Terapia e prevenzione cardiovascolare: Tra novità, certezze e dubbi

Brescia, 10 Novembre 2018

Terapia medica della cardiopatia ischemica cronica: quali novità?

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Spedali Civili di Brescia

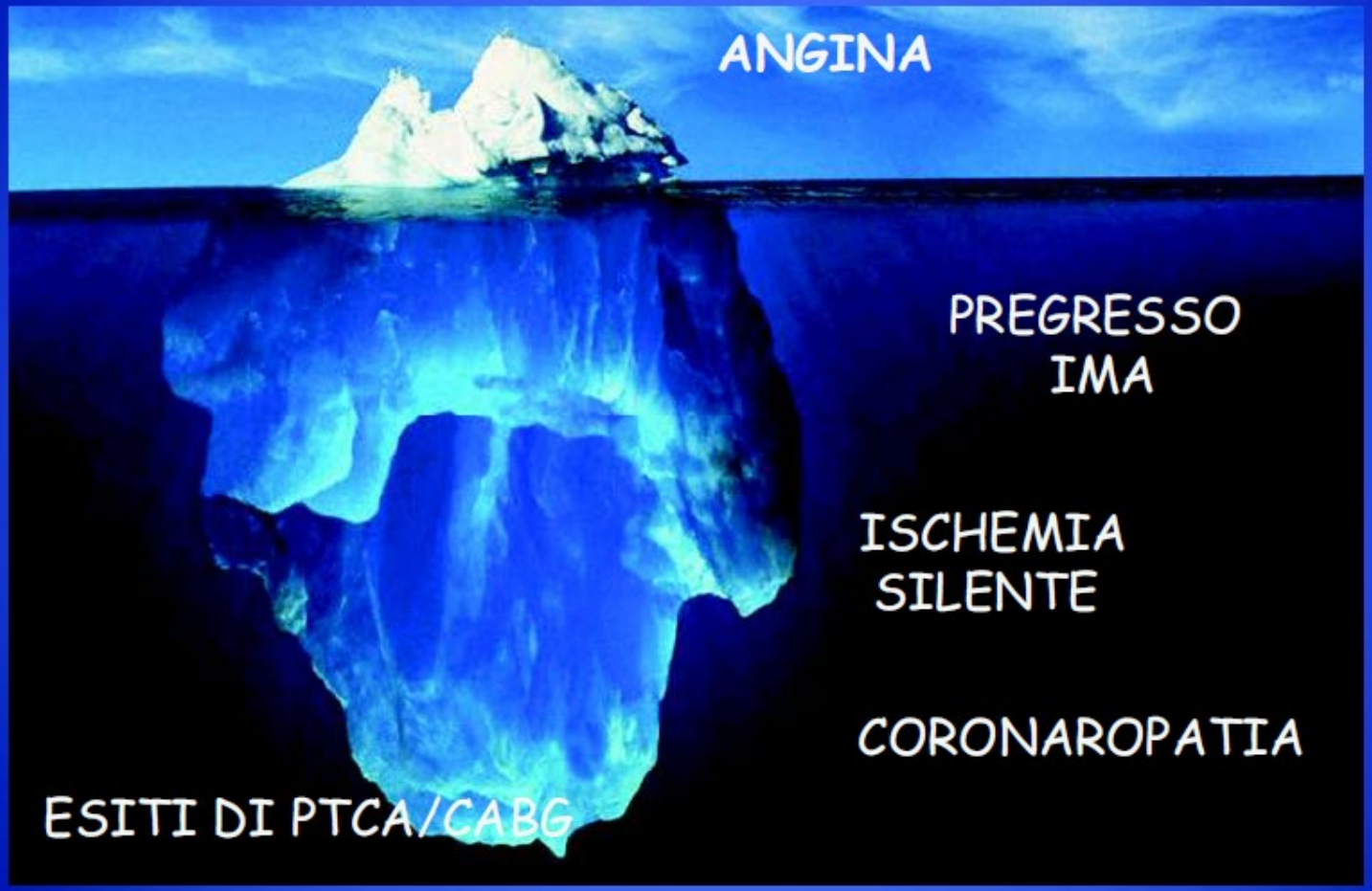
Cardiopatia ischemica cronica “stabile”

(**SCAD**)

1. pz. con angina pectoris (o equivalenti anginosi) stabile dovuta a CAD
2. pz precedentemente sintomatici per CAD, critica o no, divenuti asintomatici grazie a trattamento e che necessitano di regolare follw-up
3. pz che per la prima volta lamentano angina, ma giudicati in condizione cronica stabile

Non esiste nulla di più controverso della SCA ed a stabilirne la sua stabilità

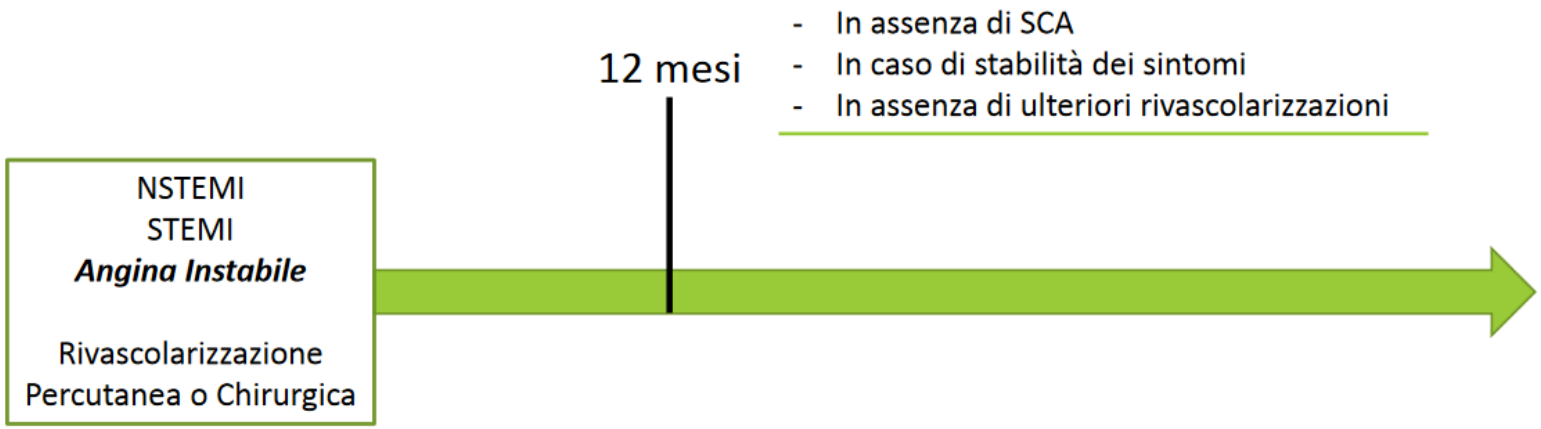
Cardiopatia ischemica cronica



Cardiopatia ischemica cronica

Rivascolarizzazione incompleta
Restenosi intrastent/occlusione BPAC
Malattia microvascolare
Progressione della malattia aterosclerotica
Terapia inadeguata o impossibilità a titolare i farmaci tradizionali per effetti collaterali

Quando finisce una SCA e inizia una SCAD?

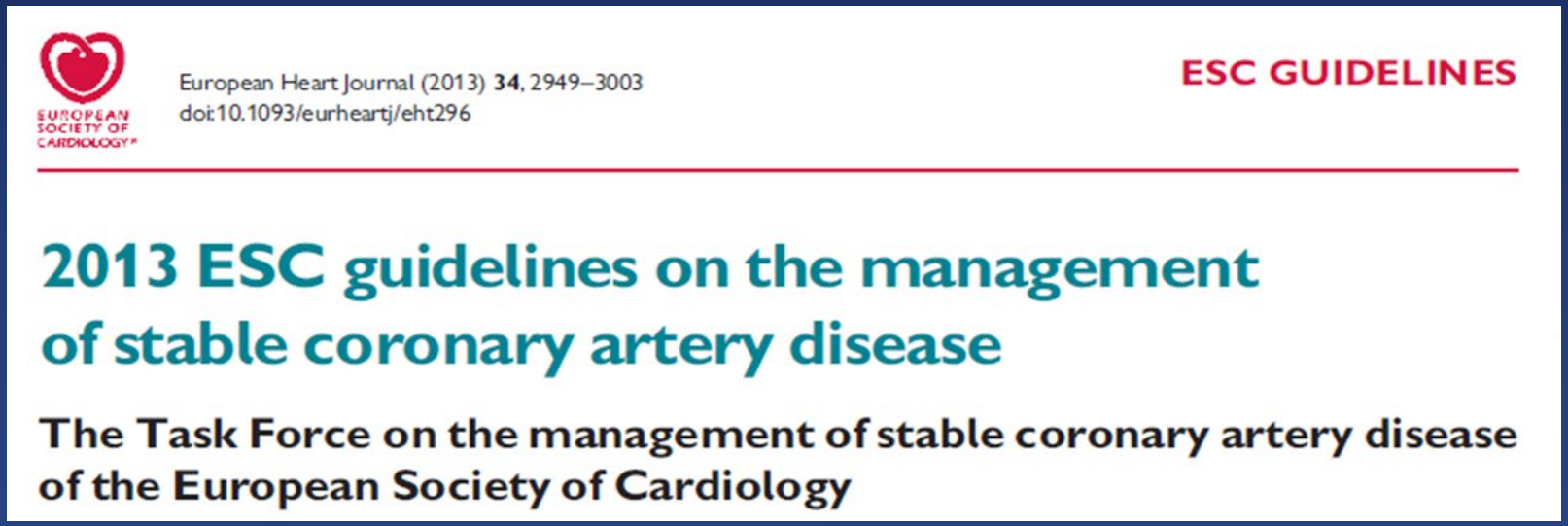


"the transition from unstable to stable syndromes is a continuum, without a clear boundary" *(ESC 2013)*

L’angina stabile è la manifestazione clinica più frequente di malattia coronarica

Interessa più del 5 % della popolazione al di sopra dei 40 anni nei paesi industrializzati

Problematica rilevante dal punto di vista medico ed economico



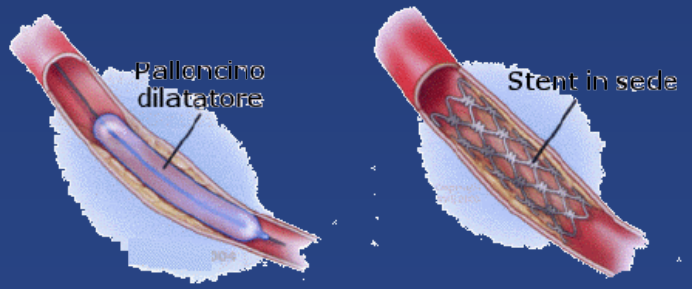
Il trattamento della CAD stabile ha due obiettivi:

1) Miglioramento della qualità di vita del paziente tramite il controllo dei sintomi

2) Miglioramento della prognosi

Per ottenere questi risultati 2 strategie :

TERAPIA MEDICA o RIVASCOLARIZZAZIONE (percutanea o chirurgica)



TERAPIA MEDICA: CONSIDERAZIONI GENERALI

Optimal medical treatment indicates at least one drug for angina/ischaemia relief plus drugs for event prevention.	I	C
It is recommended to educate patients about the disease, risk factors and treatment strategy.	I	C
It is indicated to review the patient's response soon after starting therapy.	I	C

La terapia medica ottimale non è mai alternativa ma sempre complementare alle altre strategie terapeutiche.

COURAGE: Clinical Outcomes Utilizing Revascularization and Aggressive Guideline – Driven Drug Evaluation

Optimal Medical Therapy with or without PCI for Stable Coronary Disease

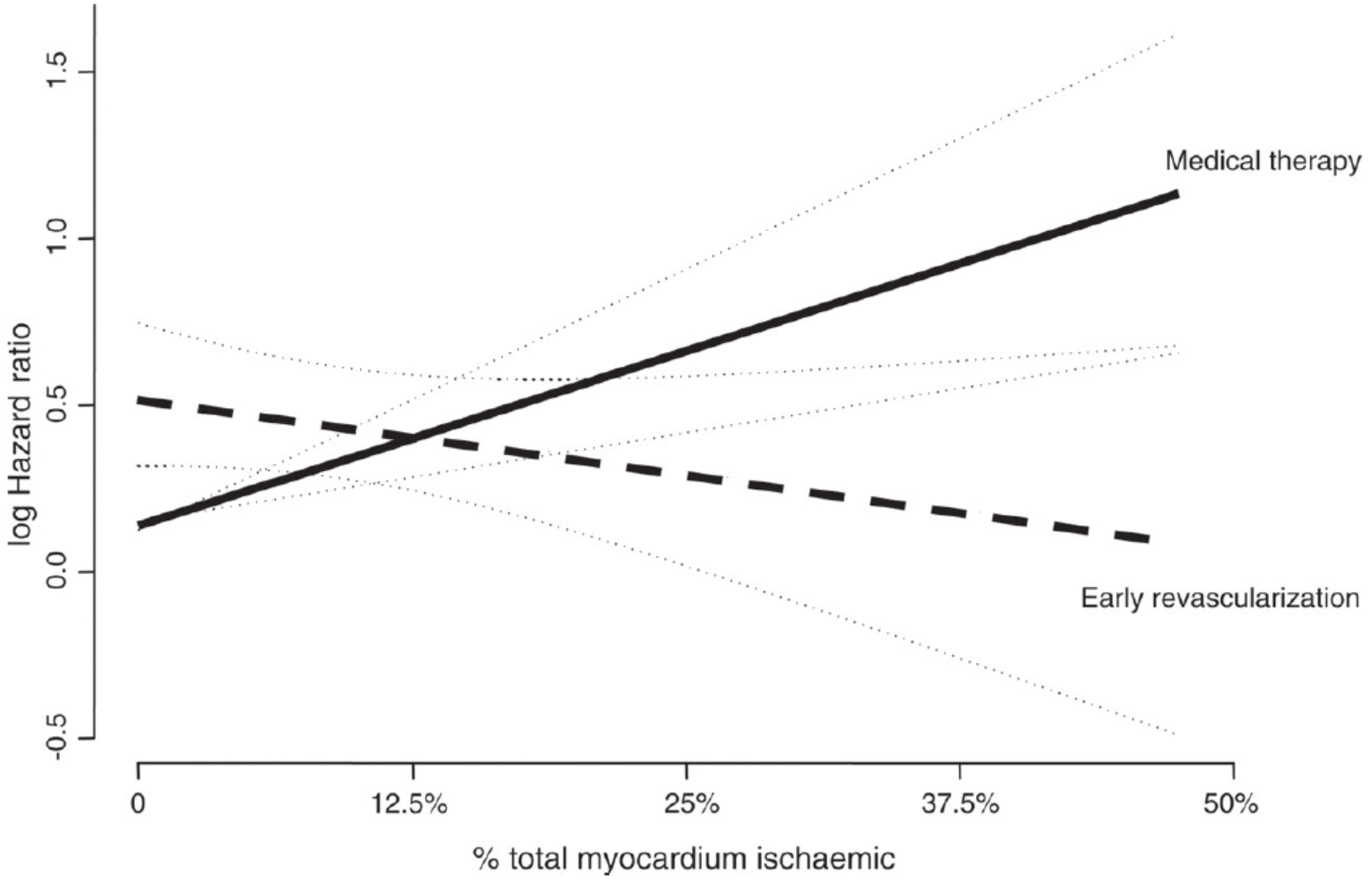
William E. Boden, M.D., Robert A. O'Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merril Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm.D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, M.D., for the COURAGE Trial Research Group*

CONCLUSIONS

As an initial management strategy in patients with stable coronary artery disease, PCI did not reduce the risk of death, myocardial infarction, or other major cardiovascular events when added to optimal medical therapy. (ClinicalTrials.gov number, NCT00007657.)

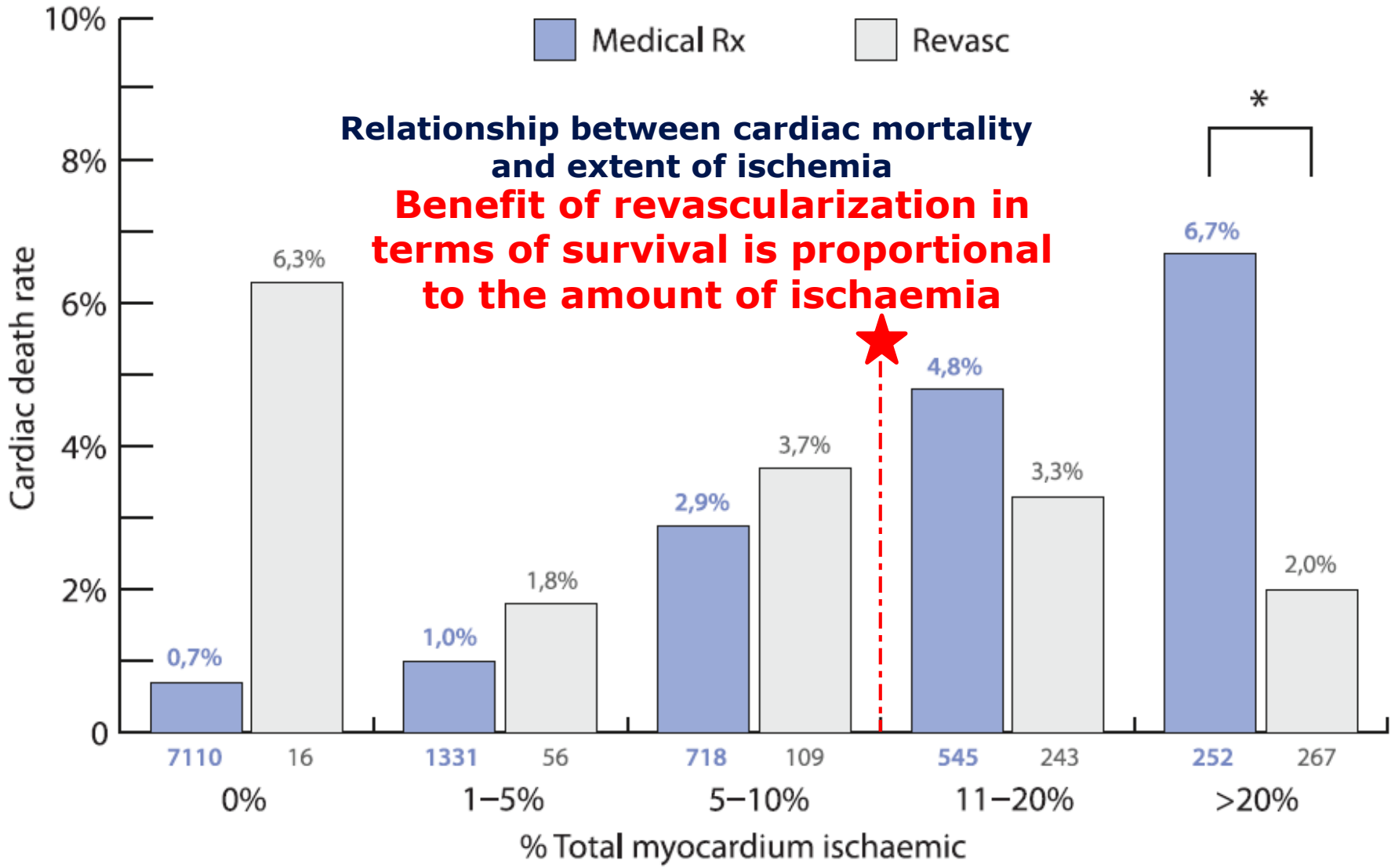
Boden WE, et al. NEJM 2007;356:1503

Rapporto di rischio per la rivascolarizzazione precoce vs terapia medica in funzione della % miocardio ischemico nei pazienti con



Hachamovitch R et al. Eur Heart J 2011;32:1012-1024

2013 ESC guidelines on the management of stable coronary artery disease



Patterns and Intensity of Medical Therapy in Patients Undergoing Percutaneous Coronary Intervention

Borden W, JAMA 2011

William B. Borden, MD
Rita F. Redberg, MD, MSc
Alvin I. Mushlin, MD, ScM
David Dai, PhD
Lisa A. Kaltenbach, MS
John A. Spertus, MD, MPH

Context The Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) study, which provided optimal medical therapy (OMT) to all patients and demonstrated no incremental advantage of percutaneous coronary intervention (PCI) on outcomes other than angina-related quality of life in stable coronary artery disease (CAD), suggests that a trial of OMT is warranted before PCI. It is unknown to what degree OMT is applied before PCI in routine practice or whether its use increased after the COURAGE trial.

Objective To examine the use of OMT in patients with stable angina undergoing PCI before and after the publication of the COURAGE trial.

Design, Setting, and Participants An observational study of patients with

…undergoing PCI, less than half were receiving OMT ….

PCI) between the 2 study periods.

Results Among all 467 211 patients (173 416 before [37.1%] and 293 795 after [62.9%] the COURAGE trial) meeting study criteria, OMT was used in 206 569 patients (44.2%; 95% confidence interval [CI], 44.1%-44.4%) before PCI and in 303 864 patients (65.0%; 95% CI, 64.9%-65.2%) at discharge following PCI ($P<.001$). Before PCI, OMT was applied in 75 381 patients (43.5%; 95% CI, 43.2%-43.7%) before the COURAGE trial and in 131 188 patients (44.7%; 95% CI, 44.5%-44.8%) after the COURAGE trial ($P<.001$). The use of OMT at discharge following PCI before and after the COURAGE trial was 63.5% (95% CI, 63.3%-63.7%) and 66.0% (95% CI, 65.8%-66.1%), respectively ($P<.001$).

Conclusion Among patients with stable CAD undergoing PCI, less than half were receiving OMT before PCI and approximately two-thirds were receiving OMT at discharge following PCI, with relatively little change in these practice patterns after publication of the COURAGE trial.

JAMA. 2011;305(18):1882-1889 www.jama.com

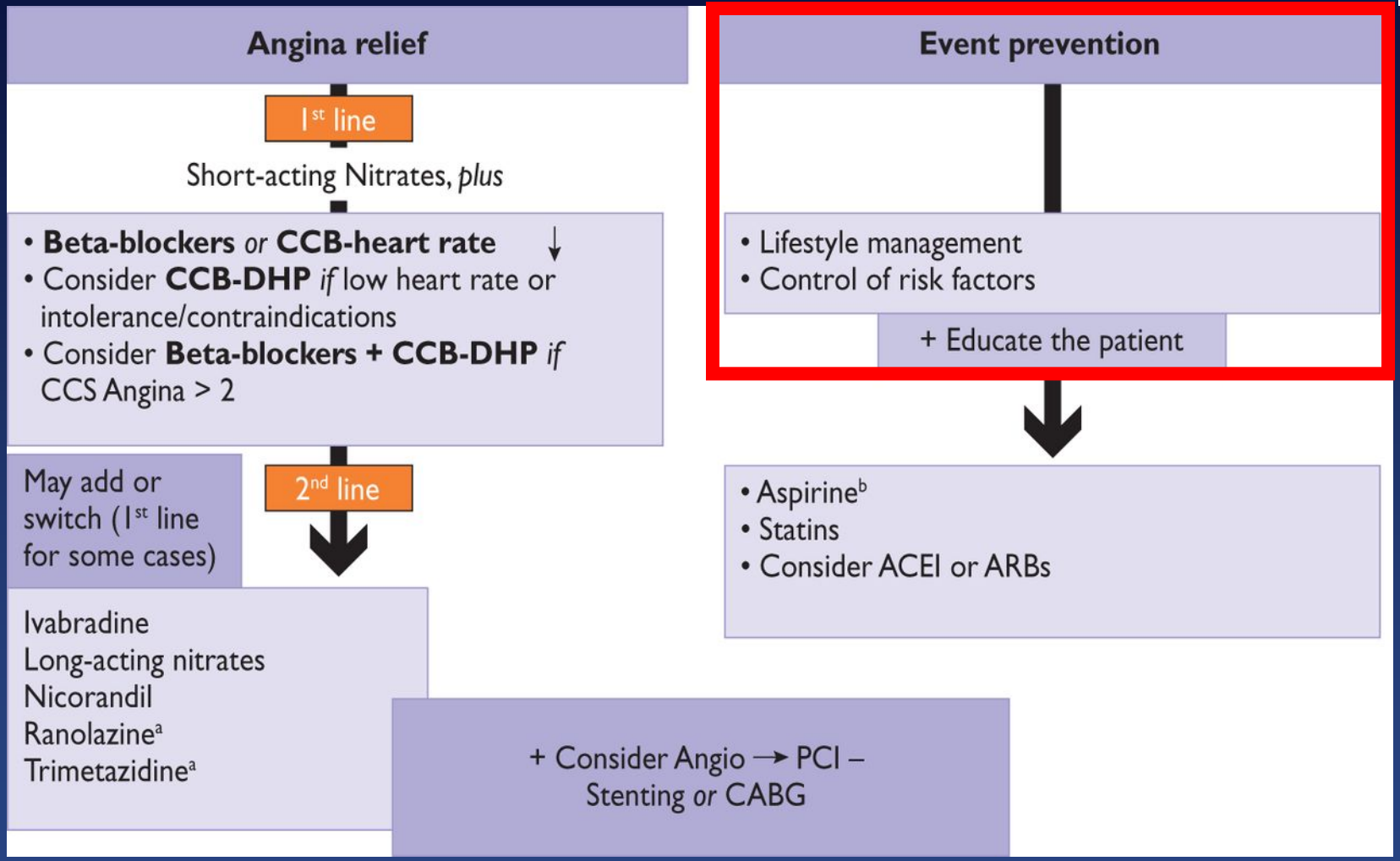
ALTHOUGH PERCUTANEOUS coronary intervention (PCI)

a meta-analysis of 11 trials[2] concluded that there was no benefit of PCI in preventing myocardial infarction or death in patients with stable CAD. The most definitive randomized trial comparing the effectiveness of OMT vs OMT plus PCI in patients with stable CAD was the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) study.[3] In the COURAGE trial, patients with stable CAD underwent diagnostic coronary angiography to define their coronary anatomy and received aggressive secondary prevention therapy,[4] with half

Qual’è la terapia ottimale nell’angina stabile secondo le Linee Guida?

ESC GUIDELINES

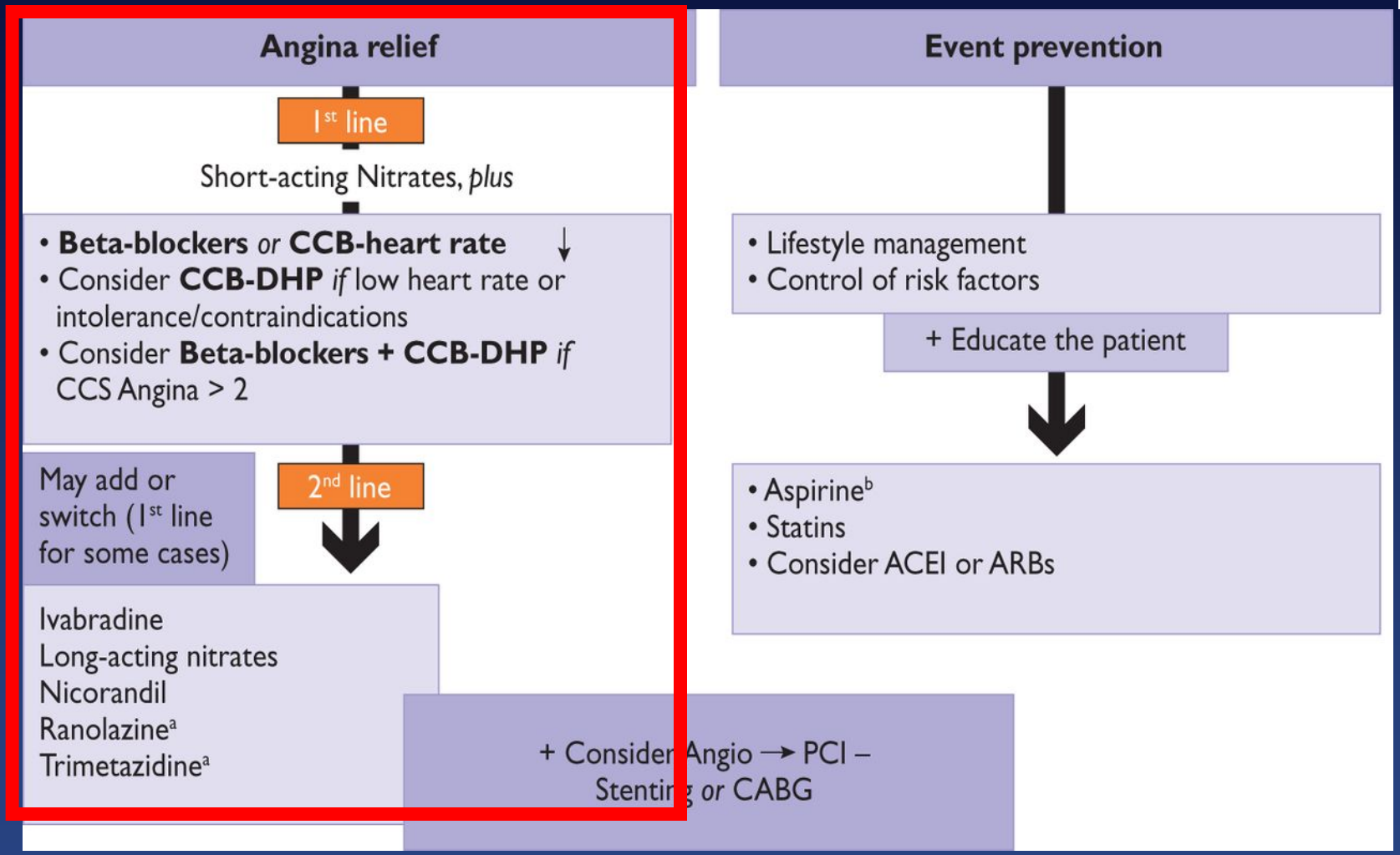
Medical management of patients with stable coronary artery disease.



ESC Guidelines. Eur Heart J 2013; 34: 2949-3003

ESC GUIDELINES

Medical management of patients with stable coronary artery disease.



ESC Guidelines. Eur Heart J 2013; 34: 2949-3003

Nonostante l'efficacia della rivascolarizzazione, circa il 10-25% dei pazienti continua ad avere angina

e

il 60-80% richiede terapia anti-anginosa entro un anno dalla procedura

Questi pazienti hanno spesso una ridotta qualità di vita a causa della loro impossibilità a svolgere normali attività quotidiane senza sintomi anginosi

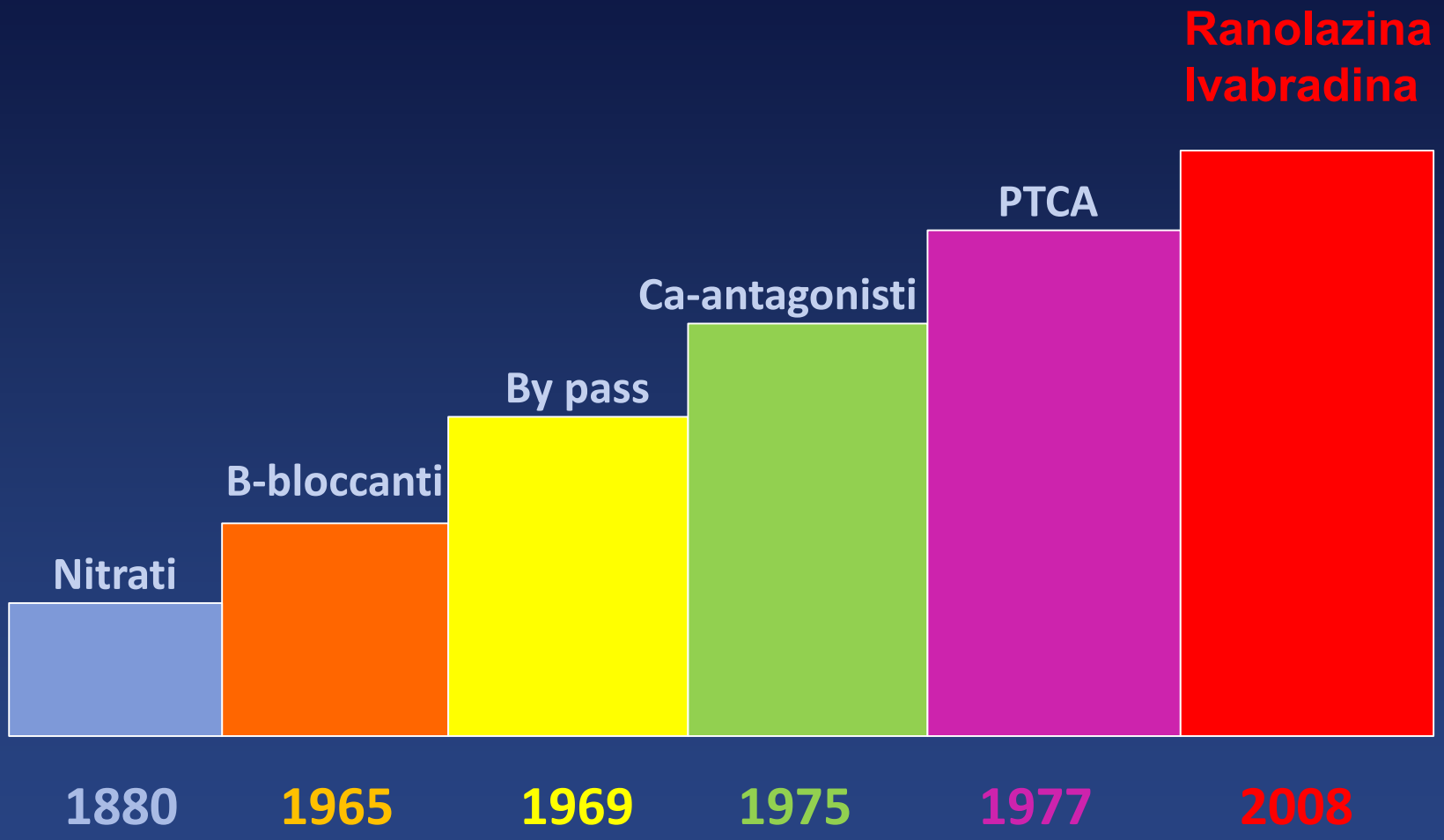
Bonadei I, Vizzardi E et al. Rec Patent Cardiovascular Dis 2011 6(3) 215-21

I pazienti possono avere controindicazioni o non riuscire a tollerare il dosaggio iniziale o dosaggi terapeutici più alti di uno o più dei convenzionali anti-anginosi

Ciò spesso è dovuto a comorbidità come asma, malattie croniche delle vie respiratorie, bradicardia, o ipotensione

Bonadei I, Vizzardi E et al. Rec Patent Cardiovascular Dis 2011 6(3) 215-21

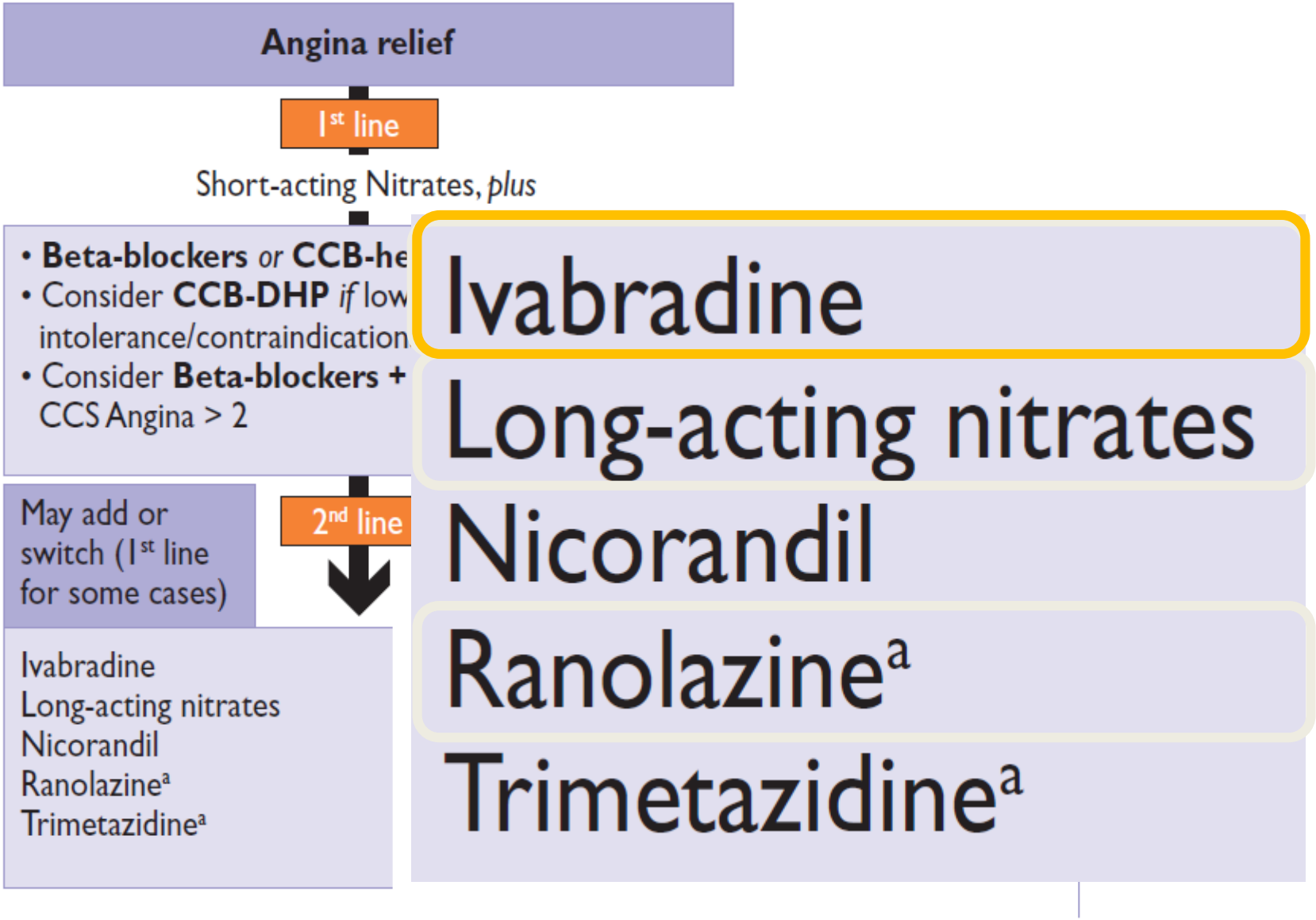
Evoluzione della terapia antianginosa



2013 ESC guidelines on the management of stable coronary artery disease

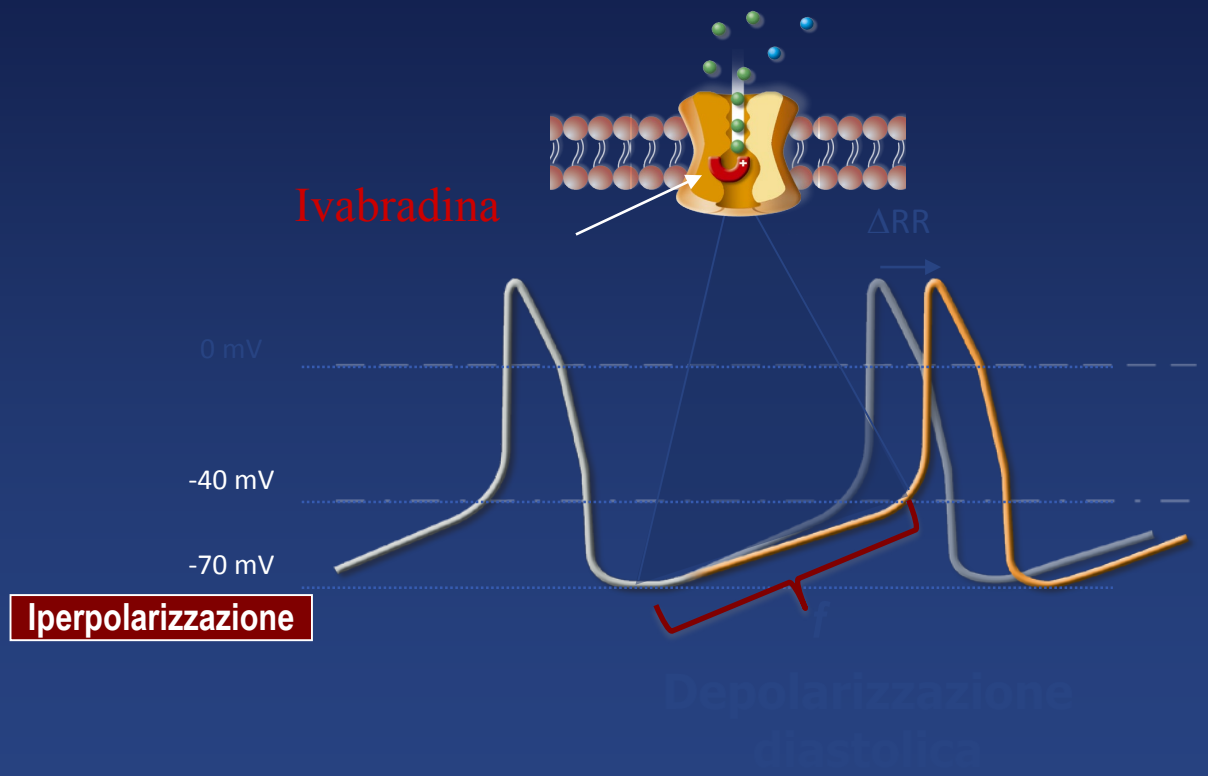
Eur Heart J , August 30, 2013

Medical management of patient with stable CAD



IVABRADINA

Il 1° inibitore selettivo e specifico dei canali If



- **Specifico legame ai canali If delle cellule pacemaker**
- **Inibizione selettiva dei canali quando sono in stato di apertura**
- **Riduzione pura della frequenza cardiaca**
- **Funzione cardiaca completamente preservata**

The prognostic value of raised resting heart rate in patient with stable coronary artery diasease

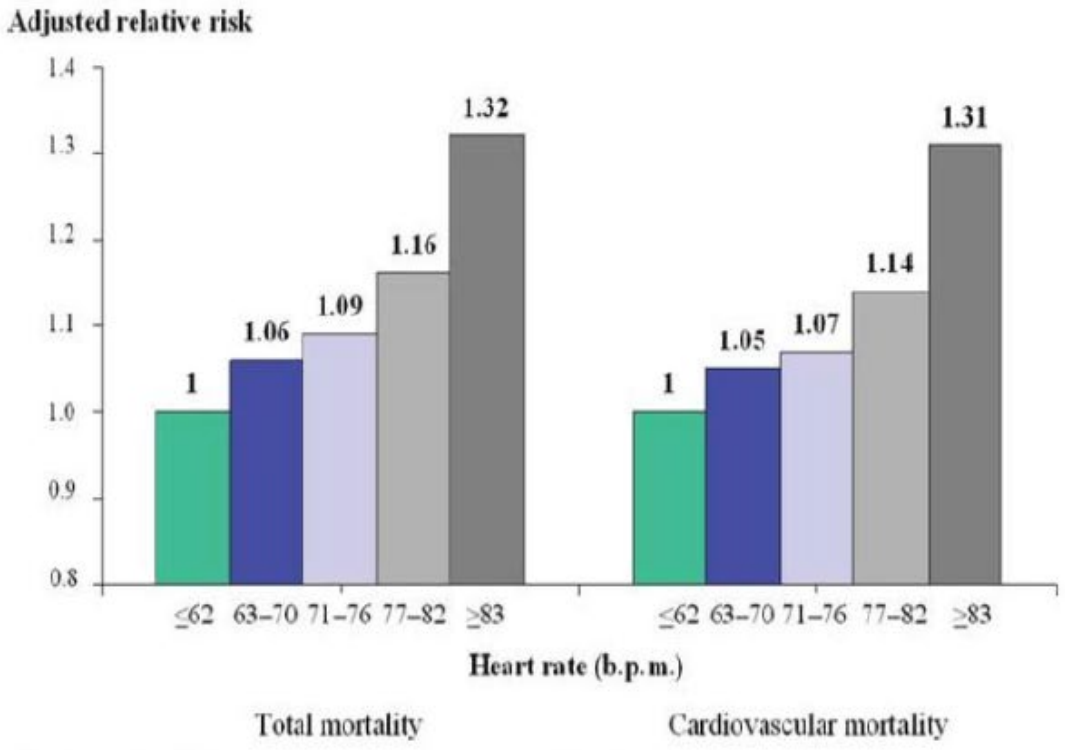
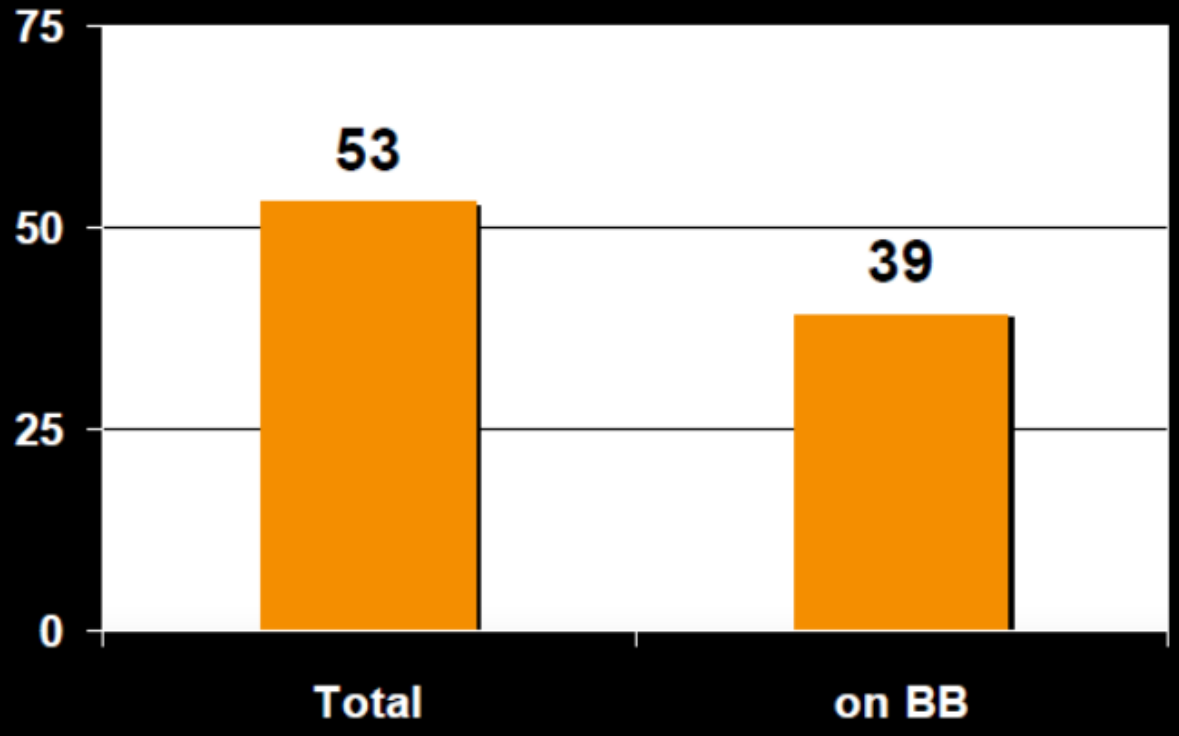


Figure 1 Total and cardiovascular mortality according to resting heart rate: multivariate Cox regression survival analysis for 24 913 patients with suspected or proven coronary artery disease in the Coronary Artery Surgery Study (CASS). Data from Diaz *et al.*[25]

Data from CASS Registry

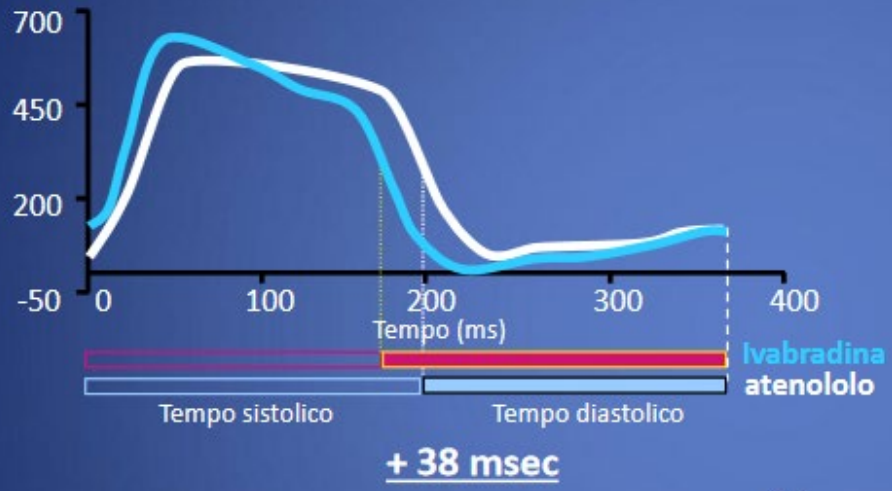
Despite β-blockers, many CAD patients have a heart rate >70 bpm

Mean resting HR at initial assessment in the overall patient population (n = 3 674) and in patients with β-blockers (n= 2 005) from The Euro Heart Survey



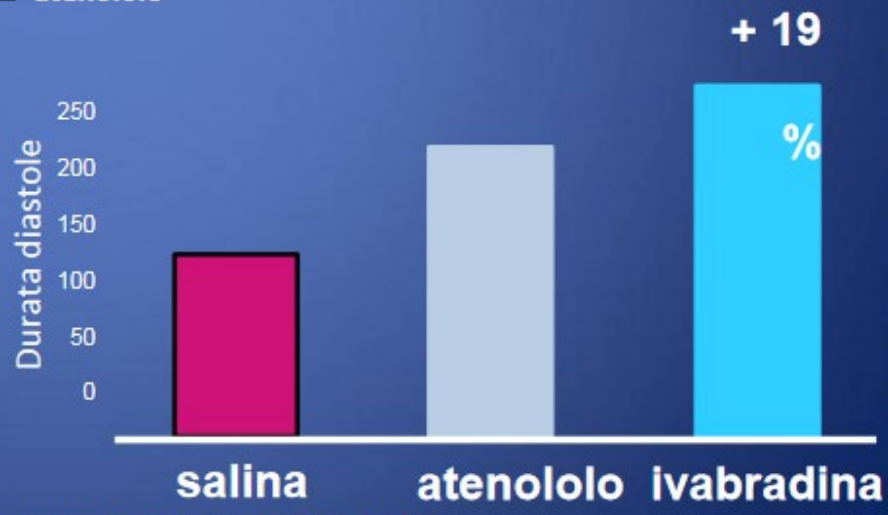
Aumenta il tempo di riempimento diastolico

A parità di riduzione della FC



+ 38 msec

+ 2,5 ore al giorno di riempimento diastolico



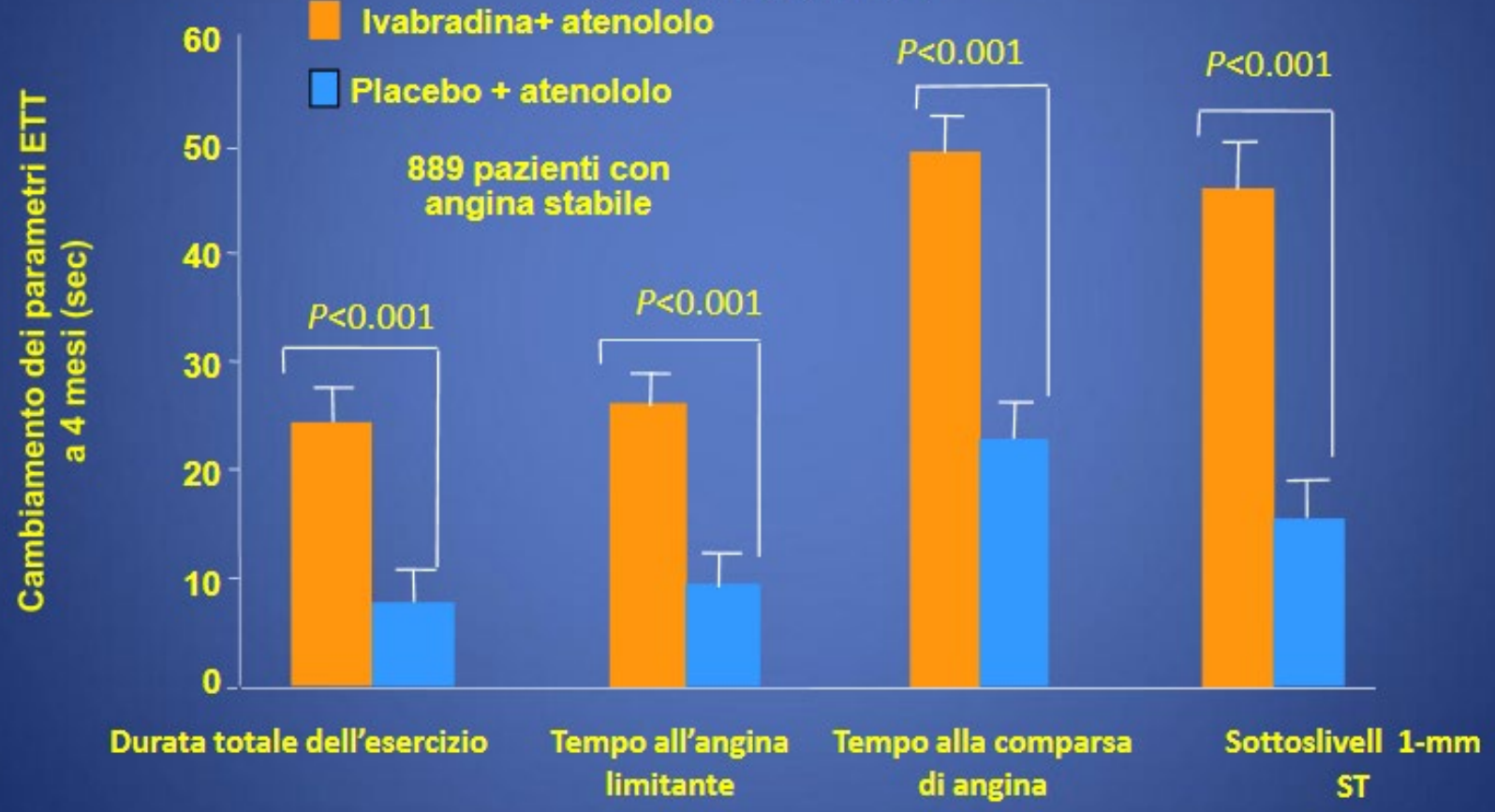
- Colin P, et al. Am J Physiol Heart Circ Physiol. 2003;284:H676-H682.

Cosa regala ivabradina in aggiunta alla terapia standard?

- aumenta il tempo di riempimento diastolico
- preserva la contrattilità miocardica e il rilasciamento ventricolare
- aumenta il flusso coronarico e la riserva coronarica sotto sforzo

ASSOCIATE

Il trattamento con Ivabradina migliora tutti I parametri del test da sforzo in pazienti già trattati con BB



*Valutato a valle dell'attività del farmaco

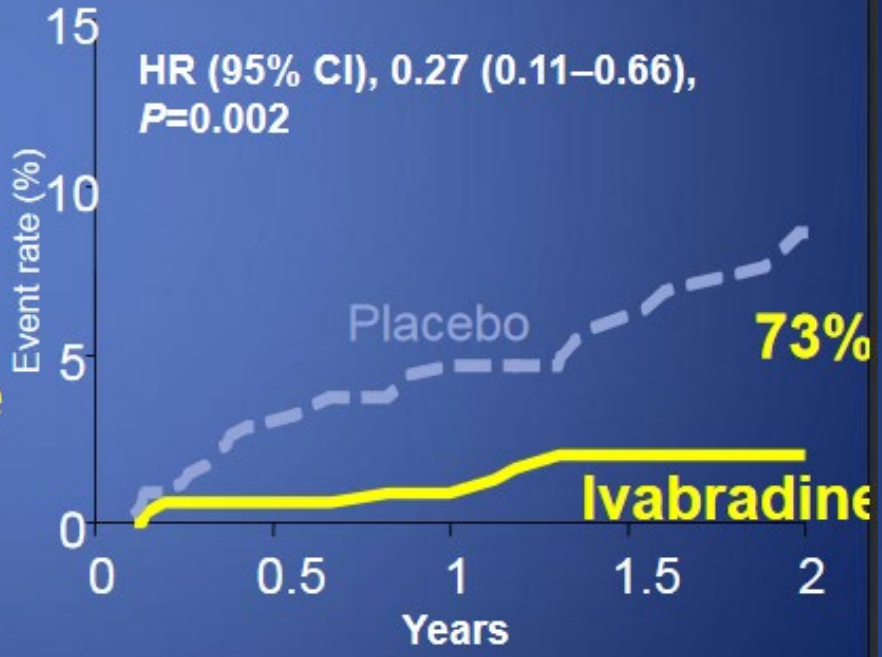
Tardif JC et al. Eur Heart J. 2009;30:540–548.

BEAUTIFUL – Angina substudy

Effetti della riduzione della FC con ivabradina

Primary end point (rivascolarizzazioni), HR ≥70 bpm

Hospitalization for MI, HR ≥70 bpm

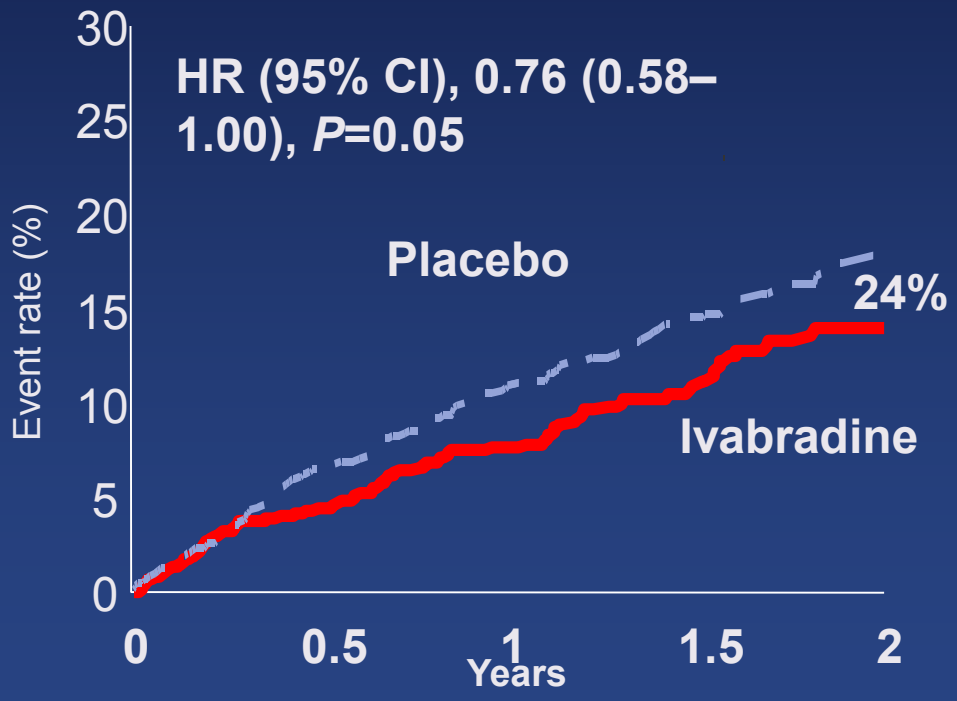


Fox et al. *Eur Heart J*. 2009;30:2337-45.

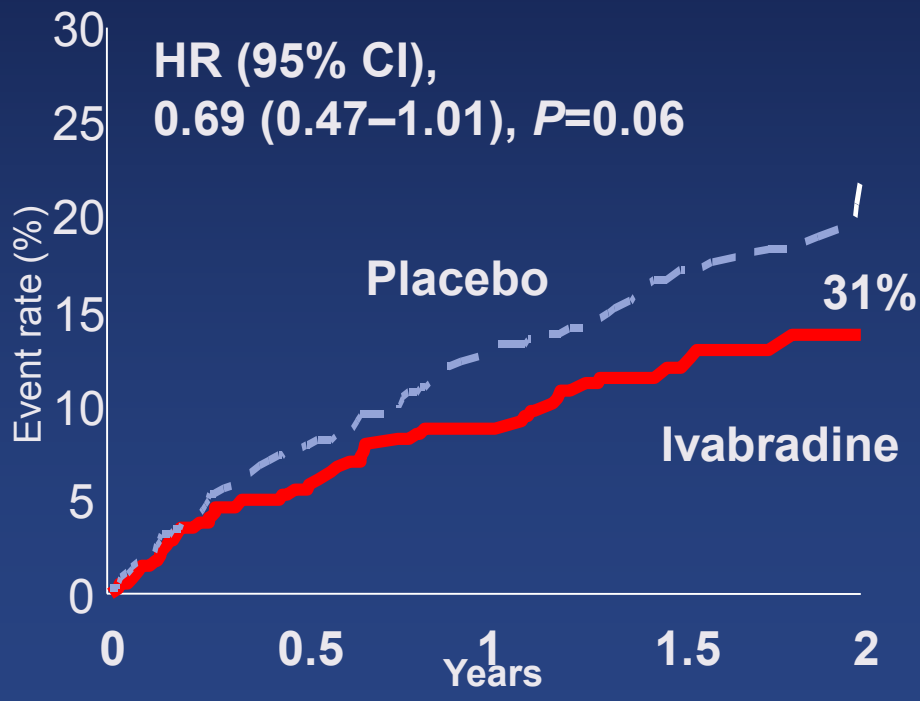
On primary composite end point

Fox et al. Eur Heart J. 2009

All angina patients 1507 pz



HR ≥70 bpm

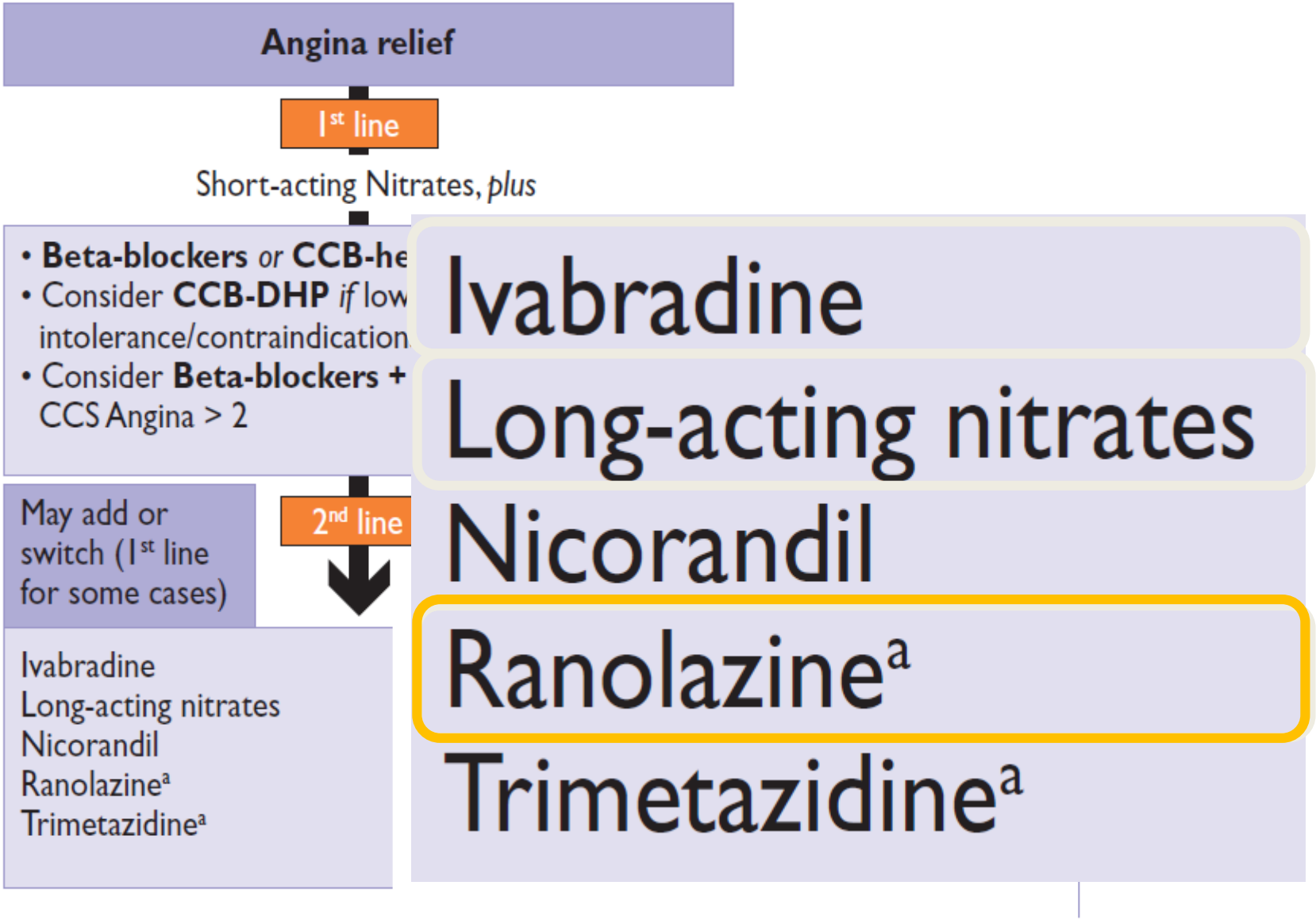


Composite of cardiovascular mortality or hospitalization for fatal and nonfatal myocardial infarction or heart failure

2013 ESC guidelines on the management of stable coronary artery disease

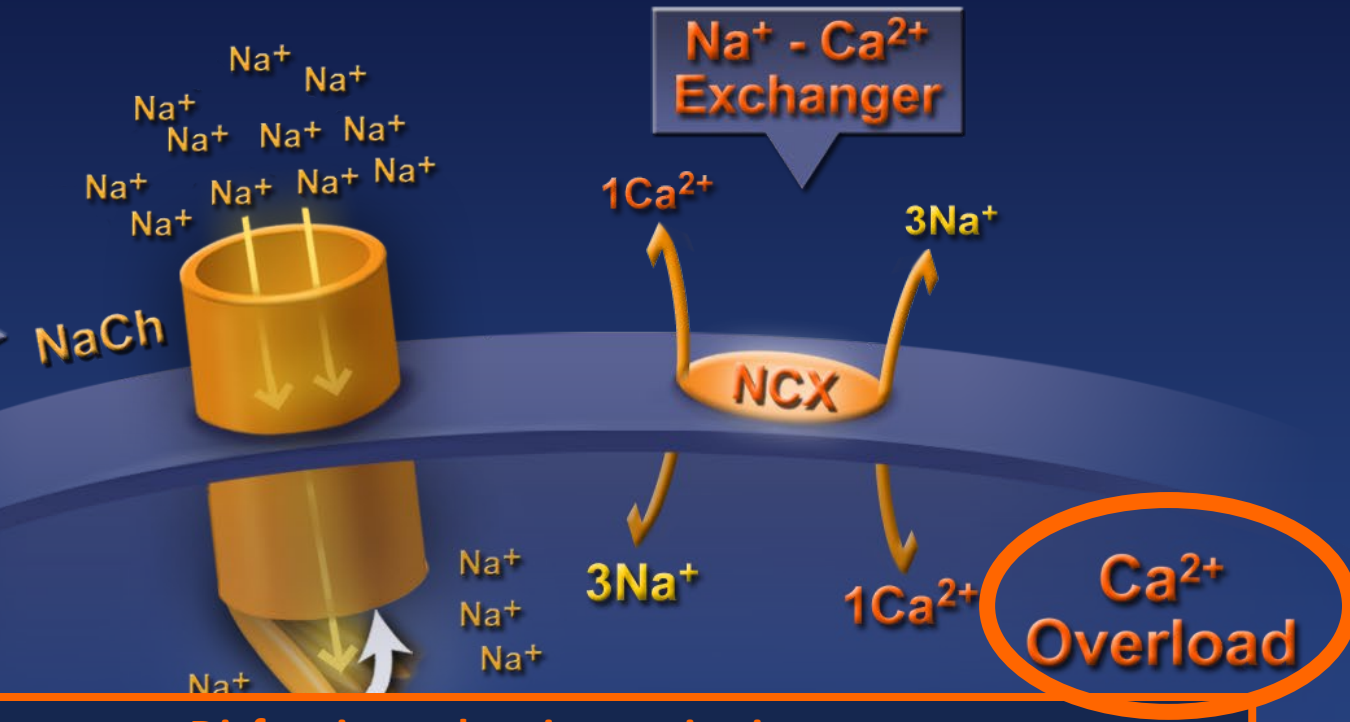
Eur Heart J , August 30, 2013

Medical management of patient with stable CAD



Ranolazina: meccanismo d'azione

Nell'ISCHEMIA MIOCARDICA si verifica un'attivazione prolungata della corrente tardiva del sodio

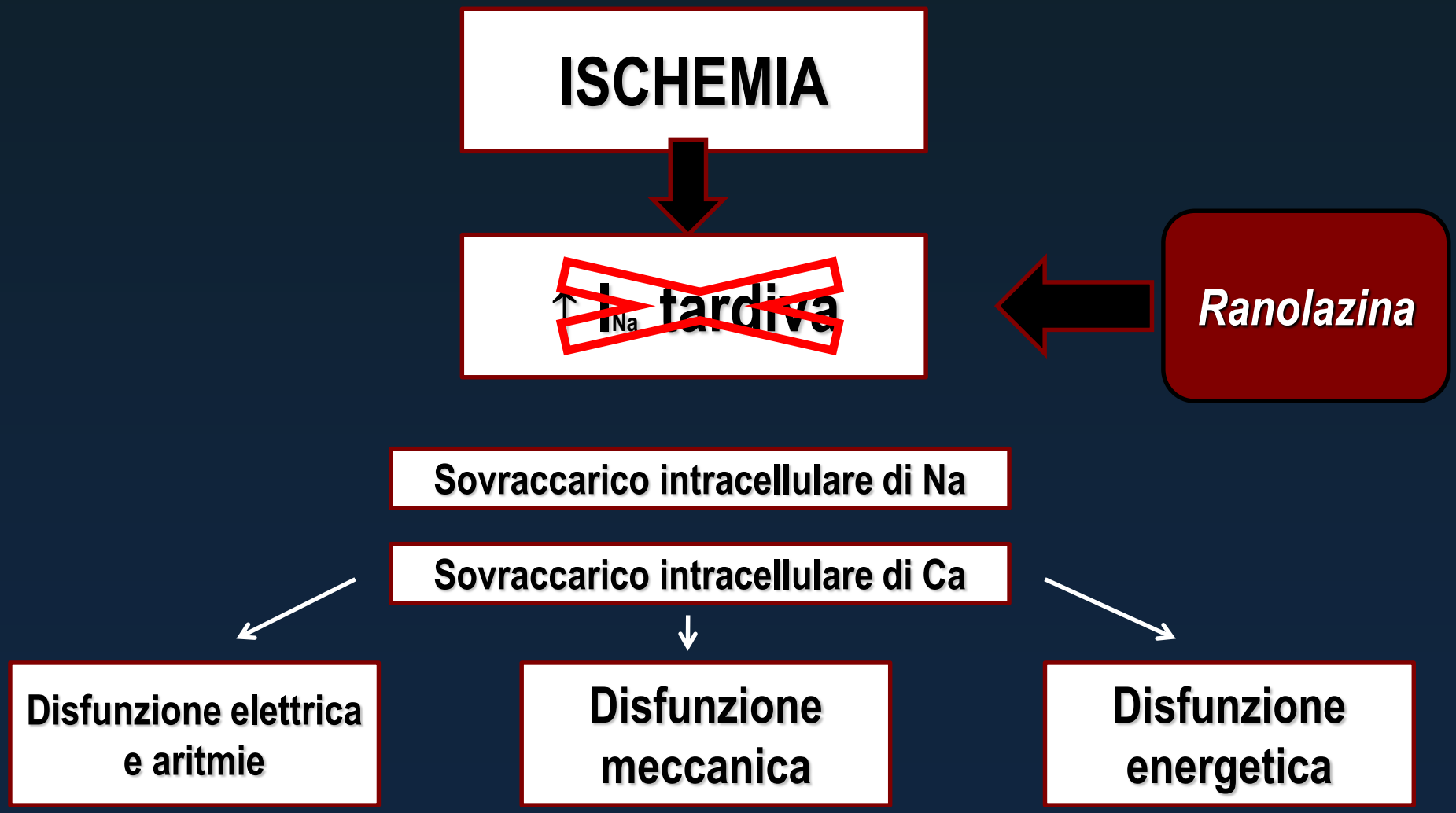


Disfunzione elettrica e aritmie

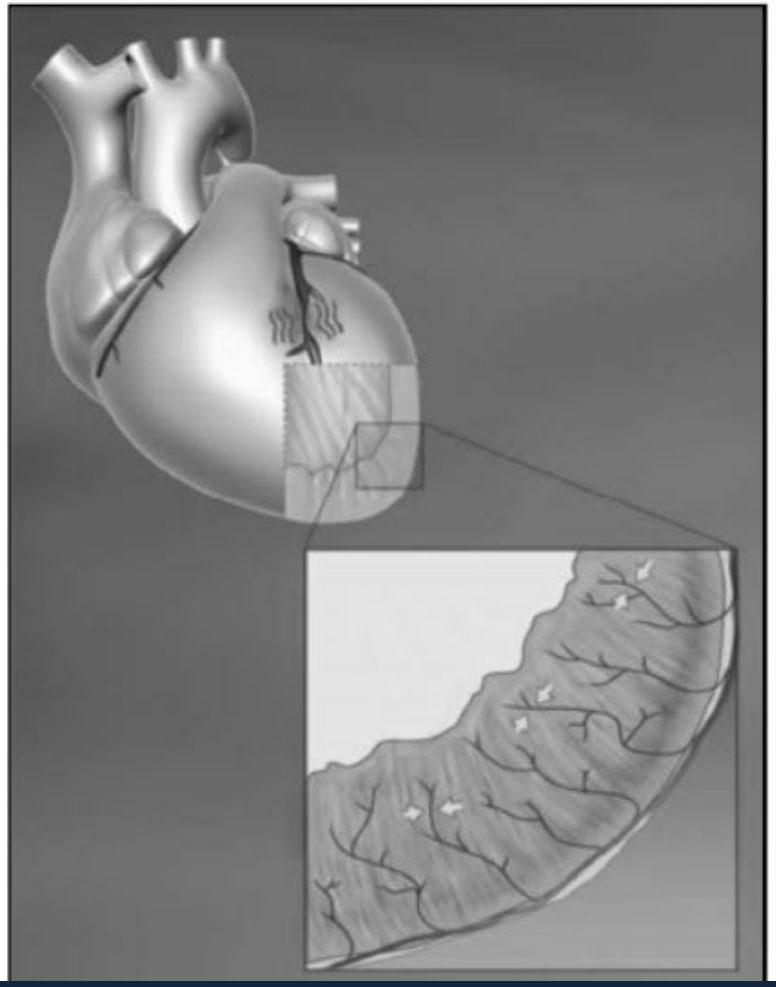
Disfunzione meccanica

Disfunzione metabolica

Trattamento dell'ischemia miocardica: Ranolazina



Alterato rilasciamento diastolico
Aumento del Consumo di O_2 e Ridotto Apporto di O_2



La contrazione protratta del miocardio ischemico durante la diastole:

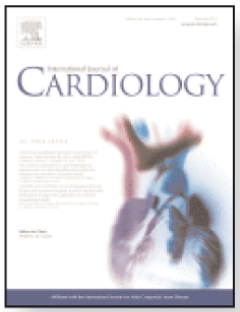
- Aumenta il consumo miocardico di O_2
- Comprime i piccoli vasi intramurali
  - Riduce il flusso ematico miocardico

(in diastole avviene la massima parte dell'apporto di flusso coronarico)

Ranolazina previene la rigidità diastolica preservando il flusso ematico miocardico

Studi Clinici Principali

MARISA	CARISA	ERICA	MERLIN-TIMI 36	TERISA
N=191	N=823	N=565	N=6560	N=949
Stable Angina	Stable Angina	Stable Angina	ACS-NST	Diabetes + Stable Angina
Ranolazina monoterapy vs placebo	Ranolazina vs placebo plus Standard therapy	Ranolazina vs placebo plus amlodipina 10 mg	Ranolazina vs placebo plus Standard therapy	Ranolazina monoterapy vs placebo



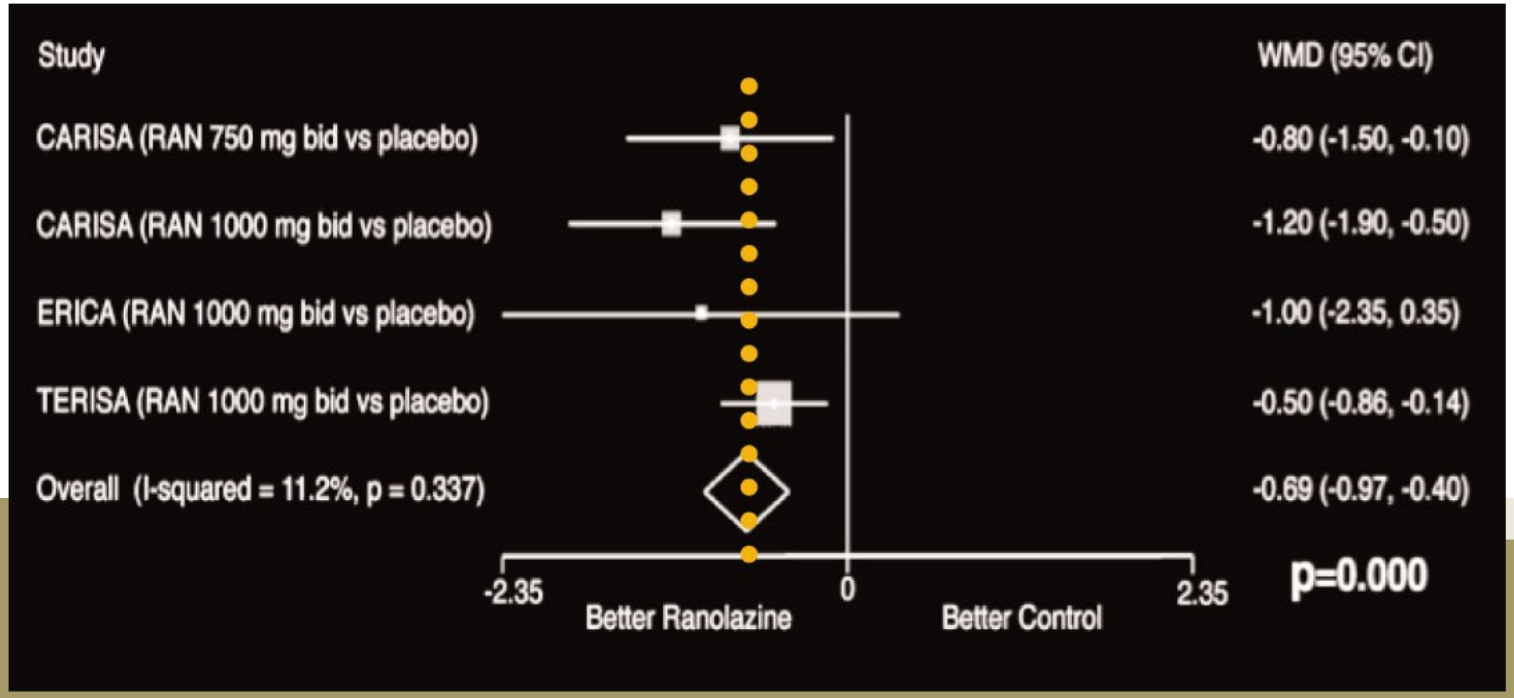
Effects of ranolazine in symptomatic patients with stable coronary artery disease. A systematic review and meta analysis

Savarese, Int. J Cardiol 2013

Gianluigi Savarese[a], Giuseppe Rosano[b], Carmen D'Amore[a], Francesca Musella[a], Giuseppe Luca Della Ratta[a], Angela Maria Pellegrino[a], Tiziana Formisano[a], Alice Vitagliano[a], Annapaola Cirillo[a], Gennaro Cice[c], Luigi Fimiani[a], Luca del Guercio[d], Bruno Trimarco[a], Pasquale Perrone-Filardi[a]*

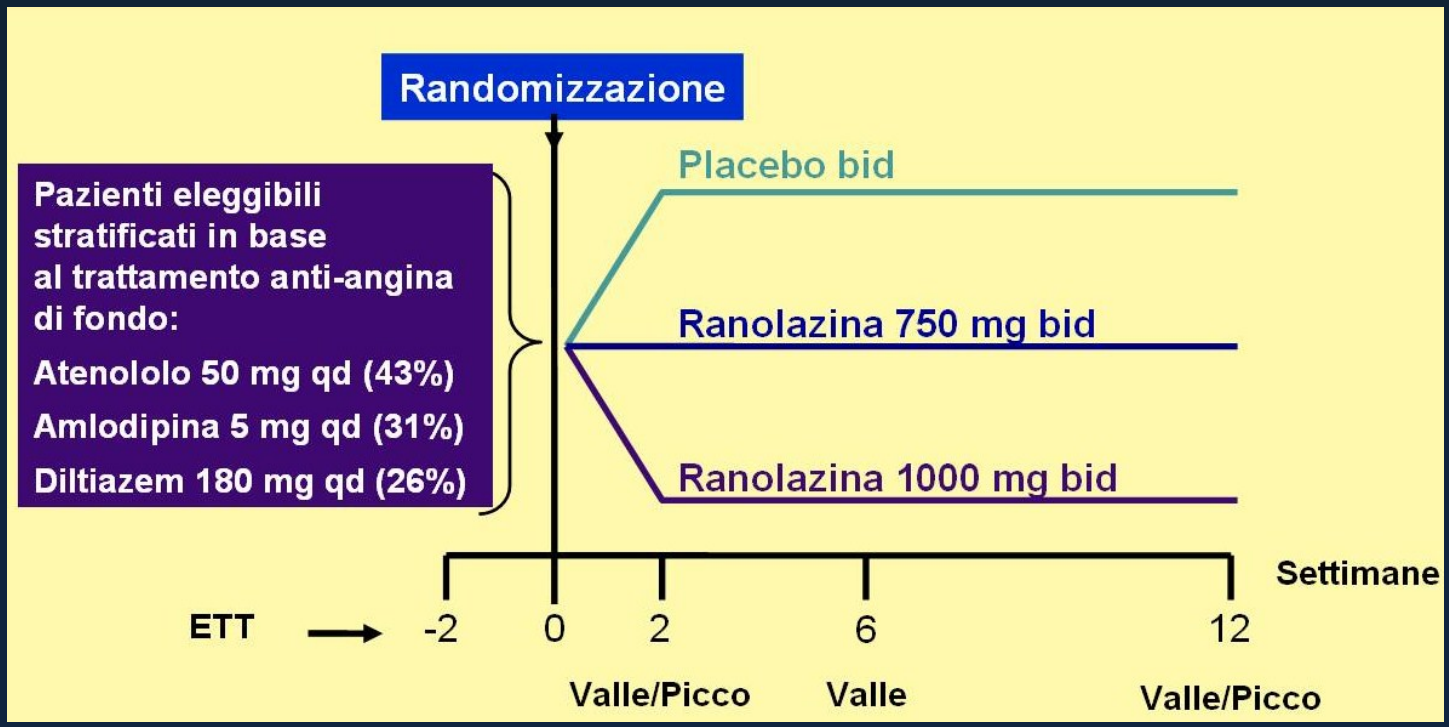
[a] Department of Advanced Biomedical Science, Federico II University, Naples, Italy / [b] Clinical and Experimental Research Center, IRCCS San Raffaele, Rome, Italy
[c] Division of Cardiology , Second University of Naples, Naples, Italy / [d] Department of vascular and Endovascular Surgery, Federico II University, Naples, Italy

Mean difference estimate of weekly angina onset in Ranolazine versus control study groups



CARISA: Combination Assessment of Ranolazine In Stable Angina

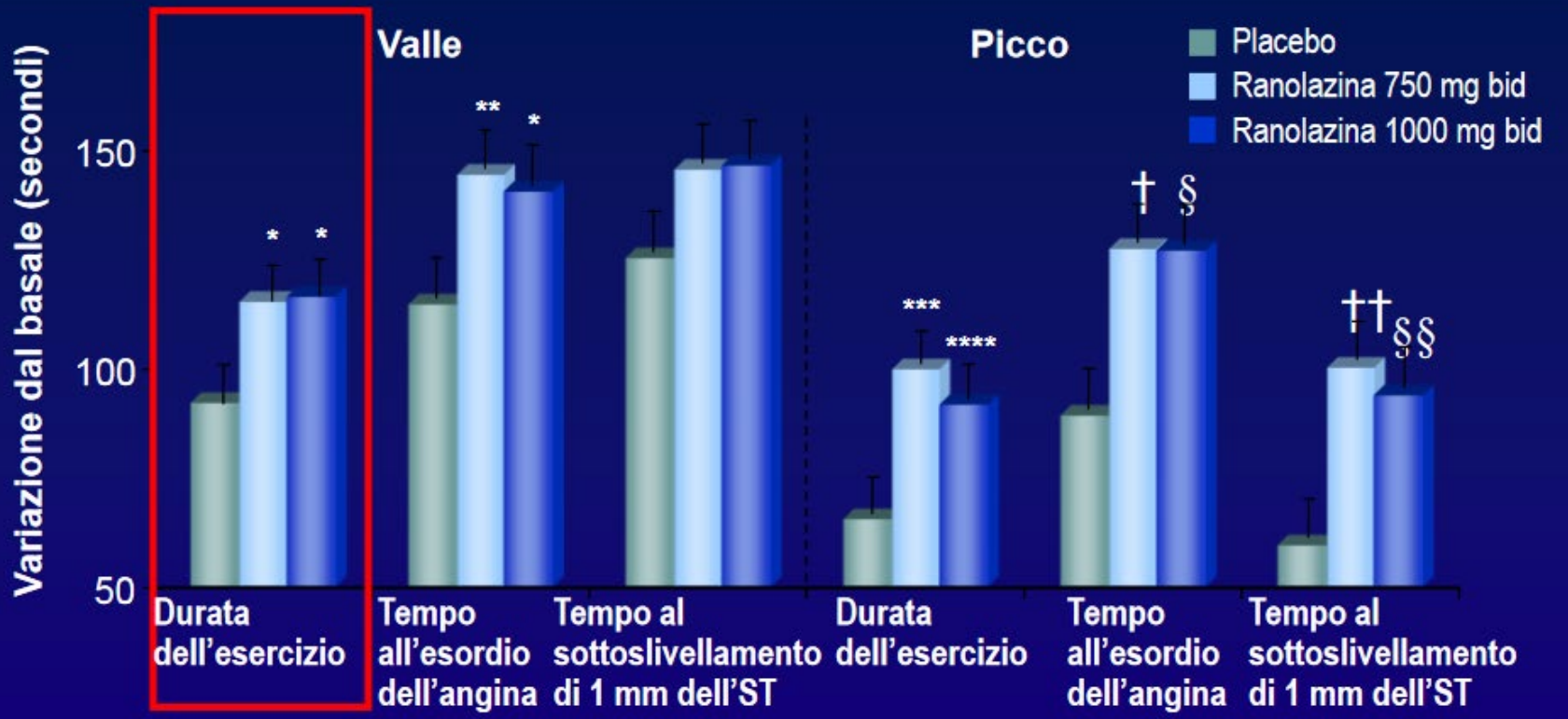
- Disegno: randomizzato, doppio cieco, placebo-controllato, per gruppi paralleli
- Popolazione: 823 pazienti con angina da sforzo da almeno 3 mesi già in trattamento con atenololo, diltiazem o amlodipina
- Obiettivo: efficacia di Ranolazina in presenza di terapia antischemica ottimizzata
- End point primario: durata dell'esercizio alla concentrazione a valle di Ranolazina



Chaitman JACC 2004; 291: 303 – 316

CARISA: efficacia

(Combination Assessment of Ranolazine In Stable Angina)



*p=0.03; **p=0.01; ***p=0.001; ****p=0.02; †p=0.002; §p=0.003; ††p<0.001; §§p=0.004 vs placebo

CARISA: parametri emodinamici

	Ranolazina 750 mg bid	
	C_{minima}	$C_{massima}$
PA sistolica a riposo	NS	NS
FC a riposo	NS	NS
PA sistolica a fine esercizio	NS	NS
FC a fine esercizio	-3.1 (p=0.01)	-2.3 (p=0.05)

Ranolazina non ha indotto variazioni clinicamente significative della PA e della FC

CARISA: Combination Assessment of Ranolazine In Stable Angina

Ranolazina aggiunge efficiacia anti-anginosa ed anti-ischemica in pazienti con angina stabile che continuano ad essere sintomatici nonostante una terapia standard ottimizzata

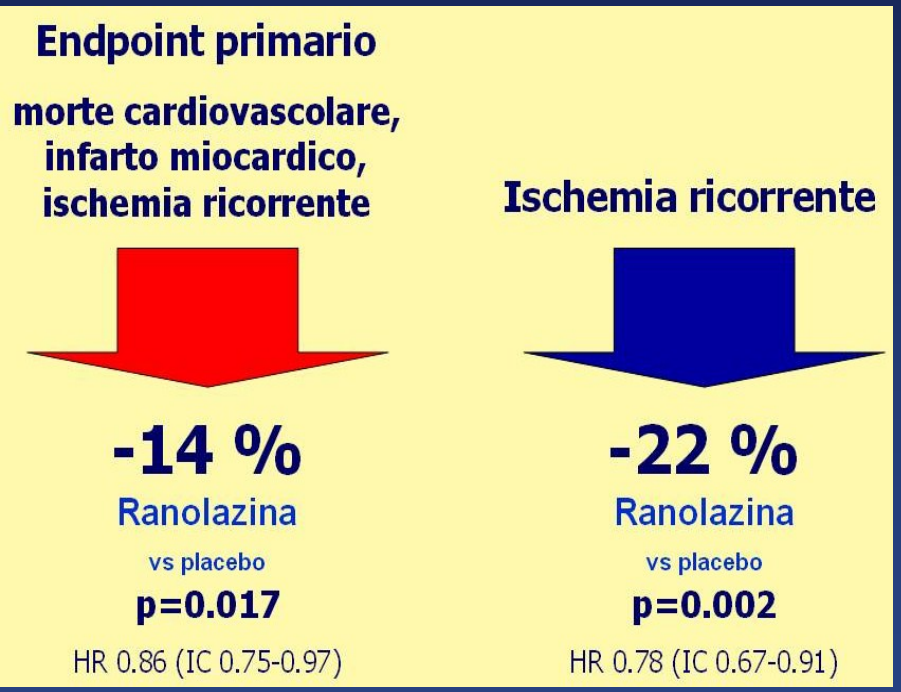
Gli effetti anti-anginosi ed anti-ischemici non dipendono dalle variazioni di pressione arteriosa o di frequenza cardiaca

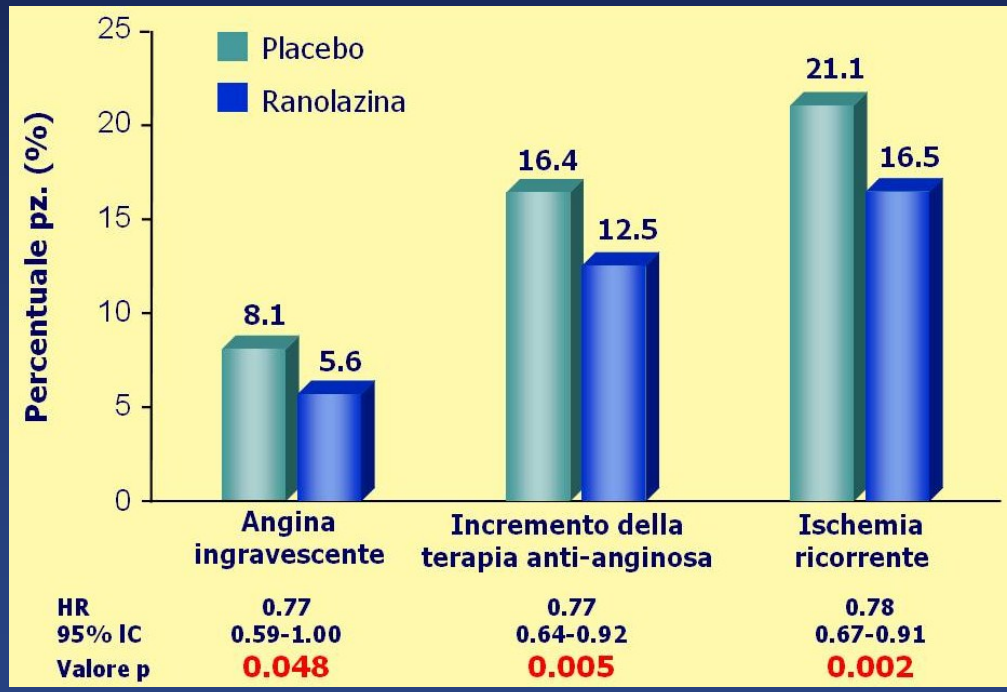
Il trattamento con Ranolazina in aggiunta alla terapia con beta-bloccanti o calcio-antagonisti è risultato ben tollerato

Chaitman JACC 2004; 291: 303 – 316

Studio MERLIN:

- **Disegno**: randomizzato, doppio cieco, placebo controllato, gruppi paralleli
- **Popolazione**: 3565 pazienti precedente arruolati nel trial MERLIN TIMI 36 con angina cronica (storia di angina media 5,2 anni)
- **Obiettivo**: efficacia di Ranolazina in aggiunta alla terapia standard
- **End point primario**: composito di morte CV, IMA e ischemia ricorrente

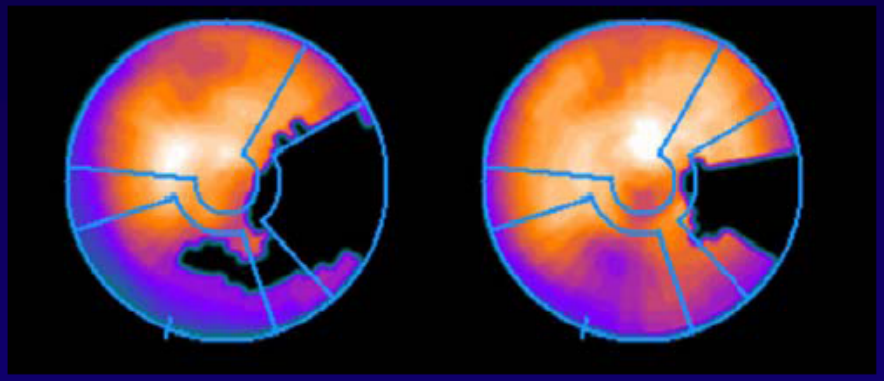




Efficacia di Ranolazina nel migliorare la perfusione miocardica

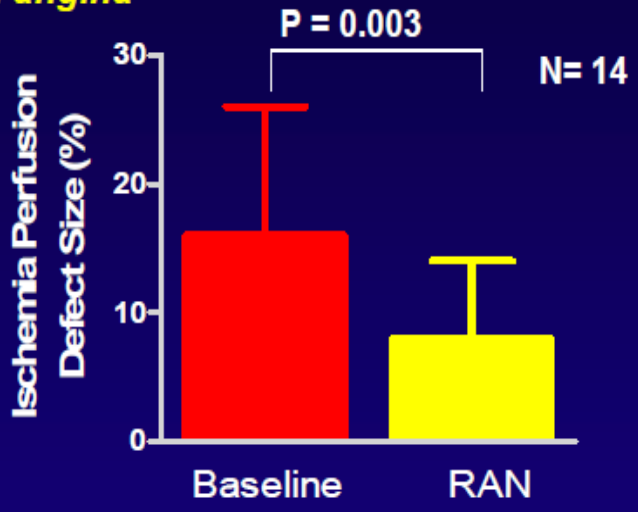
Myocardial Perfusion Imaging in Patients with Coronary Artery Disease Treated with Ranolazine

Exploratory study in 20 patients with CAD and angina



Before Ranolazine
PDS* = 25% of LV
Peak HR = 142 bpm

After Ranolazine
PDS* = 11% of LV
Peak HR = 142 bpm



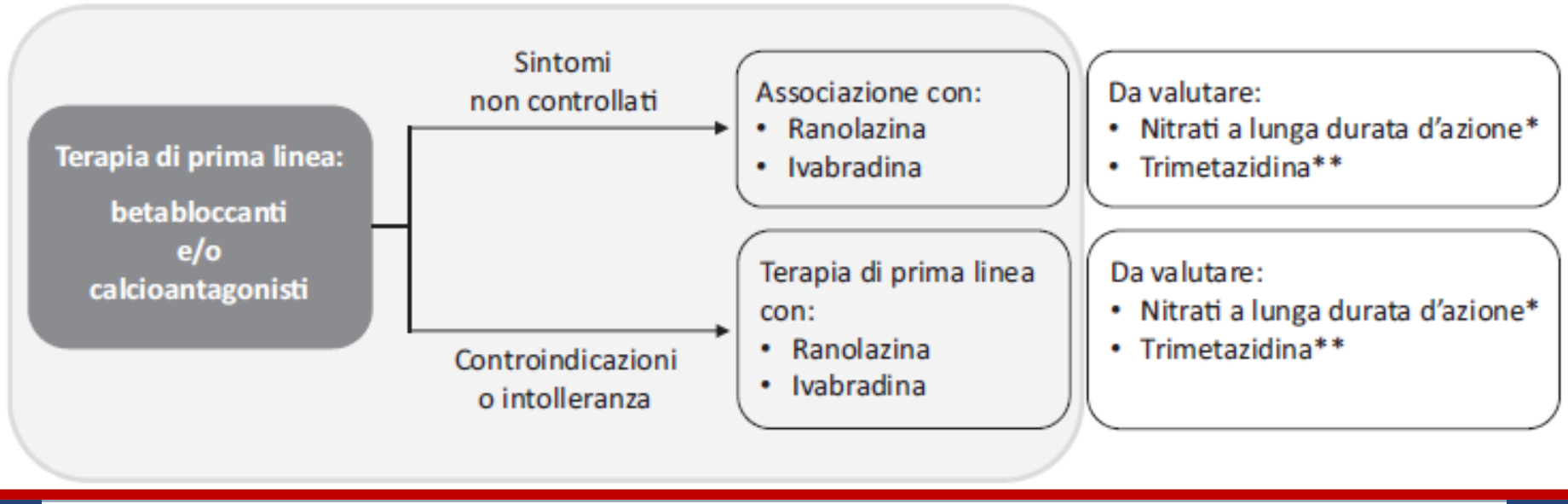
- Treadmill exercise time increased by 32 seconds (p=0.017, n=20)
- Angina reduced in 15 patients (75%) after ranolazine treatment.
- Improvement in the extent and severity of ischemia was noted in 14 patients (70%). Among these patients, ischemia PDS (% LV) decreased from 16 ± 10 to 8 ± 6 (p=0.003, n=14)
- Among the 15 patients with reduced angina, 11 (73%) had an improvement in perfusion.

/enkataraman R, et al. *JACC Imaging* 2009 (in press); Courtesy of Ami Iskandrian, MD

***PDS: perfusion defect size**

Documento ANMCO/GICR-IACPR/GISE L'organizzazione dell'assistenza nella fase post-acuta delle sindromi coronariche

Commissione ANMCO/GICR-IACPR/GISE



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Conclusioni I

La sintomatologia anginosa resta una condizione estremamente frequente nonostante l'ottimizzazione delle tecniche di rivascolarizzazione miocardica

I dati in letteratura confermano l'efficacia anti-ischemica ed anti-anginosa dei nuovi farmaci, in particolare di Ranolazina ed Ivabradina in aggiunta o in sostituzione alla terapia antianginosa classica

Buona sicurezza e tollerabilità.

Novità dalle più recenti linee guida europee su cardiopatia ischemica cronica

ESC European Society of Cardiology

European Heart Journal (2018) **39**, 213–254
doi:10.1093/eurheartj/ehx419

ESC GUIDELINES

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

The Task Force for dual antiplatelet therapy in coronary artery disease of the European Society of Cardiology (ESC) and of the European Association for Cardio-Thoracic Surgery (EACTS)

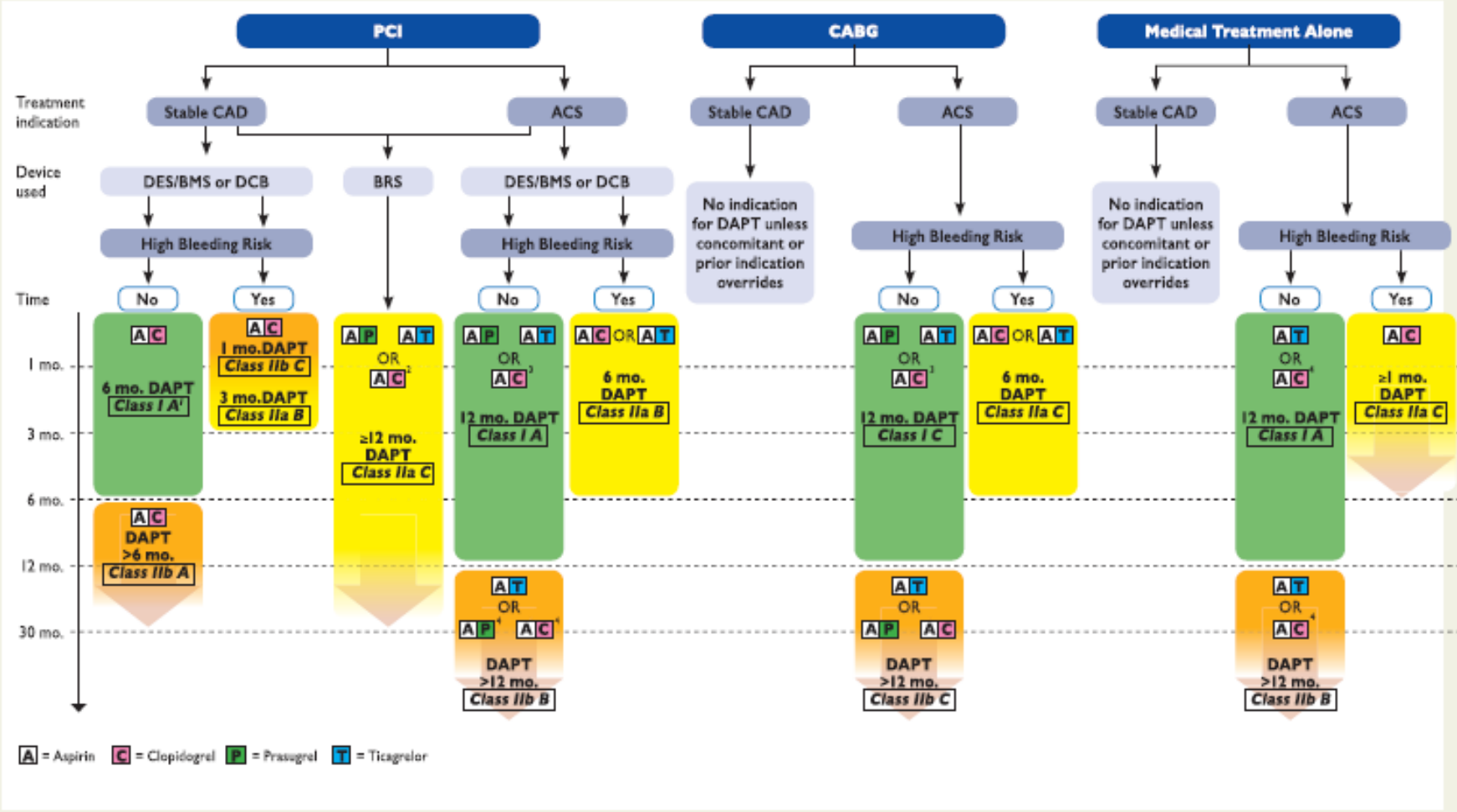

Figure 3 Algorithm for DAPT in patients with coronary artery disease. ACS = acute coronary syndrome, BMS = bare-metal stent; BRS = bioresorbable vascular scaffold; CABG = Coronary artery bypass graft; DCB = drug-coated balloon; DES: drug-eluting stent; PCI = percutaneous coronary intervention; Stable CAD = stable coronary artery disease.
High bleeding risk is considered as an increased risk of spontaneous bleeding during DAPT (e.g. PRECISE-DAPT score ≥25).
Colour-coding refers to the ESC Classes of Recommendations (green = Class I; yellow = Class IIa; orange = Class IIb).
Treatments presented within the same line are sorted in alphabetic order, no preferential recommendation unless clearly stated otherwise.
1: After PCI with DCB 6 months. DAPT should be considered (Class IIa B).
2: If patient presents with Stable CAD or, in case of ACS, is not eligible for a treatment with prasugrel or ticagrelor.
3: If patient is not eligible for a treatment with prasugrel or ticagrelor.
4: If patient is not eligible for a treatment with ticagrelor.

ESC
European Society of Cardiology
European Heart Journal (2018) **00**, 1–96
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ESC/EACTS GUIDELINES

2018 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)

5 Revascularization for stable coronary artery disease

Indications for revascularization in patients with stable angina or silent ischaemia

Extent of CAD (anatomical and/or functional)		Class[a]	Level[b]
For prognosis	Left main disease with stenosis >50%.[c] [68–71]	I	A
	Proximal LAD stenosis >50%.[c] [62,68,70,72]	I	A
	Two- or three-vessel disease with stenosis >50% with impaired LV function (LVEF ≤35%).[c] [61,62,68,70,73–83]	I	A
	Large area of ischaemia detected by functional testing (>10% LV) or abnormal invasive FFR.[d] [24,59,84–90]	I	B
	Single remaining patent coronary artery with stenosis >50%.[c]	I	C
For symptoms	Haemodynamically significant coronary stenosis[c] in the presence of limiting angina or angina equivalent, with insufficient response to optimized medical therapy.[e] [24,63,91–97]	I	A

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5 Revascularization for stable coronary artery disease

Revascularization modality

PCI vs CABG

- Surgical risk
- CAD anatomical complexity
- Completeness of revascularization

5 Revascularization for stable coronary artery disease

Revascularization modality

Recommendations on criteria for the choice between coronary artery bypass grafting and percutaneous coronary intervention

Recommendations	Class[a]	Level[b]
Assessment of surgical risk[c]		
It is recommended that the STS score is calculated to assess in-hospital or 30 day mortality, and in-hospital morbidity after CABG.[112,114,138]	I	B
Calculation of the EuroSCORE II score may be considered to assess in-hospital mortality after CABG.[112]	IIb	B
Assessment of CAD complexity		
In patients with LM or multivessel disease, it is recommended that the SYNTAX score is calculated to assess the anatomical complexity of CAD and the long-term risk of mortality and morbidity after PCI.[117–124]	I	B
When considering the decision between CABG and PCI, completeness of revascularization should be prioritized.[131,132,134–136]	IIa	B

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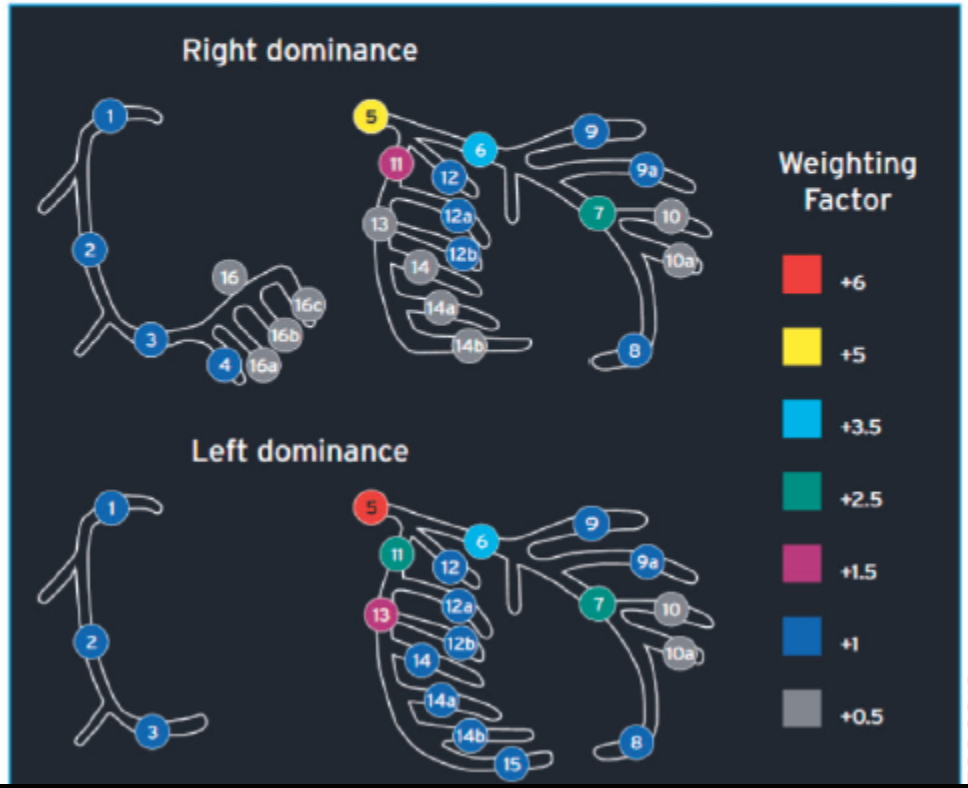
PCI vs CABG

CAD anatomical complexity

Table 6 Guide for calculating the SYNTAX score

Steps	Variable assessed	Description
Step 1	Dominance	The weight of individual coronary segments varies according to coronary artery dominance (right or left). Co-dominance does not exist as an option in the SYNTAX score.
Step 2	Coronary segment	The diseased coronary segment directly affects the score as each coronary segment is assigned a weight depending on its location, ranging from 0.5 (i.e. the posterolateral branch) to 6 (i.e. left main in case of left dominance).



Step 3	Diameter stenosis	The score of each diseased coronary segment is multiplied by two in case of a stenosis 50–99% and by five in case of total occlusion. In case of total occlusion, additional points will be added as follows: • Age >3 months or unknown +1 • Blunt stump +1 • Bridging +1 • First segment visible distally +1 per non-visible segment • Side branch at the occlusion +1 if <1.5 mm diameter +1 if both <1.5 mm and ≥1.5 mm diameter +0 if ≥1.5 mm diameter (i.e. bifurcation lesion)
Step 4	Trifurcation lesion	The presence of a trifurcation lesion adds additional points based on the number of diseased segments: • 1 segment +3 • 2 segments +4 • 3 segments +5 • 4 segments +6
Step 5	Bifurcation lesion	The presence of a bifurcation lesion adds additional points based on the type of bifurcation according to the Medina classification:[126] • Medina 1,0,0–0,1,0–1,1,0 +1 • Medina 1,1,1–0,0,1–1,0,1–0,1,1 +2 Moreover, the presence of a bifurcation angle <70° adds one additional point
Step 6	Aorto-ostial lesion	The presence of aorto-ostial lesion segments adds one additional point
Step 7	Severe tortuosity	The presence of severe tortuosity proximal of the diseased segment adds two additional points
Step 8	Lesion length	Lesion length >20 mm adds one additional point
Step 9	Calcification	The presence of heavy calcification adds two additional points
Step 10	Thrombus	The presence of thrombus adds one additional point
Step 11	Diffuse disease/ small vessels	The presence of diffusely diseased and narrowed segments distal to the lesion (i.e. when at least 75% of the length of the segment distal to the lesion has a vessel diameter <2 mm) adds one point per segment number

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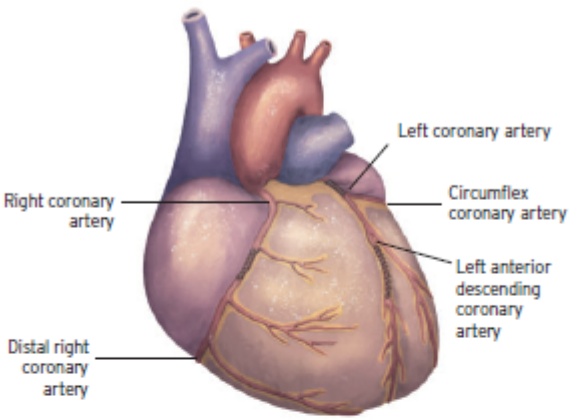
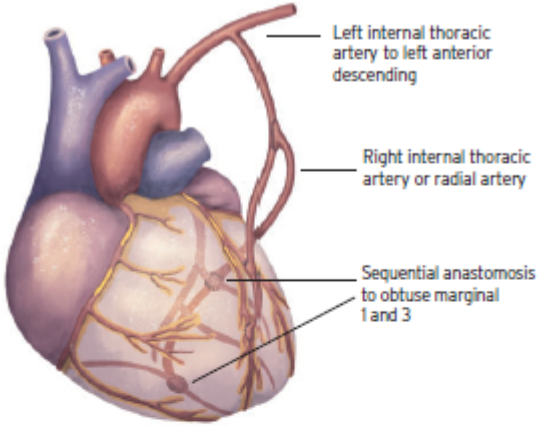
PCI vs CABG

CAD anatomical complexity





FAVOURS PCI
Clinical characteristics
Presence of severe co-morbidity (not adequately reflected by scores)
Advanced age/frailty/reduced life expectancy
Restricted mobility and conditions that affect the rehabilitation process
Anatomical and technical aspects
MVD with SYNTAX score 0–22
Anatomy likely resulting in incomplete revascularization with CABG due to poor quality or missing conduits
Severe chest deformation or scoliosis
Sequelae of chest radiation
Porcelain aorta[a]

FAVOURS CABG
Clinical characteristics
Diabetes
Reduced LV function (EF ≤35%)
Contraindication to DAPT
Recurrent diffuse in-stent restenosis
Anatomical and technical aspects
MVD with SYNTAX score ≥23
Anatomy likely resulting in incomplete revascularization with PCI
Severely calcified coronary artery lesions limiting lesion expansion
Need for concomitant interventions
Ascending aortic pathology with indication for surgery
Concomitant cardiac surgery

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Conclusioni II

Nella coronaropatia stabile il problema principale è definire quali pazienti possono beneficiare di una rivascolarizzazione miocardica e quando.

La terapia medica ottimizzata (OMT) rappresenta il fondamento del management del paziente con SCAD

“Terapia medica” non è intesa come assenza di rivascolarizzazione ma un insieme di interventi intensivi sia di tipo farmacologico che sullo stile di vita.