Societat Catalana de Farmacia Clínica. 2017

Polypill – ¿una solución para la falta de adherencia en la prevención cardiovascular?

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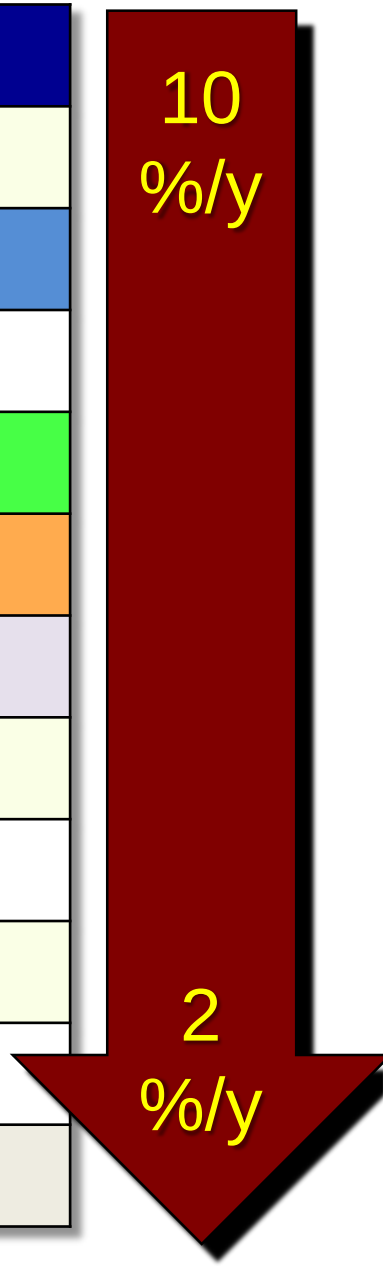
Disclosures:

Research Grants: AZ, Boehringer Ingelheim, Pfizer, Novartis, Daichii-Sankyo, Sanofi-Aventis, Bayer, MSD, Servier, Ferrer

Consultant/Honorarium. AZ, Boehringer-Ingelheim, Bayer, Pfizer, BMS, MSD, Daichii-Sankyo, Servier, Menarini, Ferrer, Angem

IHD 2ªPrev. An Extraordinary Journey

Innovation	Year	Impact
B-Blockers	70´	↓Mortality
ASA	**80´**	**↓Mortality**
Life-style changes/Rehab	70-15´	↓Mortality
ACE Ih	80-90´	↓Morbi-mortality
Statins	**90´**	**↓Morbi-Mortality**
Empaglifocin/Liragutide	16´	↓Morbi/mortality
Revasc (subgroups)	00´	↓Morbi-mortality
Vorapaxar	13´	↓Morbi-mortality
Rivaroxaban	13´	↓Morbi-mortality
Ticagrelor	15´	↓Morbi-mortality
Ezetimibe	**15´**	**↓Morbi-mortality**



Potential Cumulative Impact of 4 Simple Secondary Prevention Treatments

Risk Factors Control and Direct CV and Kidney Protection

	RRR	Event rate
None		8%
ASA	25%	6%
β-Blockers	25%	4.5%
Lipid lowering	30%	3.0%
ACE-inhibitors	25%	2.3%

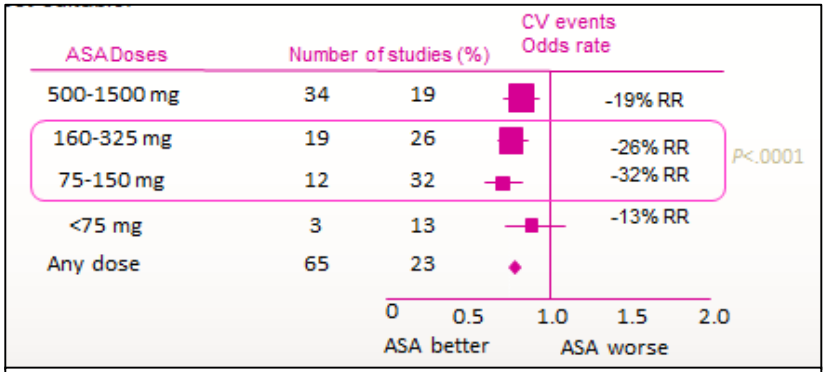
CUMULATIVE BENEFITS ARE LIKELY TO BE IN EXCESS OF 75% RRR, WHICH IS SUBSTANTIAL

Rationale for the selection of “Polypill” components for secondary prevention

ACETYLSALCYLIC ACID 100mg

- **22%** RRR of stroke
- **20%** RRR of coronary events

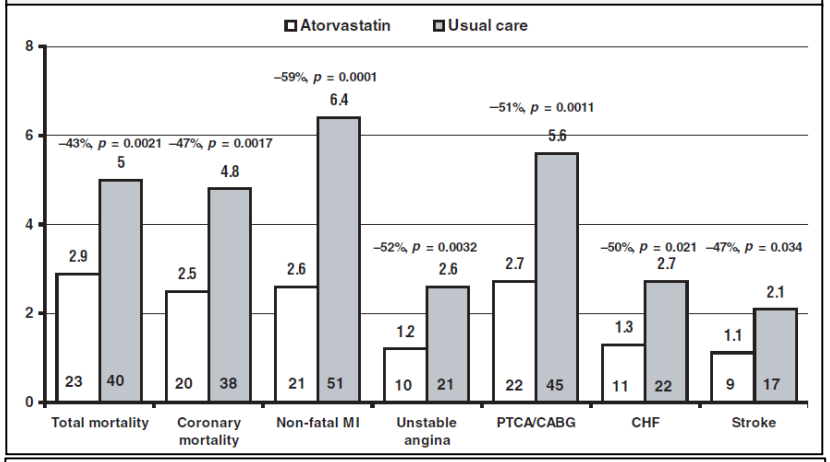
AT trialists collaboration. Baignent. BMJ 2002;324:71-86



ATORVASTATIN 20mg

- **43%** RRR of total mortality
- **52%** RRR of non fatal MI
- **47%** RRR of coronary mortality
- **47%** RRR of stroke

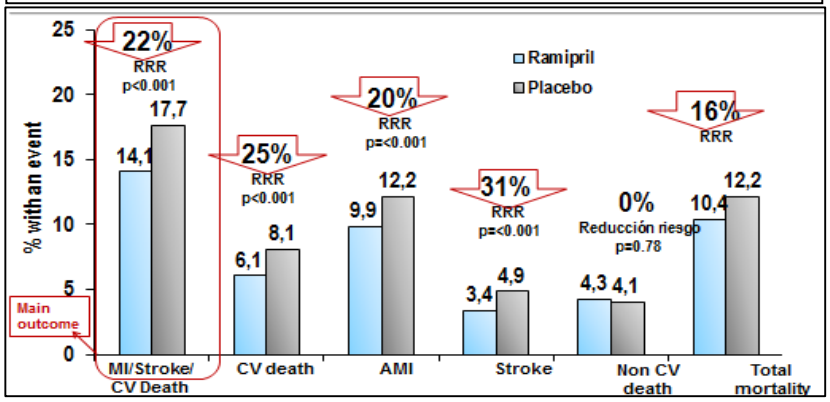
Atorvastatin SmPC. GREACE study. Athyros GV.. Curr Med Res Opinion 2002. 220-228



RAMIPRIL 10mg

- **26%** RRR of cardiovascular death
- **20%** RRR of AMI
- **31%** RRR of stroke

HOPE Yusuf S et al. NEJM 2000;342(3):145-53



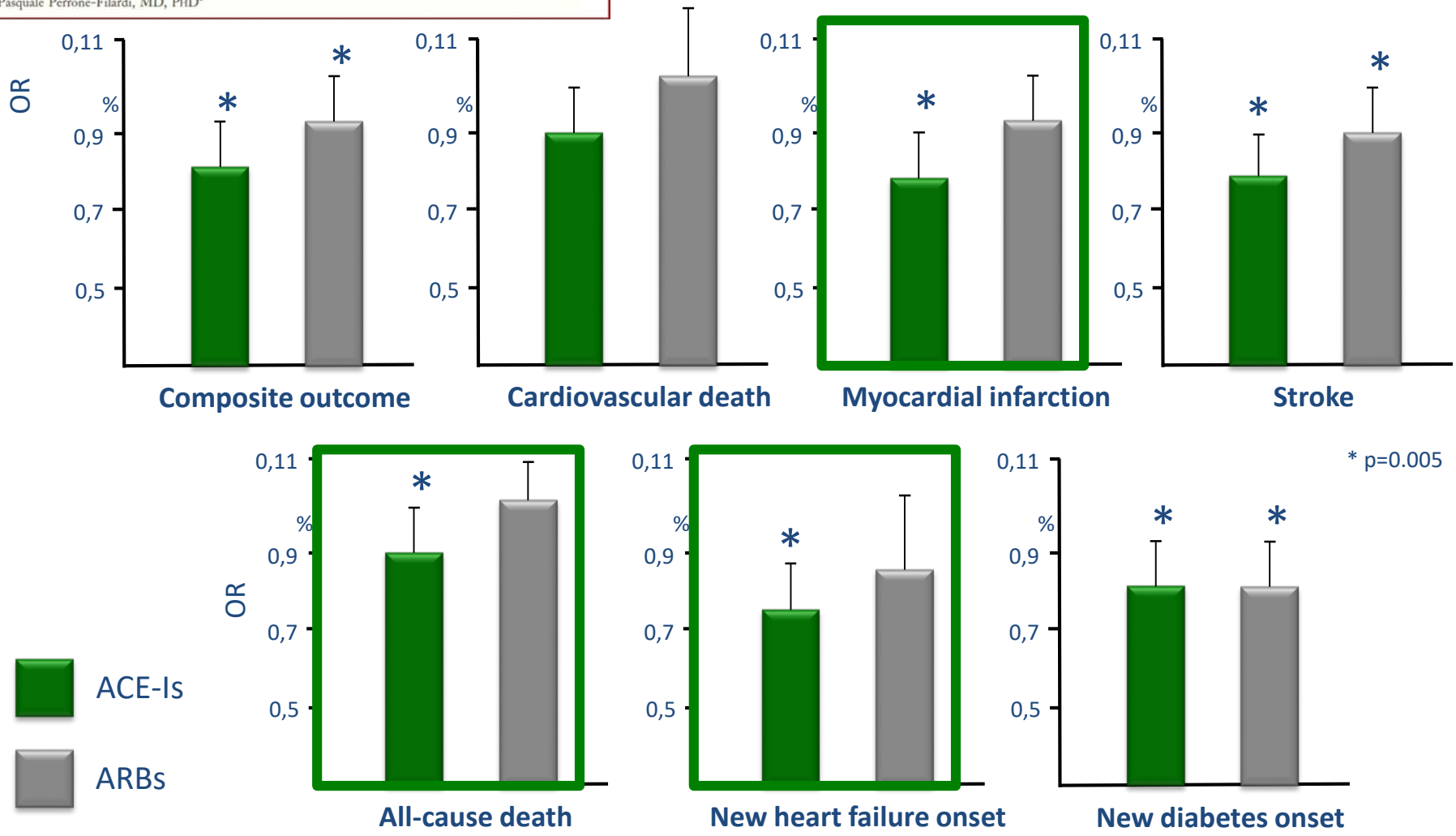
RRR: relative risk reduction

CLINICAL RESEARCH Cardiovascular Risk

A Meta-Analysis Reporting Effects of Angiotensin-Converting Enzyme Inhibitors and Angiotensin Receptor Blockers in Patients Without Heart Failure

Gianluigi Savarese, MD,* Pierluigi Costanzo, MD,*† John George Franklin Cleland, MD,†
Enrico Vassallo, MD,* Donatella Ruggiero, MD,* Giuseppe Rosano, MD, PHD,‡
Pasquale Perrone-Filardi, MD, PHD*

Main results



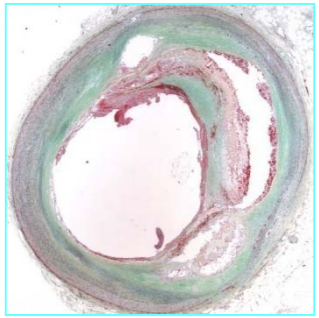
* outcome significantly reduced as compared to placebo (p<0.005)

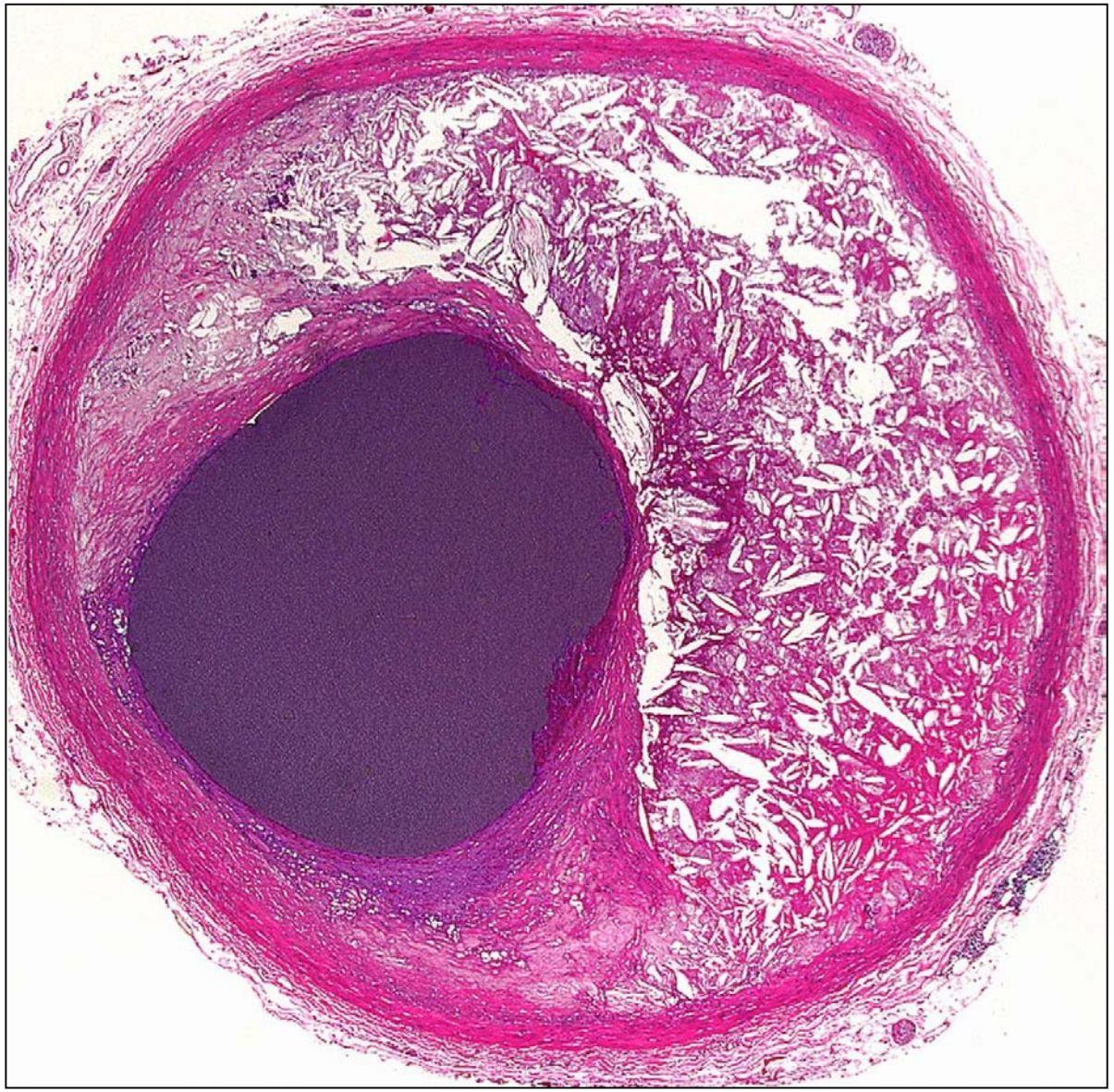
Savarese G, et al. JACC 2013; 61: 131-142

Picking Plaques That Pop!

Narula & DeMaria

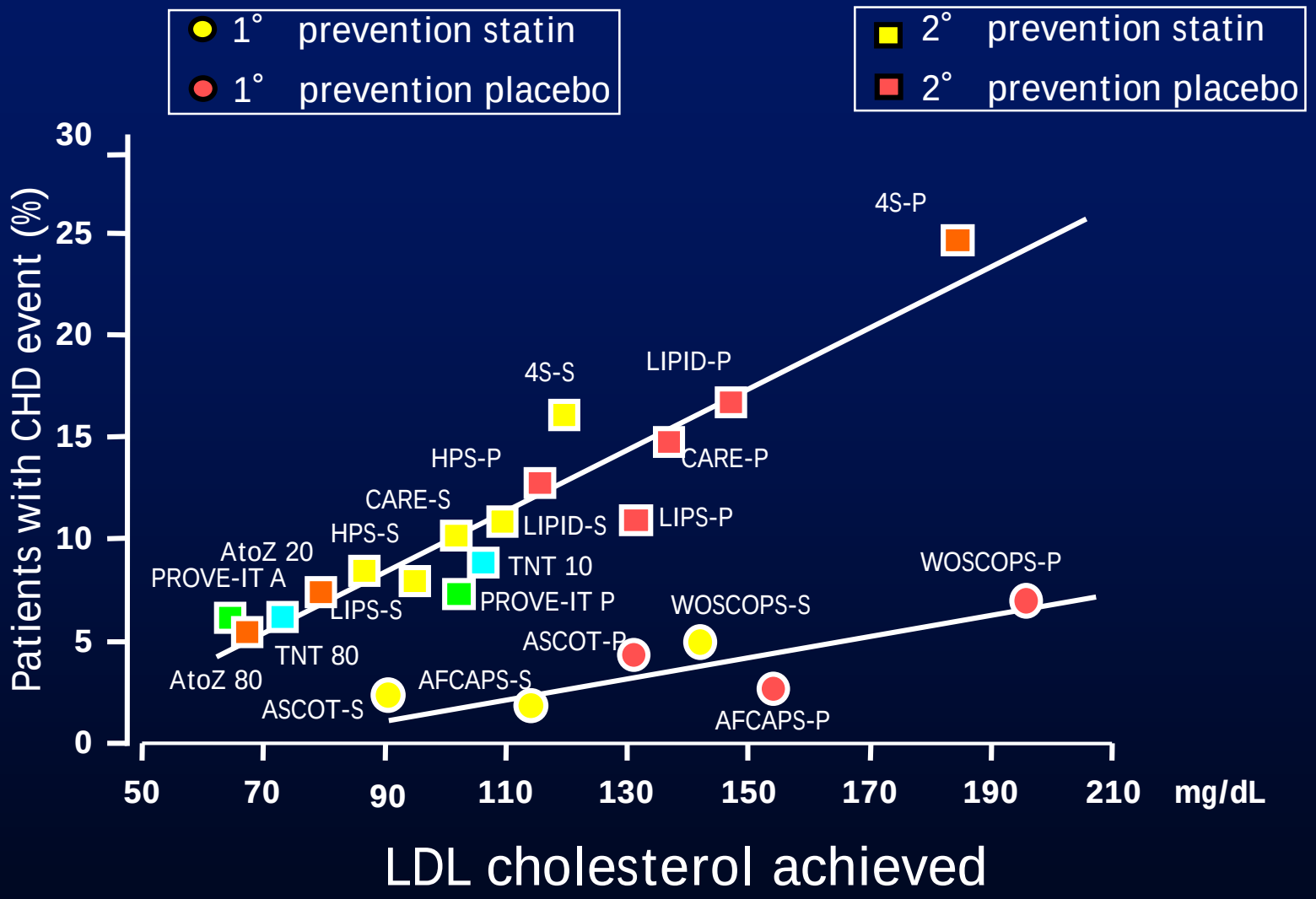
J Am Coll Cardiol [Editorial] 2005





From Virmani, Narula, Leon, Willerson; The Vulnerable Atherosclerotic Plaques: 2007

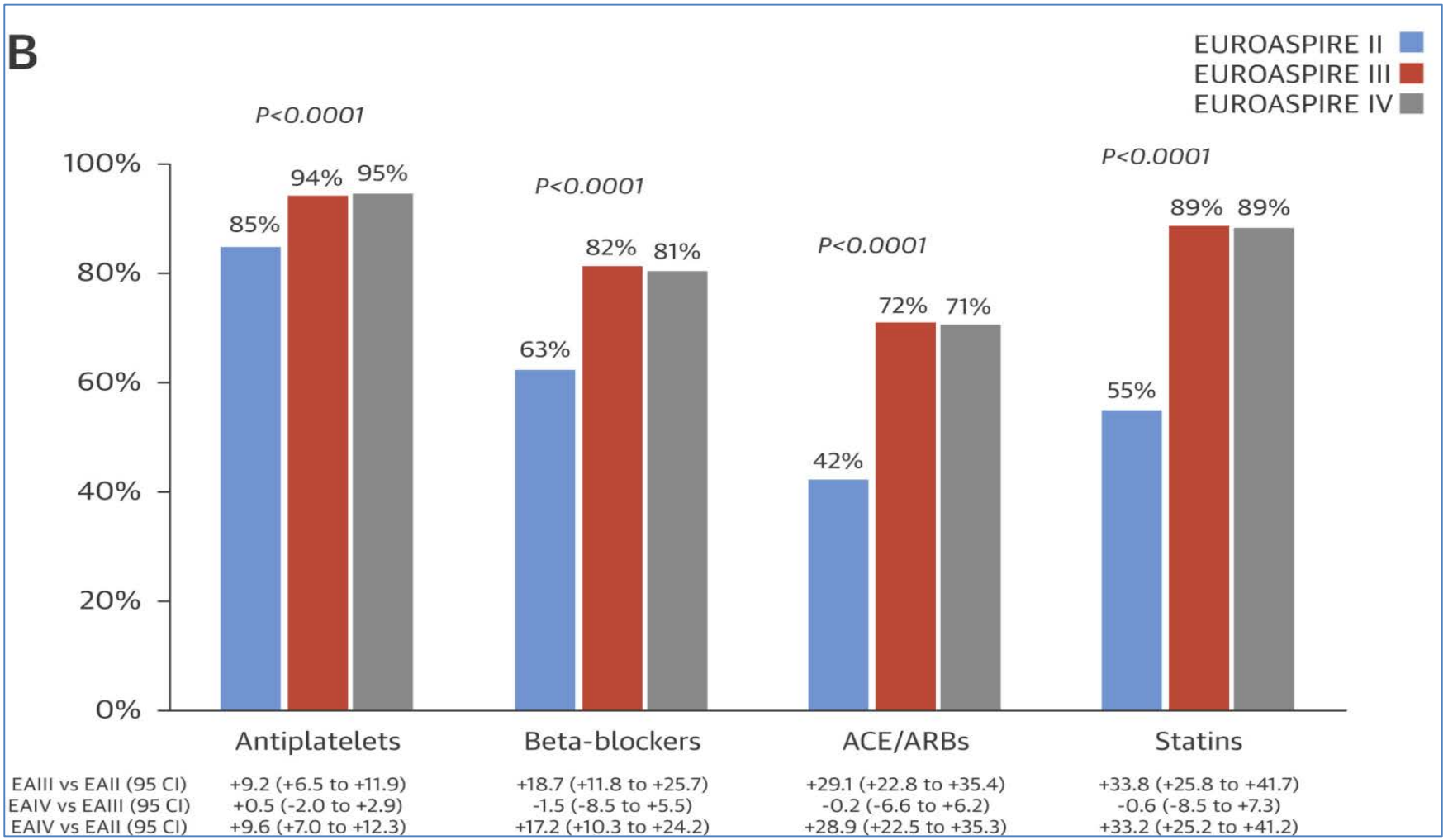
LDLc reduction and CV Protection



J.R.G. JUANATEY
C.H.U.Santiago

Ballantyne CM. Am J Cardiol 1998; O'Keefe JH et al, JACC 2004

Evidence based treatments in EUROASPIRE



Kotseva et al. J Am Coll Cardiol. 2015;66:1634-1636.

WHY ARE WE FAILING TO IMPLEMENT KNOWLEDGE:

A GLOBAL GAP IN TREATMENT OF CARDIVOVASCULAR DISEASE

Knowledge

ESC GUIDELINES

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

The Task Force on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology (ESC)

Authors/Task Force Members: Ph. Gabriel Steg (Chairperson) (France)*, Stefan K. James (Chairperson) (Sweden)*, Dan Atar (Norway), Luigi P. Badano (Italy), Carina Blömstrom-Lundqvist (Sweden), Michael A. Borger (Germany), Carlo Di Mario (United Kingdom), Kenneth Dickstein (Norway), Gregory Ducrocq (France), Francisco Fernandez-Aviles (Spain), Anthony H. Gershlick (United Kingdom), Pantaleo Gianrossi (Italy), Sigrun Halvorsen (Norway), Kurt Huber (Austria), Peter Juni (Switzerland), Adnan Kastrati (Germany), Juhani Knuuti (Finland), Mattie J. Lenzen (Netherlands), Kenneth W. Mahaffey (USA), Marco Valgimigli (Italy), Arnoud van 't Hof (Netherlands), Petr Widimsky (Czech Republic), Doron Zahger (Israel)

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Document Reviewers: David Hasdai (CPG Review Coordinator) (Israel), Felicita Astin (UK), Karin Åström-Olsson (Sweden), Andrzej Budaj (Poland), Peter Clemmensen (Denmark), Jean-Philippe Collet (France), Keith A. Fox (UK), Ahmet Hamdi Pusat (UK), Olivija Gustiene (Lithuania), Christian W. Hamm (Germany), Petr Kala (Czech Republic), Patrick Lancellotti (Belgium), Aldo Pietro Maggioni (Italy), Béla Merkely (Hungary), Franz-Josef Neumann (Germany), Massimo F. Piepoli (Italy), Frans Van de Werf (Belgium), Freek Verheugt (Netherlands), Lars Wallentin (Sweden)

System

Physician

Patient

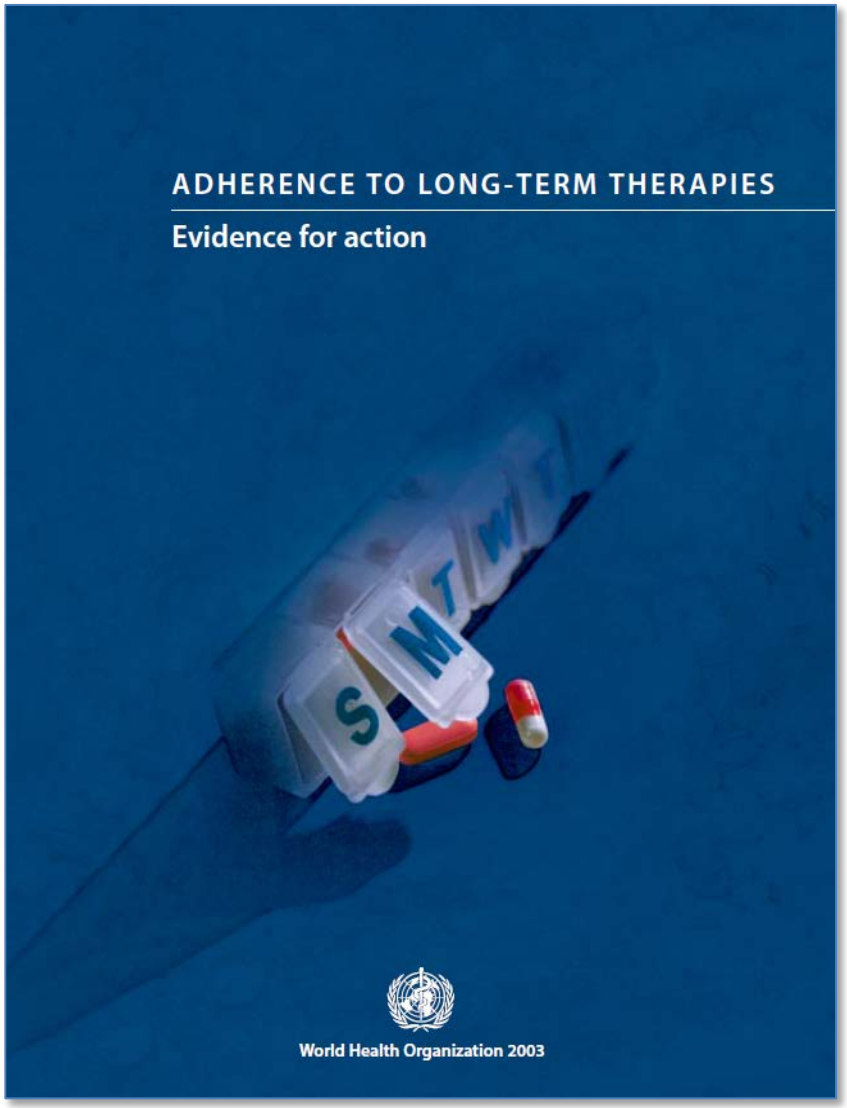
Accessibility

Adherence

Adherence

Implementation

Medication Non-Adherence

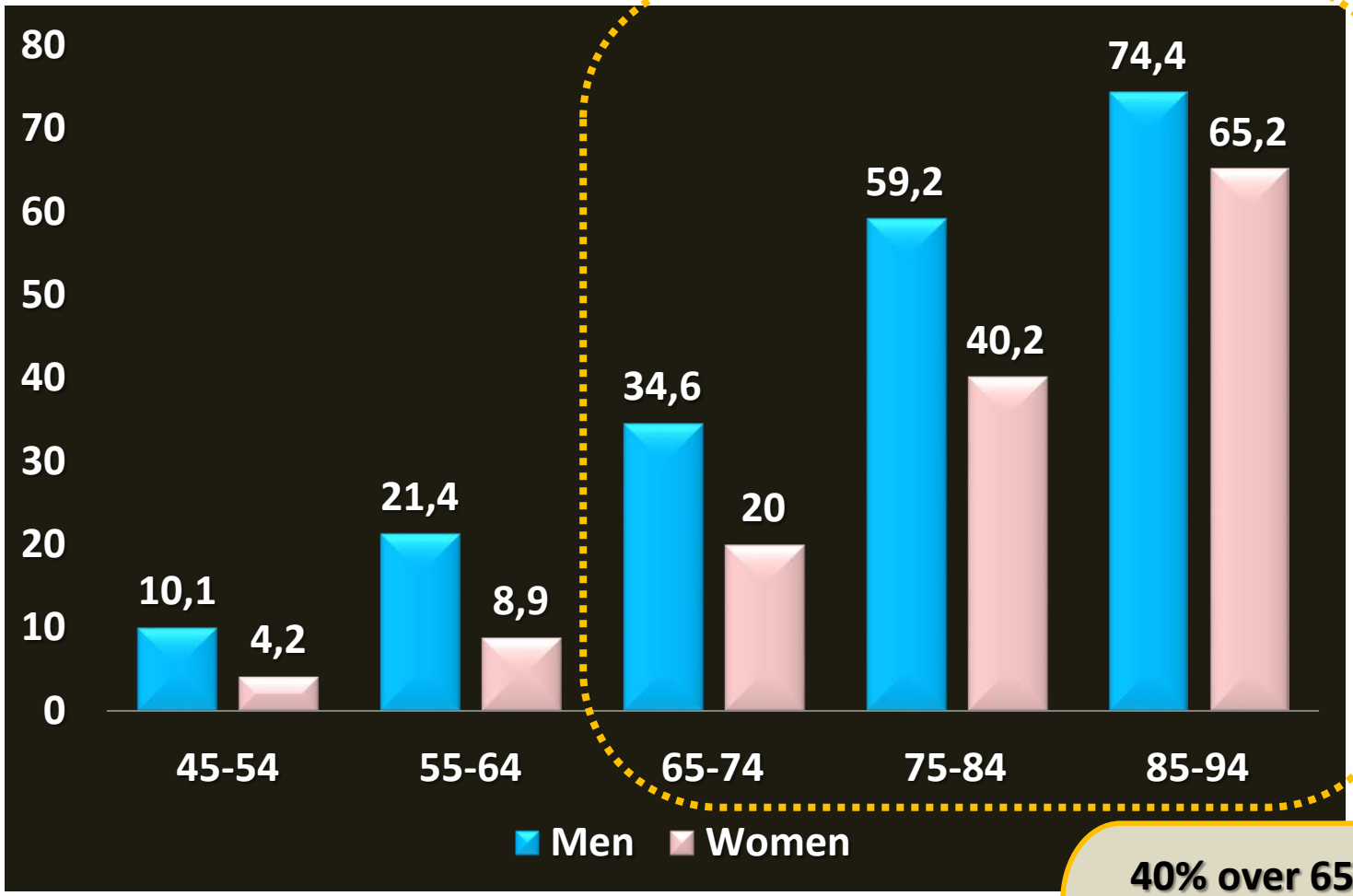


"Adherence is the degree to which a person's behavior in taking medication corresponds with agreed recommendations from a health care provider"

ADHERENCE TO LONG TERM THERAPIES: EVIDENCE FOR ACTION. WHO 2003

Importance of Age on Adherence to Cardiovascular Medications

Incidence (%) of Cardiovascular Disease by sex and age

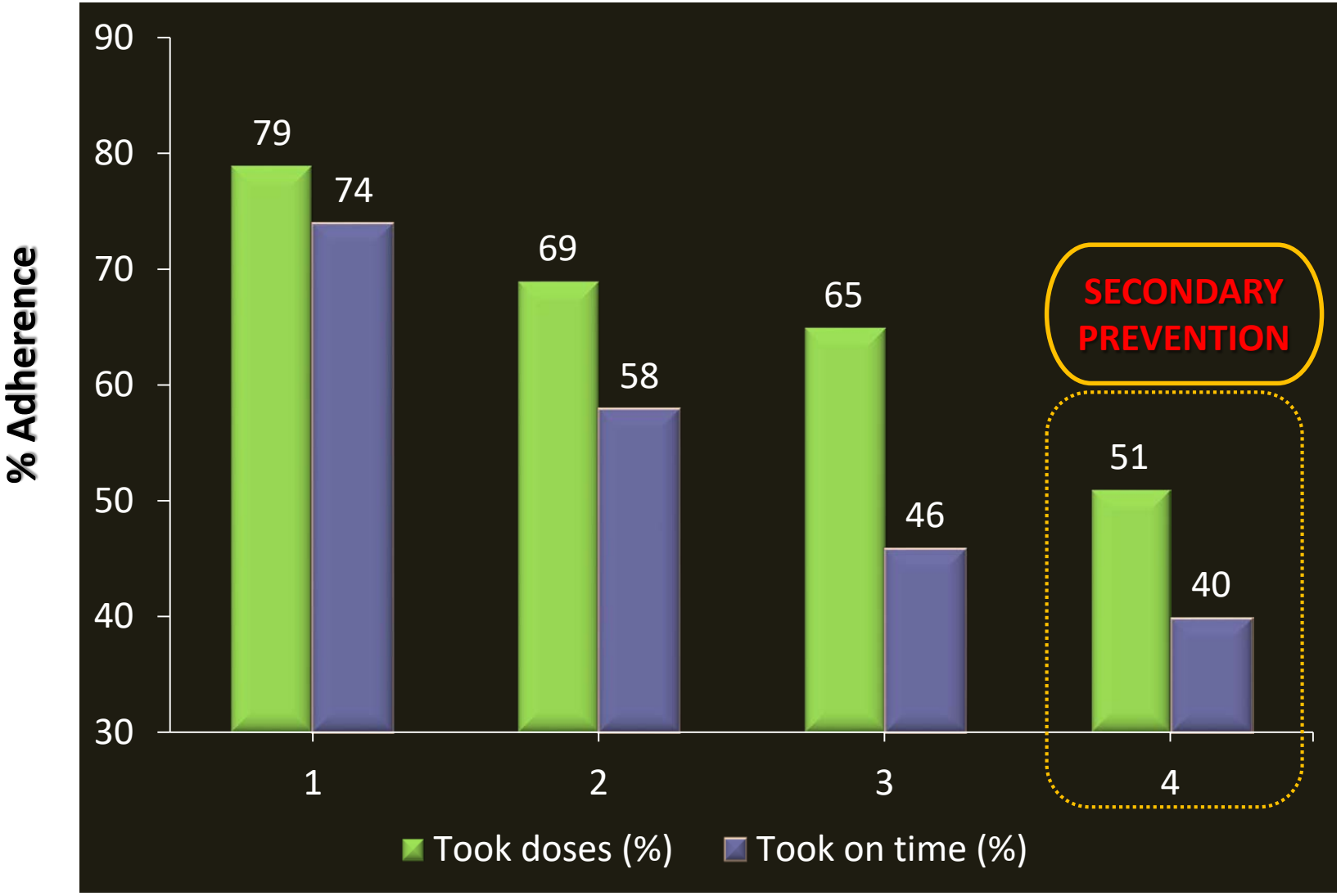


40% over 65 take over 4 pills

Go A. et al. AHA Statistical Update, Circulation, 2013; 129, 24-292

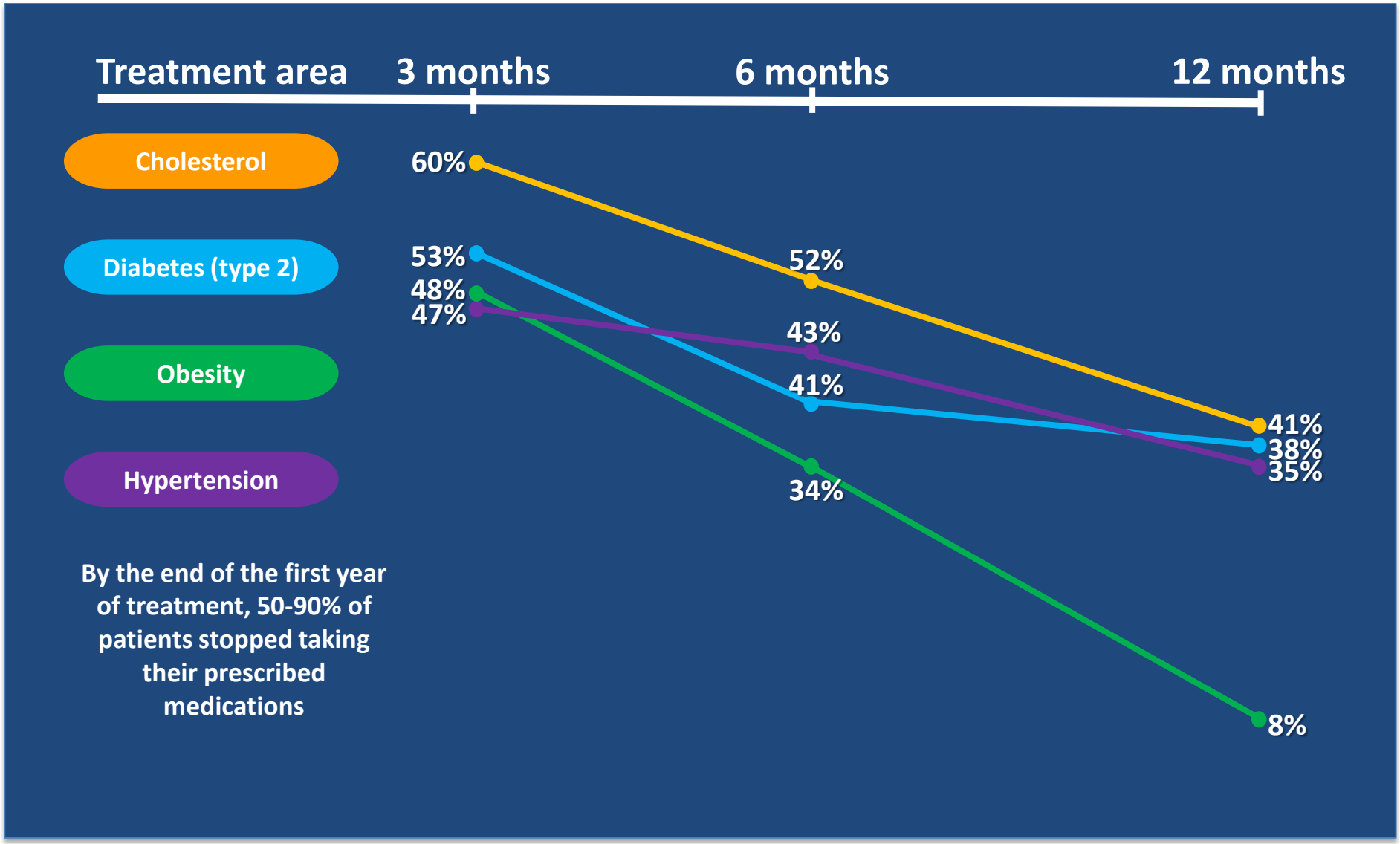
Haider SI et al. International Journal of Clinical Pharmacology and Therapeutics, 2007 45 (12): 643–653.

Direct association between dosing frequency and medication adherence



Claxon et al, Clinical Therapeutics, 2001. Vol 23, 8: 1296-1310

Adherence drops after first six months



Castellano JM, et al. , *Global Heart*. **2013** ;8:263

Prevalence of Good Adherence to CV Medications

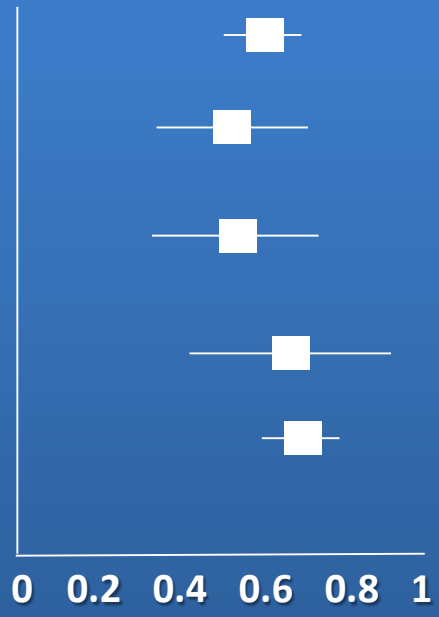
European Heart Journal
doi:10.1093/eurheartj/eht295

CLINICAL RESEARCH
Prevention and epidemiology

Adherence to cardiovascular therapy: a meta-analysis of prevalence and clinical consequences

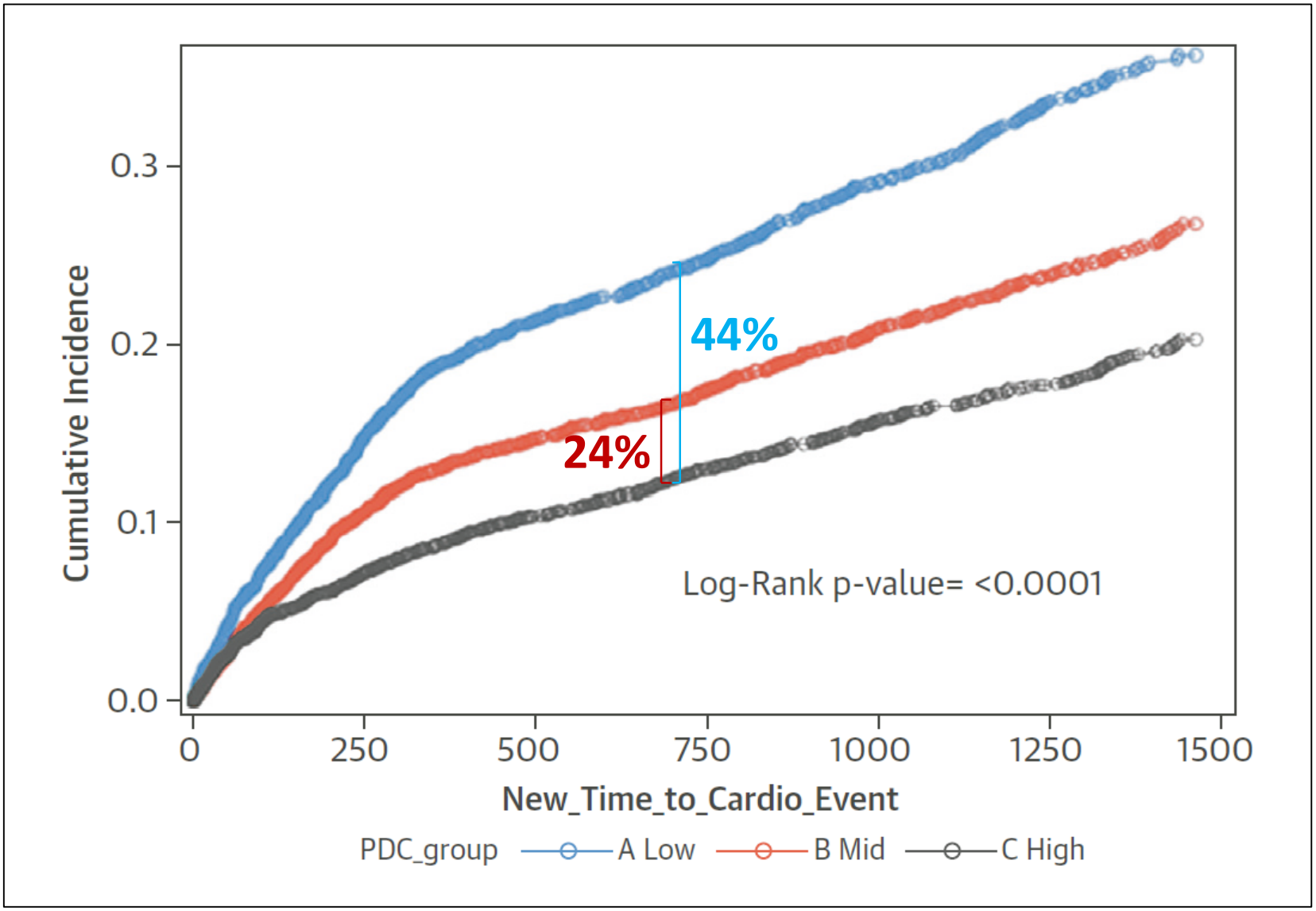
n=1,978,919 (135,627 CVD events and 94,126 cases of all-cause mortality)

	No. of Studies	No. of Participants	Proportion (95% CI)
Adherence to any CVD Medication	34	1.230.382	0,60 (0,52-0,68)
Adherence to STATINS	12	771.323	0,54 (0,41-0,67)
Adherence to ANTIHYPERTENSIVES	11	363.819	0,54 (0,42-0,77)
Adherence to ASPIRIN	2	11.068	0,70 (0,49-0,91)
Adherence to ANTIDIABETIC AGENTS	2	1112	0,69 (0,59-0,78)



Chowdhury R et al. EHJ, 2013;34(38):2940-8.

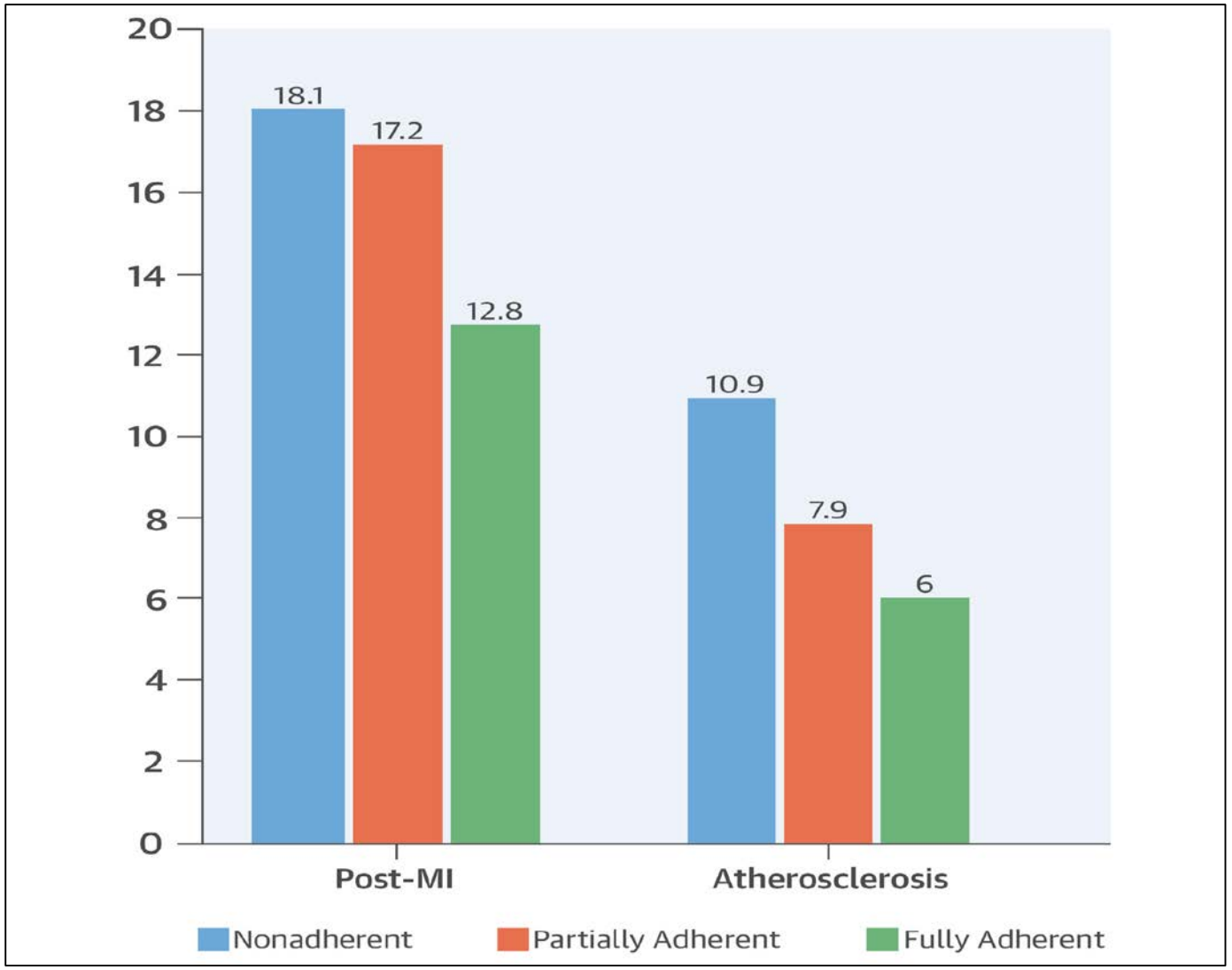
Time to Major cardiac Event by Adherence Levels



Bansilal S, Castellano JM, Fuster V et al, . *J Am Coll Cardiol*. 2016 Aug 23;68(8):789-801

Adherence Levels and MACE

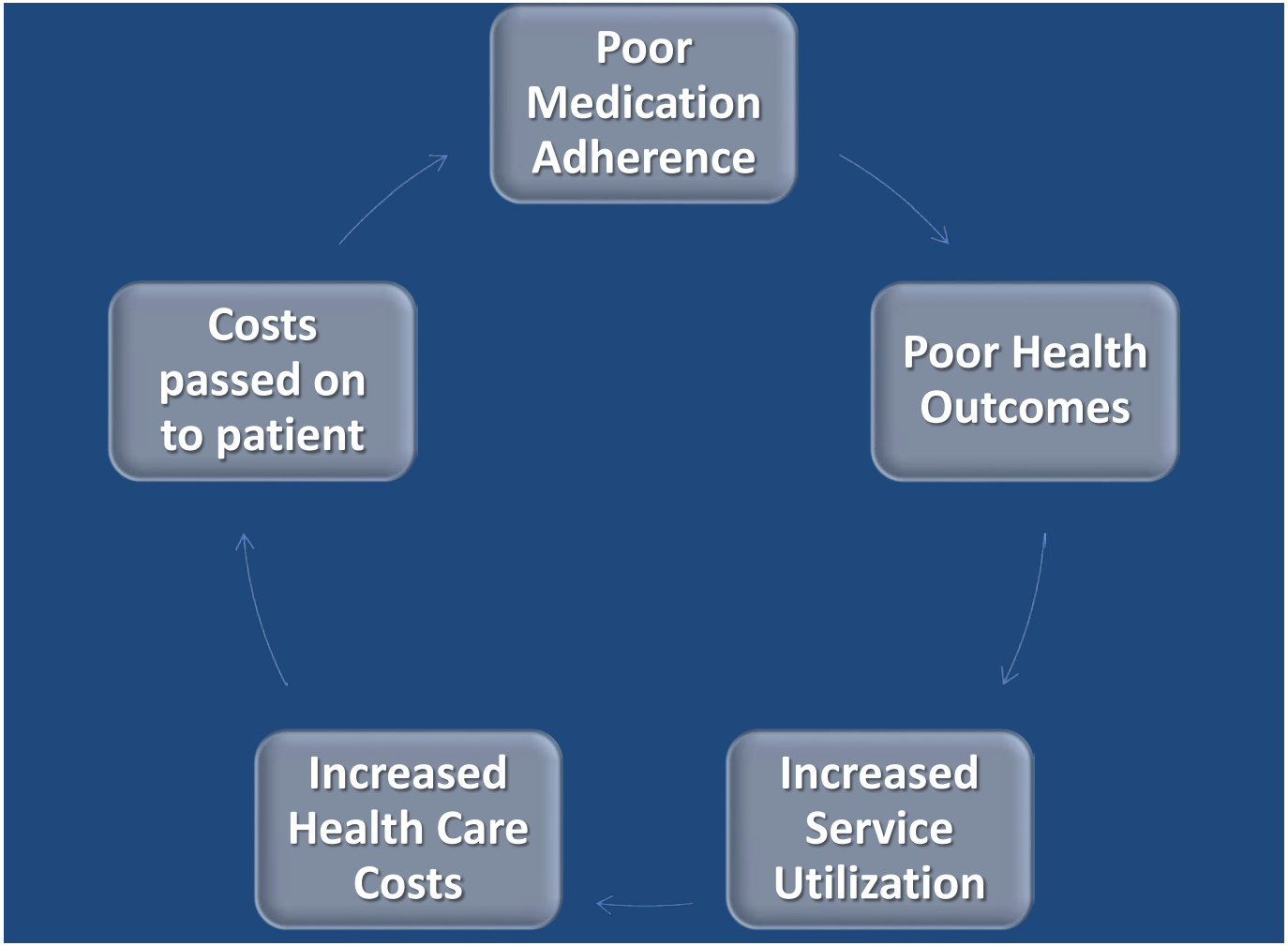
(Hospitalizations per 100 Patient – years)



Bansilal S, Castellano JM, Fuster V et al, . *J Am Coll Cardiol*. 2016 Aug 23;68(8):789-801

Medication Non-Adherence

Impact on Health Care Costs

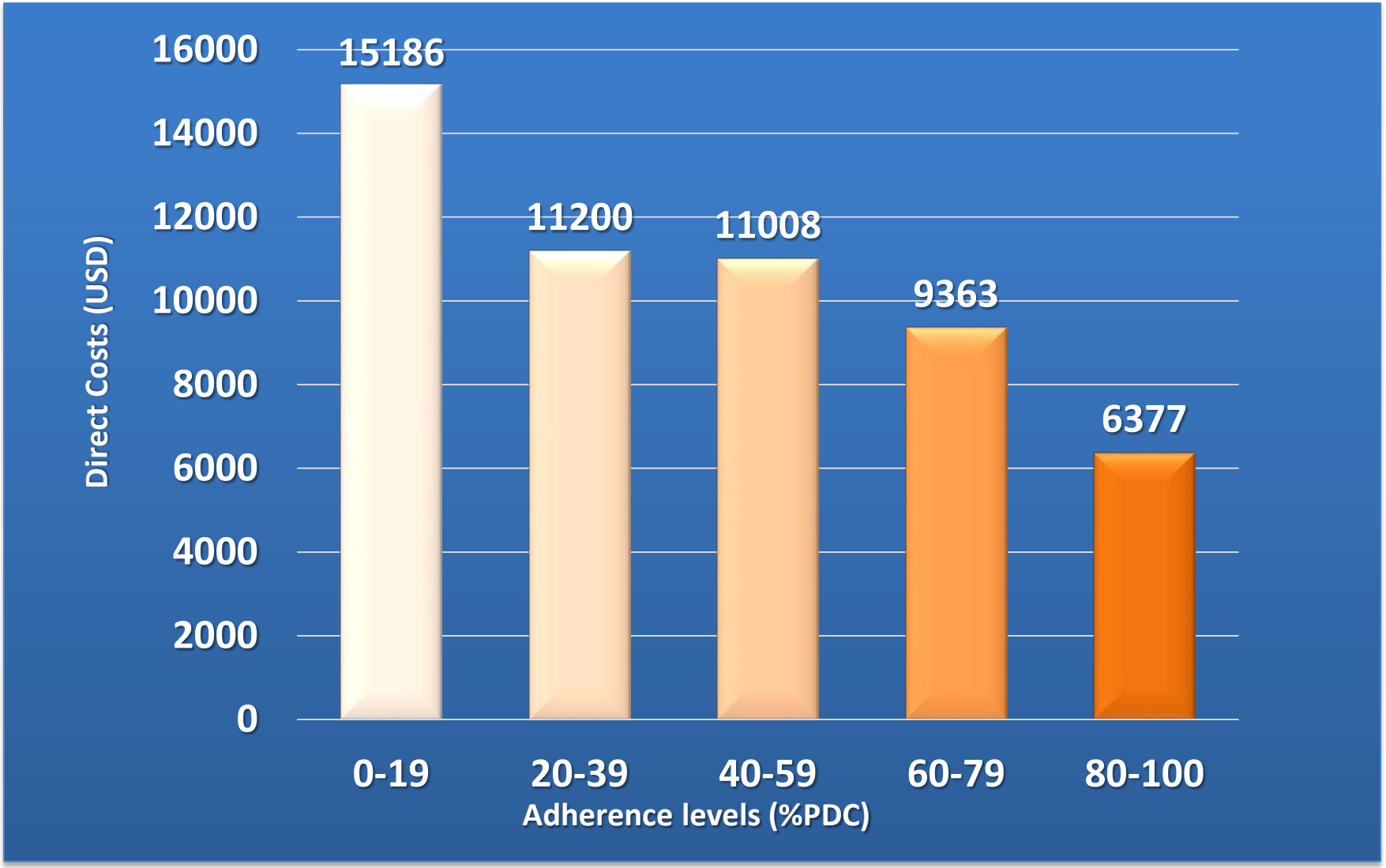


Iuga A. et al. *Risk Management and Health Care Policy*. 2014:7 35-44

Medication Non-Adherence

Impact on Health Care Costs

n=137227 DM, HT, Hchol, CHF



Sokol M et al 2005 *Medical Care*. 43(6):521-530..

Adherence to Medication in the Guidelines

From "get on with the guidelines" to "strategies to improve adherence"

European Heart Journal Advance Access published May 23, 2016

European Heart Journal
doi:10.1093/eurheartj/ehw106

JOINT ESC GUIDELINES

2016 European Guidelines on cardiovascular disease prevention in clinical practice

The Sixth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of 10 societies and by invited experts)

Developed with the special contribution of the European Association for Cardiovascular Prevention & Rehabilitation (EACPR)

Authors/Task Force Members: Massimo F. Piepoli* (Chairperson) (Italy), Arno W. Hoes* (Co-Chairperson) (The Netherlands), Stefan Agewall (Norway)[1], Christian Albus (Germany)[9], Carlos Brotons (Spain)[10], Alberico L. Catapano (Italy)[3], Marie-Therese Cooney (Ireland)[1], Ugo Corrà (Italy)[1], Bernard Cosyns (Belgium)[1], Christi Deaton (UK)[1], Ian Graham (Ireland)[1], Michael Stephen Hall (UK)[7], F. D. Richard Hobbs (UK)[10], Maja-Lisa Løchen (Norway)[1], Herbert Löllgen (Germany)[8], Pedro Marques-Vidal (Switzerland)[1], Joep Perk (Sweden)[1], Eva Prescott (Denmark)[1], Josep Redon (Spain)[5], Dimitrios J. Richter (Greece)[1], Naveed Sattar (UK)[2], Yvo Smulders (The Netherlands)[1], Monica Tiberi (Italy)[1], H. Bart van der Worp (The Netherlands)[6], Ineke van Dis (The Netherlands)[4], W. M. Monique Verschuren (The Netherlands)[1]

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Arno W. Hoes, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, PO Box 85500 (HP Str. 6.131), 3508 GA Utrecht, The Netherlands, Tel: +31 88 756 8193, Fax: +31 88 756 8099, E-mail: a.w.hoes@umcutrecht.nl.

ESC Committee for Practice Guidelines (CPG) and National Cardiac Societies document reviewers: listed in the Appendix.

ESC entities having participated in the development of this document:

Associations: European Association for Cardiovascular Prevention & Rehabilitation (EACPR), European Association of Cardiovascular Imaging (EACVI), European Association of Percutaneous Cardiovascular Interventions (EAPCI), Heart Failure Association (HFA).

Councils: Council on Cardiovascular Nursing and Allied Professions, Council for Cardiology Practice, Council on Cardiovascular Primary Care.

Working Groups: Cardiovascular Pharmacotherapy

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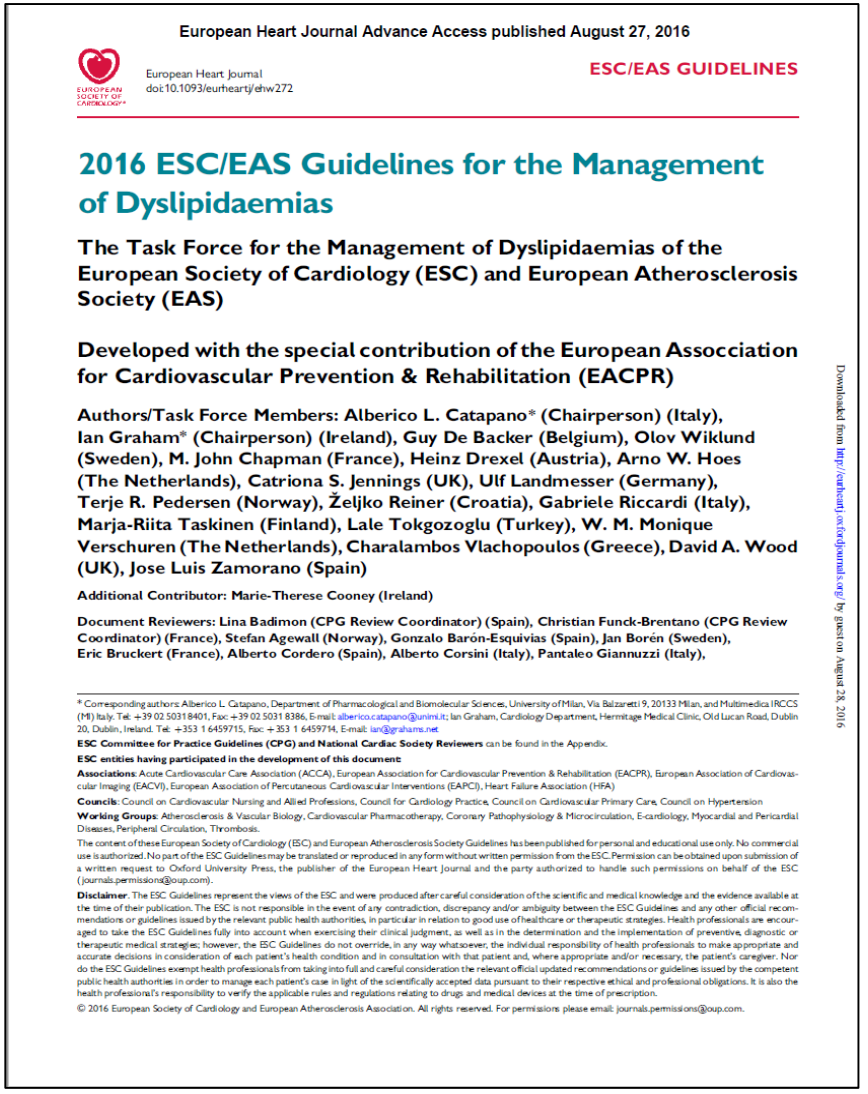

European Heart Journal Advance Access published August 27, 2016

European Heart Journal
doi:10.1093/eurheartj/ehw272

ESC/EAS GUIDELINES

2016 ESC/EAS Guidelines for the Management of Dyslipidaemias

The Task Force for the Management of Dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS)

Developed with the special contribution of the European Assocciation for Cardiovascular Prevention & Rehabilitation (EACPR)

Authors/Task Force Members: Alberico L. Catapano* (Chairperson) (Italy), Ian Graham* (Chairperson) (Ireland), Guy De Backer (Belgium), Olov Wiklund (Sweden), M. John Chapman (France), Heinz Drexel (Austria), Arno W. Hoes (The Netherlands), Catriona S. Jennings (UK), Ulf Landmesser (Germany), Terje R. Pedersen (Norway), Željko Reiner (Croatia), Gabriele Riccardi (Italy), Marja-Riita Taskinen (Finland), Lale Tokgozoglu (Turkey), W. M. Monique Verschuren (The Netherlands), Charalambos Vlachopoulos (Greece), David A. Wood (UK), Jose Luis Zamorano (Spain)

Additional Contributor: Marie-Therese Cooney (Ireland)

Document Reviewers: Lina Badimon (CPG Review Coordinator) (Spain), Christian Funck-Brentano (CPG Review Coordinator) (France), Stefan Agewall (Norway), Gonzalo Barón-Esquivias (Spain), Jan Borén (Sweden), Eric Bruckert (France), Alberto Cordero (Spain), Alberto Corsini (Italy), Pantaleo Giannuzzi (Italy),

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ESC Committee for Practice Guidelines (CPG) and National Cardiac Society Reviewers can be found in the Appendix.

ESC entities having participated in the development of this document:

Associations: Acute Cardiovascular Care Association (ACCA), European Association for Cardiovascular Prevention & Rehabilitation (EACPR), European Association of Cardiovascular Imaging (EACVI), European Association of Percutaneous Cardiovascular Interventions (EAPCI), Heart Failure Association (HFA)

Councils: Council on Cardiovascular Nursing and Allied Professions, Council for Cardiology Practice, Council on Cardiovascular Primary Care, Council on Hypertension

Working Groups: Atherosclerosis & Vascular Biology, Cardiovascular Pharmacotherapy, Coronary Pathophysiology & Microcirculation, E-cardiology, Myocardial and Pericardial Diseases, Peripheral Circulation, Thrombosis.

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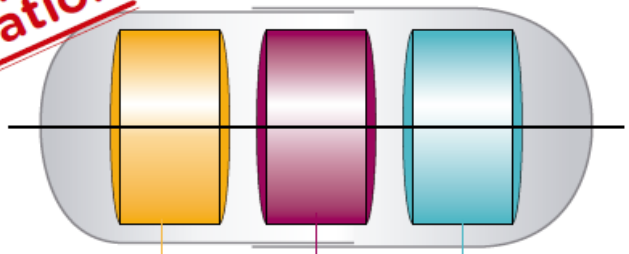
Polypill for Cardiovascular Prevention
From Research to Clinical Practice

trinomia

acetylsalicylic acid • atorvastatin • ramipril

Treatment and adherence available for everyone

galenic innovation

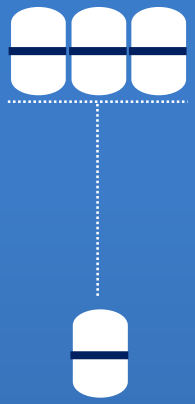


Acetylsalicylic acid
Platelet antiaggregation

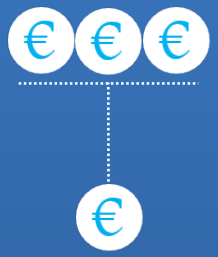
Atorvastatin
Plaque stabilisation

Ramipril
Myocardial remodelling

cnic ferrer



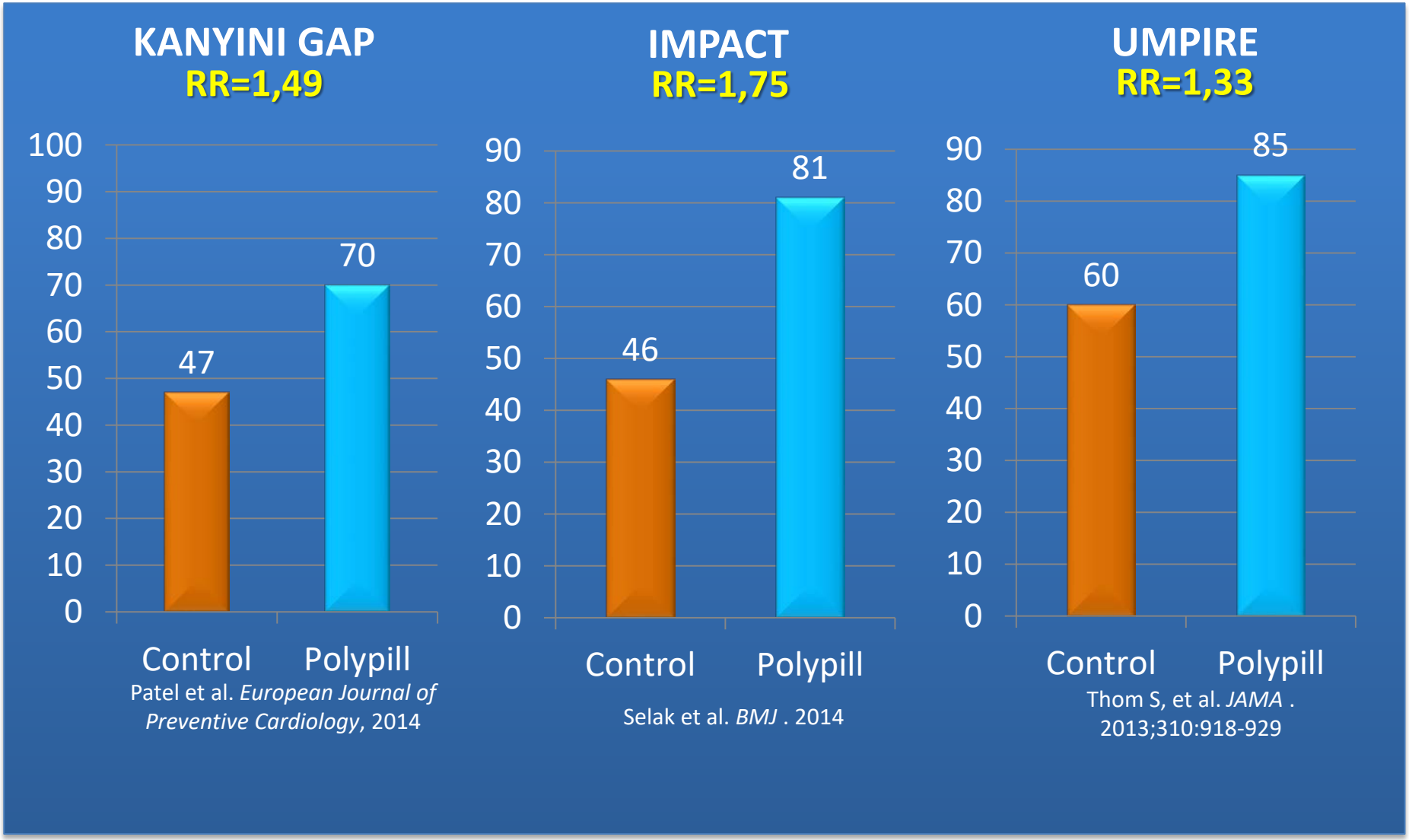
Increases Patient/Physician Compliance



Reduces Health Care Costs

Improves accesibility to proven medication

RCTS USING A POLYPILL TO STUDY THE EFFECT ON ADHERENCE



Castellano JM et al, *J Am Coll Cardiol*. 2014;64(6):613-621

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http://dx.doi.org/10.1016/j.jacc.2014.08.021

ORIGINAL INVESTIGATIONS

A Polypill Strategy to Improve Adherence

Results From the FOCUS Project

CME

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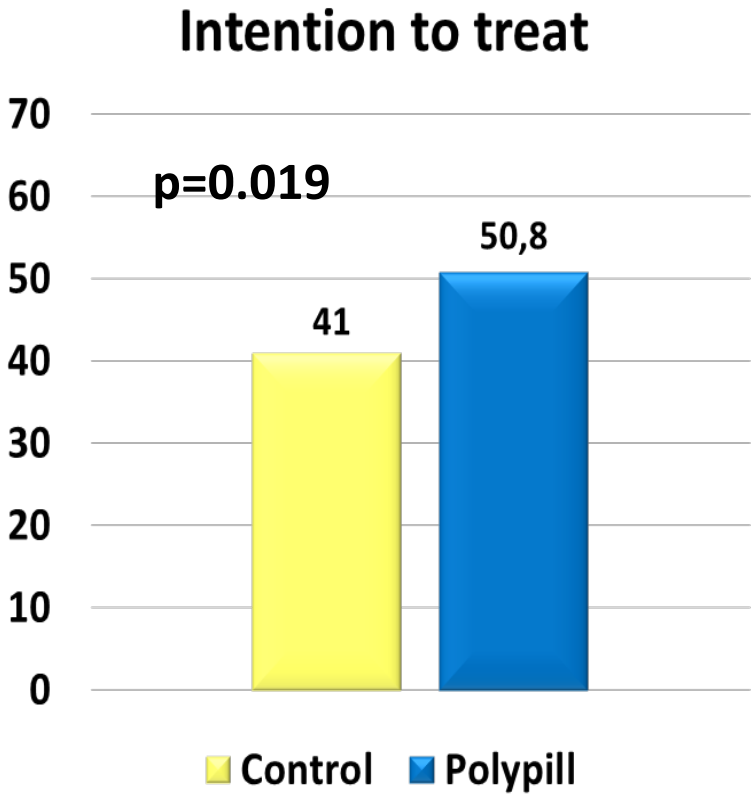
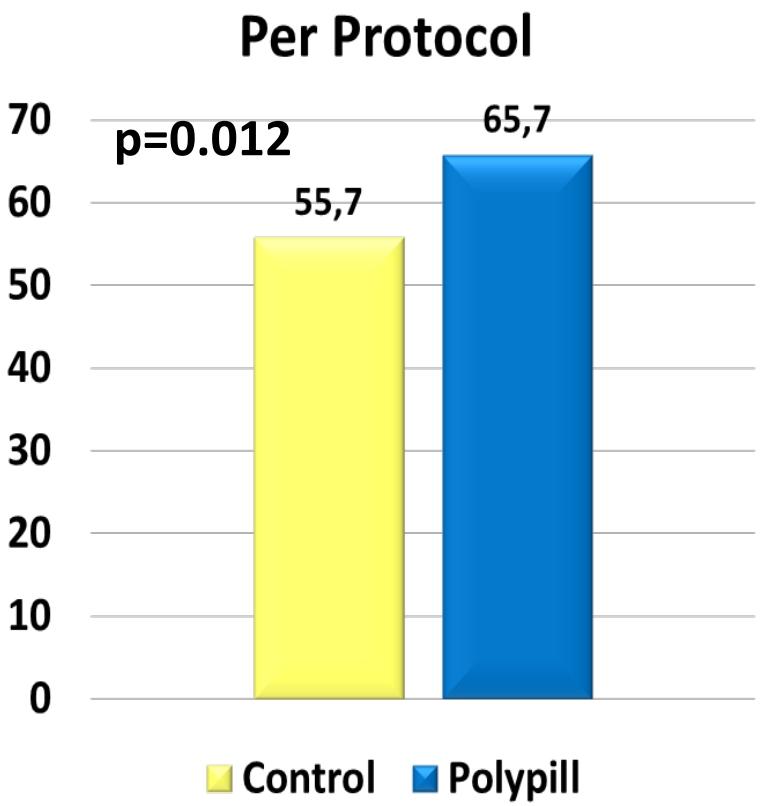
JACC JOURNAL CME

FOCUS Project: Phase 2, Results

10% adherence increase with the CNIC-Ferrer polypill (Trinomia ASR) in patients with long-term evaluated CV disease



Attending Visit 3+ MAQ=20+Pill Count 80-110



Attending all visits+MAQ=20+Pill Count 80-110

Castellano JM et al. A Polypill Strategy to Improve Adherence: Results From the FOCUS Project. J Am Coll Cardiol. 2014 Sep 1. pii: S0735-1097(14)05941-5. doi: 10.1016/j.jacc.2014.08.021 .

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SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE IN THE ELDERLY

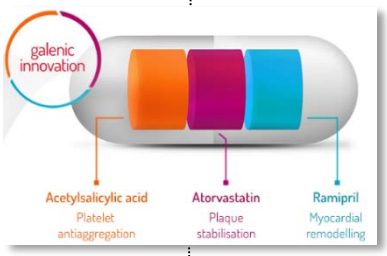
cnic · Instituto de Salud Carlos III · Charité Universitätsmedizin Berlin · Mario Negri Istituto di Ricerche Farmacologiche · CHRU Besançon · London School of Hygiene & Tropical Medicine · ferrer · UMW · Hospital Clínico San Carlos SaludMadrid · Comunidad de Madrid · ARTTIC

Hypothesis

Poor adherence leads to poor outcomes and a polypill strategy leads to better adherence. Hence the implementation of a polypill strategy in post MI setting should lead to better clinical outcomes.

Study Overview

n=3200
Post MI >65



FU: 2-4 years

MACE
Cardiovascular death
Nonfatal myocardial infarction
Nonfatal ischemic stroke
Urgent revascularization

Partners | Inclusion

ferrer

ARTTIC
INTERNATIONAL MANAGEMENT SERVICES

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

cnic

HORIZON 2020
THE FRAMEWORK PROGRAMME FOR RESEARCH AND INNOVATION

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SECONDARY PREVENTION OF CARDIOVASCULAR DISEASE IN THE ELDERLY

A step ahead in secondary prevention of cardiovascular risk

Consensus document on clinical use of the polypill

Polypill in CV secondary prevention. Clinical criteria related with a preferential access

- ***Patients with history of non-compliance*** or with predictors of drug non-compliance.
- Patients ***treated and controled with the individual polypill components.***
- Patients with history of ***non-compliance and good control with equivalent doses of the individual polypill components.***
- Patients with ***several co-morbidities and poly-pharmacy.***

Clinical situations when can be started the Polypill treatment

- During hospital admission for an ***Acute CV event*** when are expected dificulties with*:
  - Patient compliance,
  - Treatment accesibility,
  - Follow-up

✓

In stable patients after a CV event, when ***low compliance*** was identified during the follow-up.

✓

- ***In patients with ply-pharmacy*** or when asking for reduction in the number of pills, independent to the patient compliance status.

✓

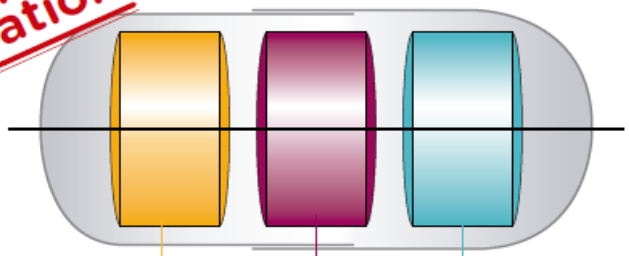
*Plypill prescription during hospital admission or after hospital discharge is related to the health care system/hospital characteristics.

The *"New Polypill"* for Cardiovascular Prevention
From Hospital to Outpatient Care

trinomia
acetylsalicylic acid • atorvastatin • ramipril

Treatment and adherence available for everyone

galenic innovation



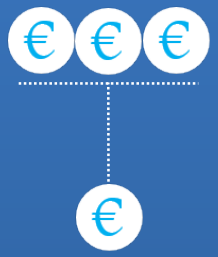
Acetylsalicylic acid
Platelet antiaggregation

Ramipril
Myocardial remodelling

Atorvastatin 40 mgs

cnic ferrer

Increases Patient/Physician Compliance from Hospital Discharge



Reduces Health Care Costs

Improves accesibility to proven medication

*Polypill in patients with high- and very-high CV Risk with Subclinical CV Disease?**

1. ***Hypertensive patients with high CV Risk*** : **hypertensive patients + any of the clinical characteristics:**
   - ❖ **LVH, microalbuminuria / proteinuria or kidney dysfunction, or high pulse wave velocity or increased carotid IMT or atherothrombotic plaque or ABI<0.9**

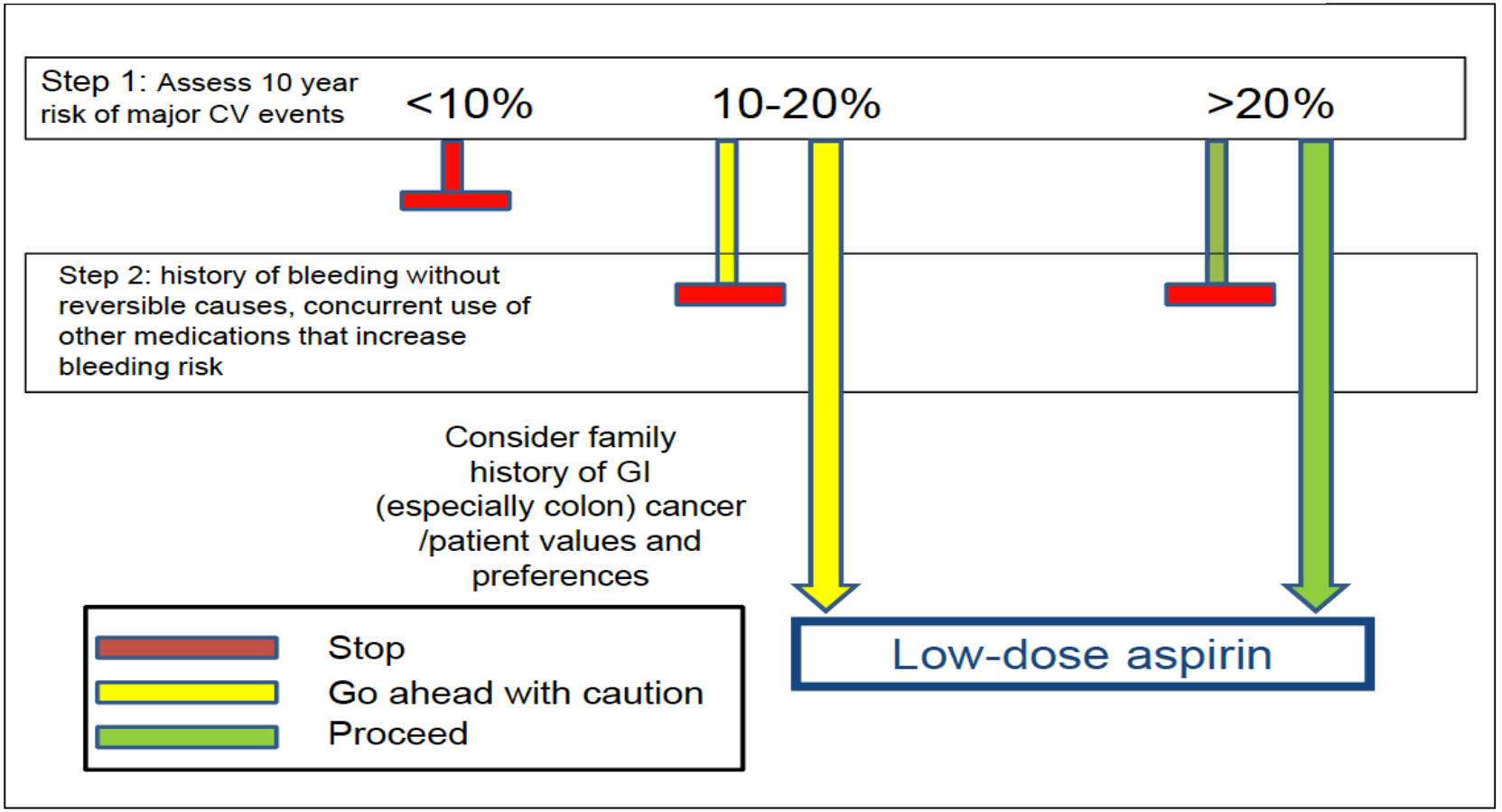
2. ***Diabetic or hypertensive patients with microalbuminuria / proteinuria*** **irrespective to the presence of other markers of subclinical CV disease**.**

*In patients without a high bleeding risk

** Also can be considered in normotensive patients.

Aspirin Therapy in Primary Cardiovascular Disease Prevention

A Position Paper of the European Society of Cardiology Working Group on Thrombosis



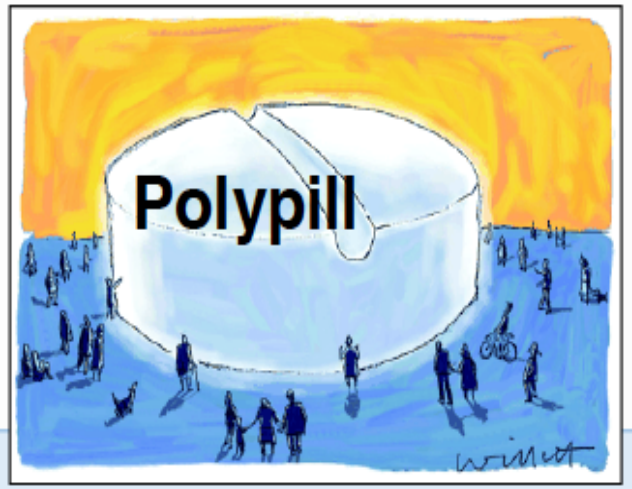
Halvorsen S et al JACC 2014; 64:319 - 327

Compliance Challenge

Patient compliance

Physician compliance

Get with the pills



Get with the guidelines


SOCIEDAD ESPAÑOLA DE
Cardiología


SOCIEDAD INTERAMERICANA DE CARDIOLOGIA
INTERAMERICAN SOCIETY OF CARDIOLOGY
SOCIETE INTERAMERICAINE DE CARDIOLOGIE
SOCIEDADE INTERAMERICANA DE CARDIOLOGIA

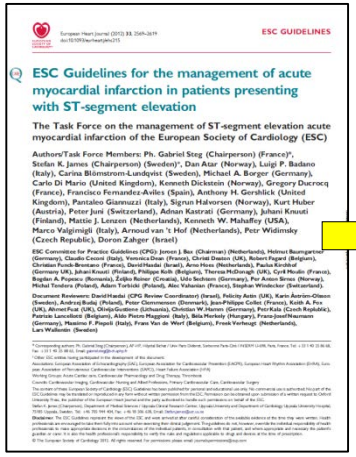

ASOCIACION NACIONAL DE CARDIOLOGOS DE MEXICO
PREVENIR ES NUESTRA META


SOCIEDAD MEXICANA DE CARDIOLOGIA
PLUS EST EN TOI


SOCIEDAD ARGENTINA
DE CARDIOLOGIA


FEDERACION ARGENTINA DE CARDIOLOGIA

WHY ARE WE FAILING TO IMPLEMENT KNOWLEDGE: A GLOBAL GAP IN TREATMENT OF CARDIVOVASCULAR DISEASE



ESC GUIDELINES

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

The Task Force on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology (ESC)

Authors/Task Force Members: Ph. Gabriel Steg (Chairperson) (France)*, Stefan K. James (Chairperson) (Sweden)*, Dan Atar (Norway), Luigi P. Badano (Italy), Carina Blömstrom-Lundqvist (Sweden), Michael A. Borger (Germany), Carlo Di Mario (United Kingdom), Kenneth Dickstein (Norway), Gregory Ducrocq (France), Francisco Fernandez-Aviles (Spain), Anthony H. Gershlick (United Kingdom), Pantaleo Giannuzzi (Italy), Sigrun Halvorsen (Norway), Kurt Huber (Austria), Peter Juni (Switzerland), Adnan Kastrati (Germany), Juhani Knuuti (Finland), Mattie J. Lenzen (Netherlands), Kenneth W. Mahaffey (USA), Marco Valgimigli (Italy), Arnoud van 't Hof (Netherlands), Petr Widimsky (Czech Republic), Doron Zahger (Israel)

"Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments"