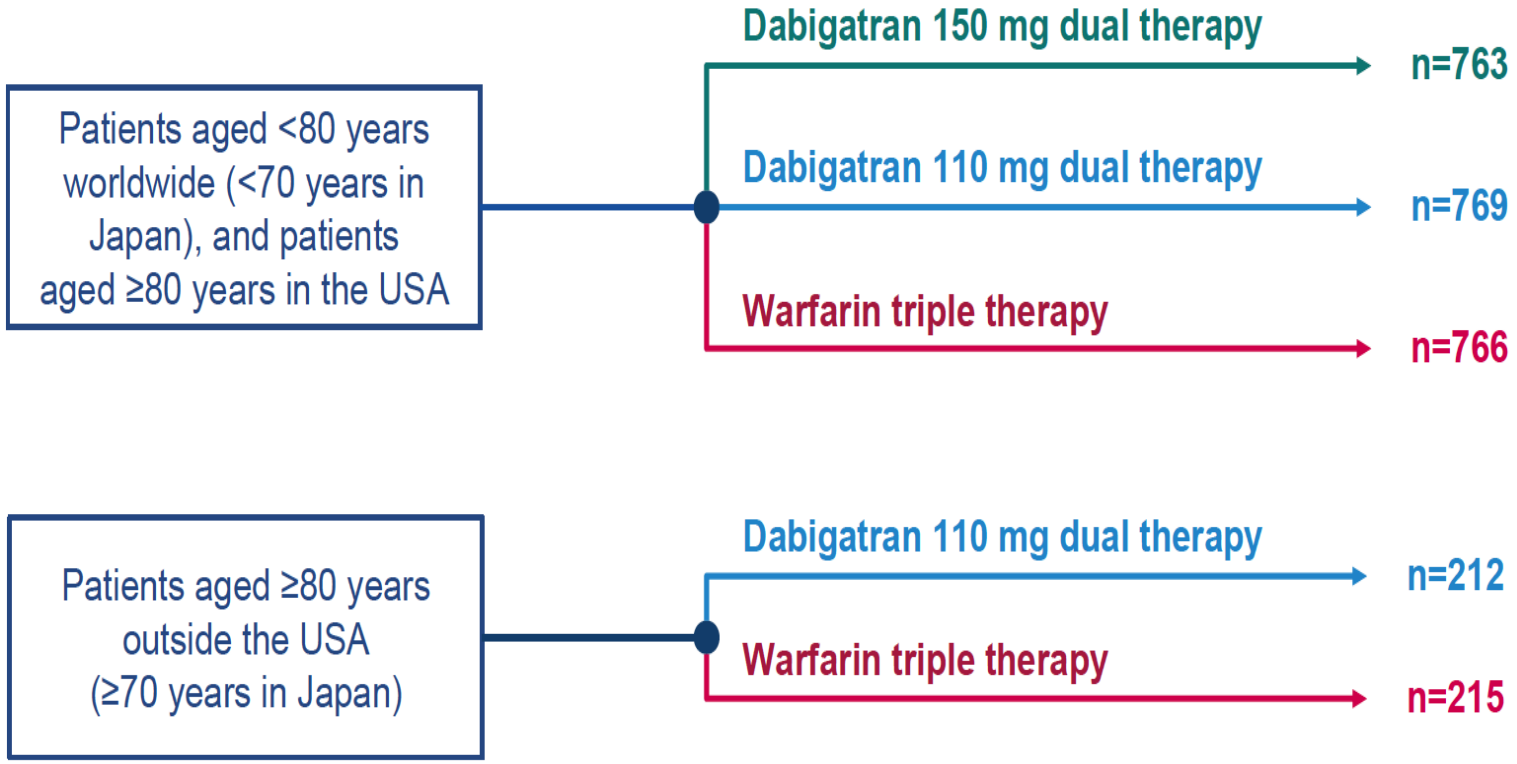
RE-DUAL PCI
Study in NVAF patients undergoing PCI



***Study drug should be administered 6 hours after sheath removal and no later than ≤120 hrs post-PCI (≤72 hrs is preferable).** PROBE, prospective, randomized, open, blinded end-point; R, randomization; BMS, bare metal stent; DES, drug-eluting stent. ClinicalTrials.gov: NCT02164864; Cannon et al. Clin Cardiol 2016

Patients were randomized based on age group and location

RE-DUAL PCI
Study in NVAF patients undergoing PCI



Inclusion and exclusion criteria

RE-DUAL PCI
Study in NVAF patients undergoing PCI

Key inclusion criteria

- Patients aged ≥18 years with paroxysmal, persistent or permanent NVAF
- ACS successfully treated by PCI and stenting (BMS or DES)
- Stable CAD with ≥1 lesion eligible for PCI that was successfully treated by elective PCI and stenting (BMS or DES)

Key exclusion criteria

- Cardiogenic shock during current hospitalization
- Use of fibrinolytics within 24 hrs of randomization that, in the investigator's opinion, will put patient at high risk of bleeding
- Stroke or major bleeding event within 1 month prior to screening visit
- Severe renal impairment (CrCl <30mL/min)

ACS, acute coronary syndrome; CAD, coronary artery disease; CrCl, creatinine clearance

Conclusions

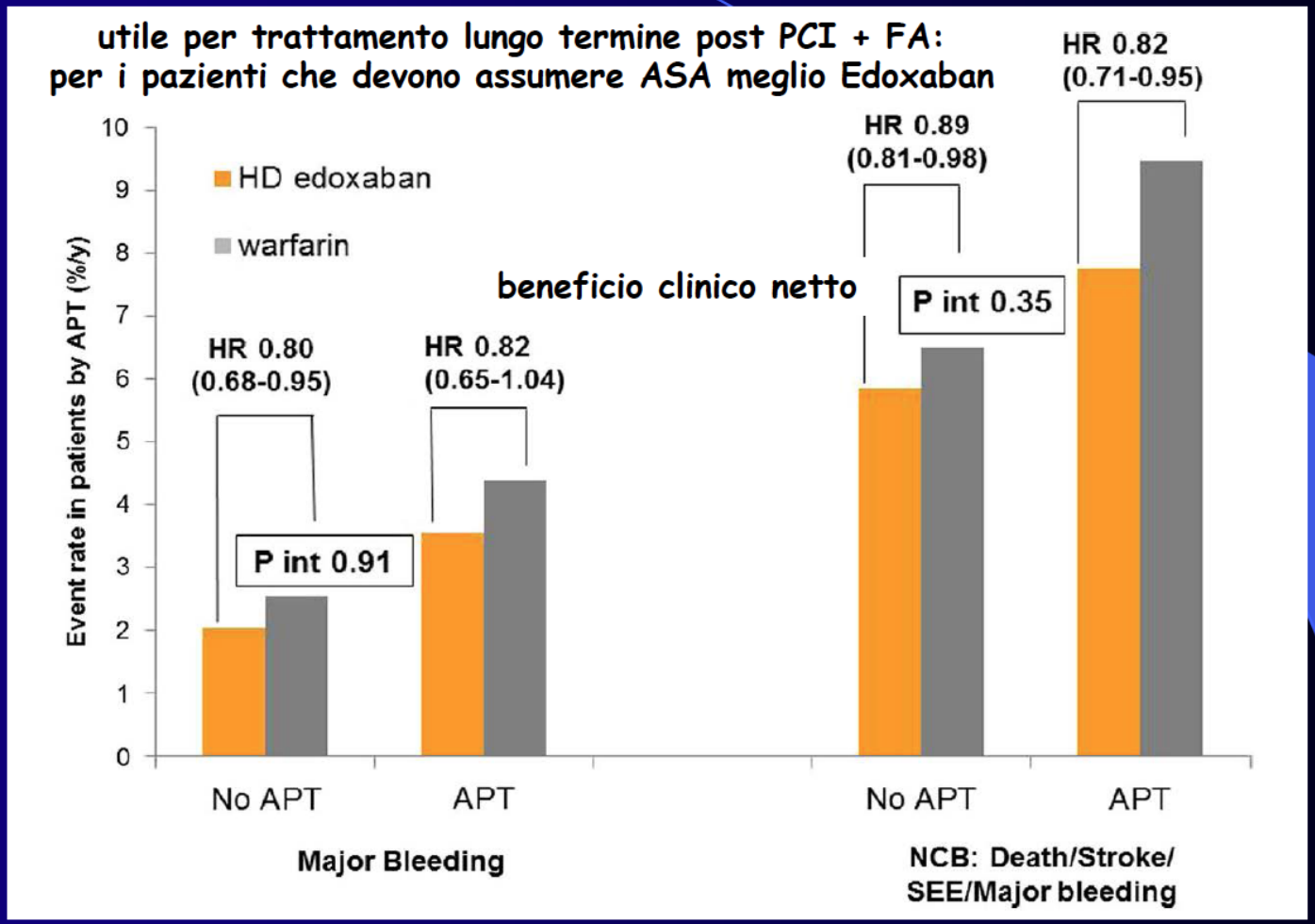
RE-DUAL PCI
Study in NVAF patients undergoing PCI

In patients with AF who have undergone PCI:

- Dual therapy with dabigatran and a P2Y12 antagonist **significantly reduced the risk of bleeding versus warfarin triple therapy**, with non-inferiority for overall thromboembolic events
- Absolute risk reductions with dabigatran dual therapy were **11.5% and 5.5%** in ISTH major or clinically relevant non-major bleeding at the 110 mg and 150 mg doses, respectively, compared with warfarin triple therapy
- These dabigatran dual therapy regimens, using doses approved worldwide for stroke prevention, offer clinicians two additional options for managing Afib patients post-PCI

associazione con Singolo AntiPiastrinico (sAPT)

>30% dei pazienti alla randomizzazione assumeva ASA
25% dei pazienti proseguiva APT dopo 3 mesi



Xu H, Ruff CT, Giugliano RP et al. J Am Heart Assoc 2016

Apixaban Plus Mono Versus Dual Antiplatelet Therapy in Acute Coronary Syndromes

Insights From the APPRAISE-2 Trial

Connie N. Hess, MD, MHS,* Stefan James, MD, PhD,† Renato D. Lopes, MD, PhD,* Daniel M. Wojdyla, MSc,* Megan L. Neely, PhD,* Danny Liaw, MD, PhD,‡ Emil Hagstrom, MD, PhD,* Deepak L. Bhatt, MD, MPH,§ Steen Husted, MD, DSc,‖ Shaun G. Goodman, MD, MSc,¶ Basil S. Lewis, MD,# Freek W.A. Verheugt, MD,** Raffaele De Caterina, MD, PhD,†† Hisao Ogawa, MD,‡‡ Lars Wallentin, MD, PhD,† John H. Alexander, MD, MHS*

CONCLUSIONS Post-ACS treatment with apixaban versus placebo showed no efficacy, but it increased bleeding regardless of concomitant therapy with aspirin alone or aspirin plus clopidogrel. (Apixaban for Prevention of Acute Ischemic Events 2 [APPRAISE-2]; NCT00831441) (J Am Coll Cardiol 2015;66:777-87) © 2015 by the American College of Cardiology Foundation.

Apixaban Versus Warfarin in Patients with AF and ACS or PCI: The AUGUSTUS Trial

Inclusion
- AF (prior, persistent, or >6 hrs duration)
- Physician decision that oral anticoag is indicated
- ACS and/or PCI with planned P2Y12 inhibitor for 6 months

Randomize
n =4,600
Patients

Exclusion
- Contraindication to DAPT
- Other reason for warfarin (prosthetic valve, mod/sev MS)

Apixaban | **Warfarin**

P2Y12 inhibitor for all patients x 6 months
Aspirin for all on the day of ACS or PCI
Aspirin versus placebo after randomization

ASA | **placebo** | **ASA** | **placebo**

Primary outcome: major/clinically relevant bleeding (through 6 months)

Secondary objective: Death, MI, stroke, stent thrombosis

Duke Clinical Research Institute

Triplice terapia e nuovi antiaggreganti

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Interventional Cardiology

CME

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

Nikolaus Sarafoff, MD,* Amadea Martischnig, MD,† Jill Wealer, MS,† Katharina Mayer, MD,† Julinda Mehilli, MD,* Dirk Sibbing, MD,* Adnan Kastrati, MD†

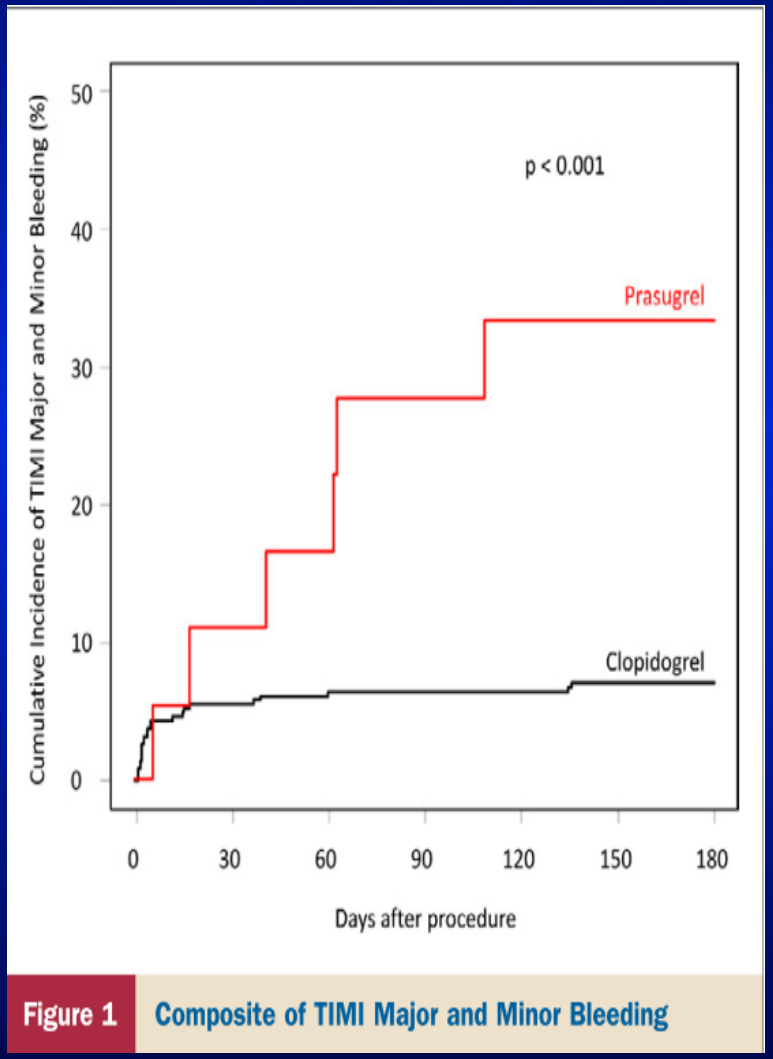

Figure 1 Composite of TIMI Major and Minor Bleeding

Limiti

Table S1

Sample size and power calculation of major adverse cardiovascular events required to detect a ≥ 15% risk reduction at a two-sided significance level of 0.05

Endpoint	Event rate	No. per group to attain 90% power	Power with 700 subjects per group
Overall			
Adverse CV event	6.0%	13,598	11.4%
CV death	1.8%	47,196	6.8%
MI	3.5%	23,883	8.6%
Stroke	1.2%	71,195	6.2%
Stent thrombosis	0.7%	122,620	5.7%

*** Gli studi sono adeguatamente potenziati per i sanguinamenti maggiori, ma sottopotenziati per eventi CV e trombosi intrastent.**

*** End-point di efficacia compositi e non inferiorità rispetto a studi che però avevano end-point diversi.**

*** Negli studi mancano i dati sul numero di vasi trattati, sui TC, sui graft, sul tipo di stent, sulla presenza di biforcazioni.**

*** Difficile valutare il diverso rischio di trombosi intrastent di questi pazienti.**

FA + CAD NEL GRANDE ANZIANO
LA MIA STRATEGIA…

- **-CORONAROPATIA ASINTOMATICA**

Solo lesioni “prognostiche” (mondo TAVI)

- **-ANGINA DA SFORZO**

Forme refrattarie alla terapia medica / “highlander”

- **SCA / UA-NSTEMI-STEMI**

Radiale / “coro incompleta” / stent a rapida endotelizzazione / DOAC+CLOP

“keep-it-as-simple-as-possible-but-not-to-simple” - STRATEGY


In ogni cammino che si biforca, da una parte vanno
i nostri passi e dall’altra i nostri dubbi.
(Eise Osman)