Lipid-lowering: the evidence, the guidelines, the clinical reality

EPCCS Summit, Barcelona

March 15, 2018

Frank L.J. Visseren

University Medical Center Utrecht

Vascular Medicine Utrecht

State of the Union 2015:

"Precision medicine gives us one of the greatest opportunities for new medical breakthroughs that we have ever seen…"

"…delivering the right treatments, at the right time, every time to the right person…"

"…the possibility of applying medicines more efficiently and more effectively so that the success rates are higher…"

"…a new wave of advances just like genetics 25 years ago…"

State of the Union 2015:

"…what we want is that we can make better life decisions and making sure that we've got a system that focuses on prevention and keeping healthy, not just on curing diseases after they happen."

"…I'm asking researchers to join us in this effort. And I'm asking entrepreneurs and non-profits to help us create tools that give patients the chance to get involved as well."

Greatest challenge for a clinician

Universitair Medisch Centrum Utrecht

Translating the results of (large) randomized clinical trials to treatment of individual patients

I. Lipid-lowering: the evidence

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- Lipids are (the most) important CV risk factor
- Overwhelming evidence
- The lower LDL-c, the lower CV risk

Most important risk factors for MI (INTERHEART study)

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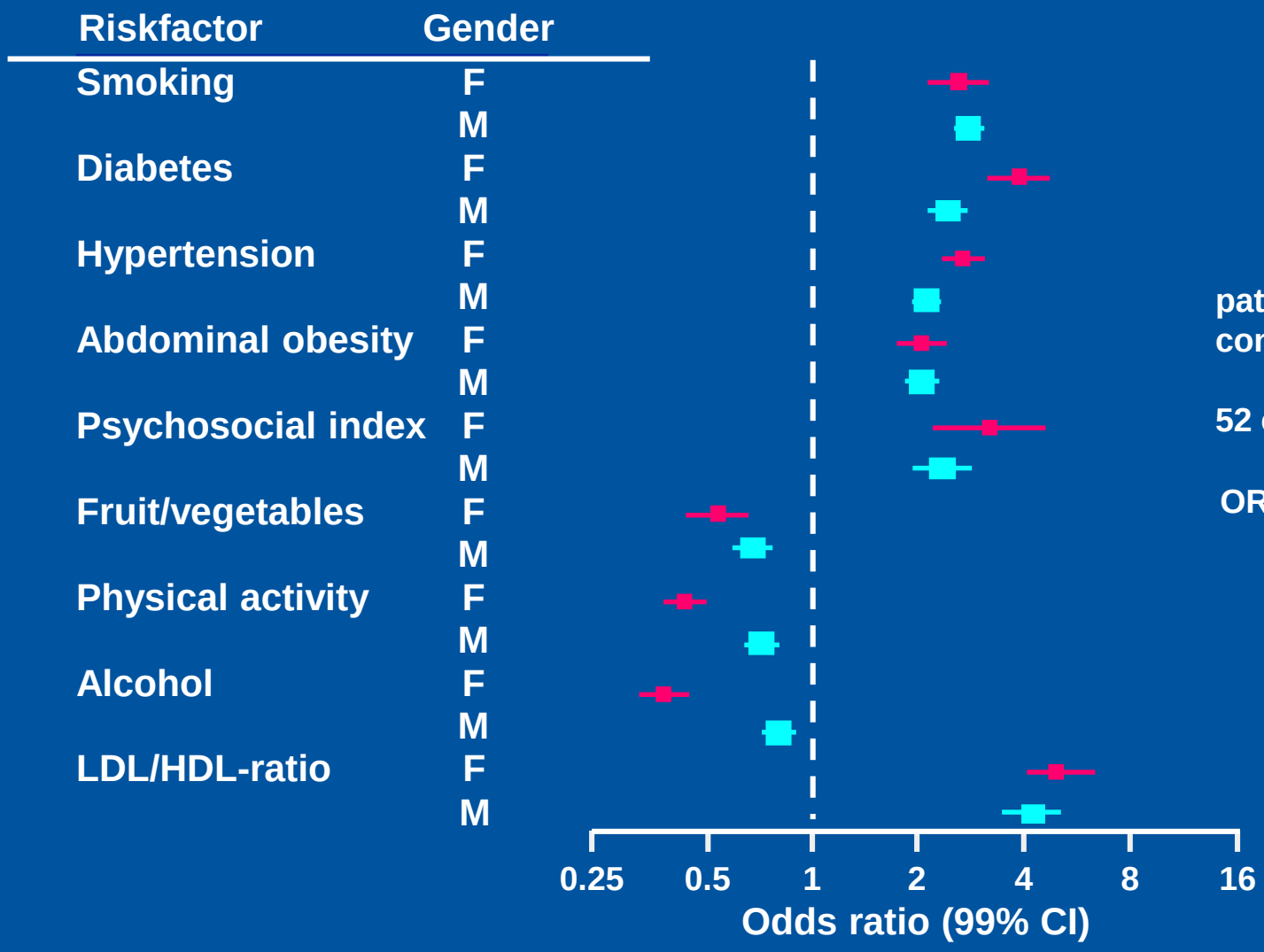


patients: 15.152
controls: 14.820

52 countries

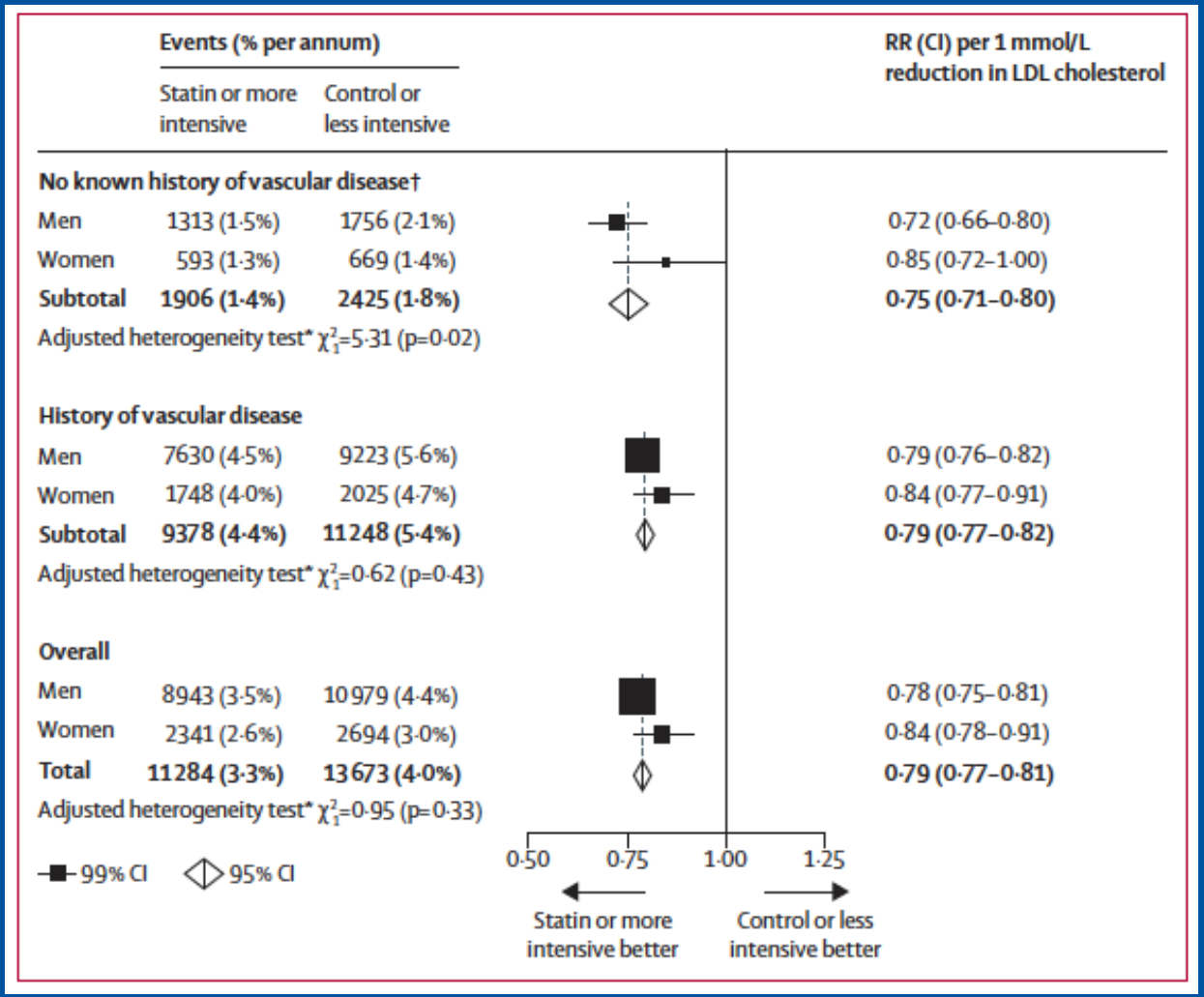
ORs adjusted for:
- age
- gender
- geographic region

Yusuf S et al. Lancet. 2004;364:937-52.

Efficacy and safety of LDL-lowering therapy among men and women: meta-analysis of individual data from 174 000 participants in 27 randomised trials

*Cholesterol Treatment Trialists' (CTT) Collaboration**

University Medical Center Utrecht



1 mmol/l ↓ LDL-c =
21% ↓ CV risk

Lancet 2015;385:1397-1405

Lower LDL-c is better in CV patients

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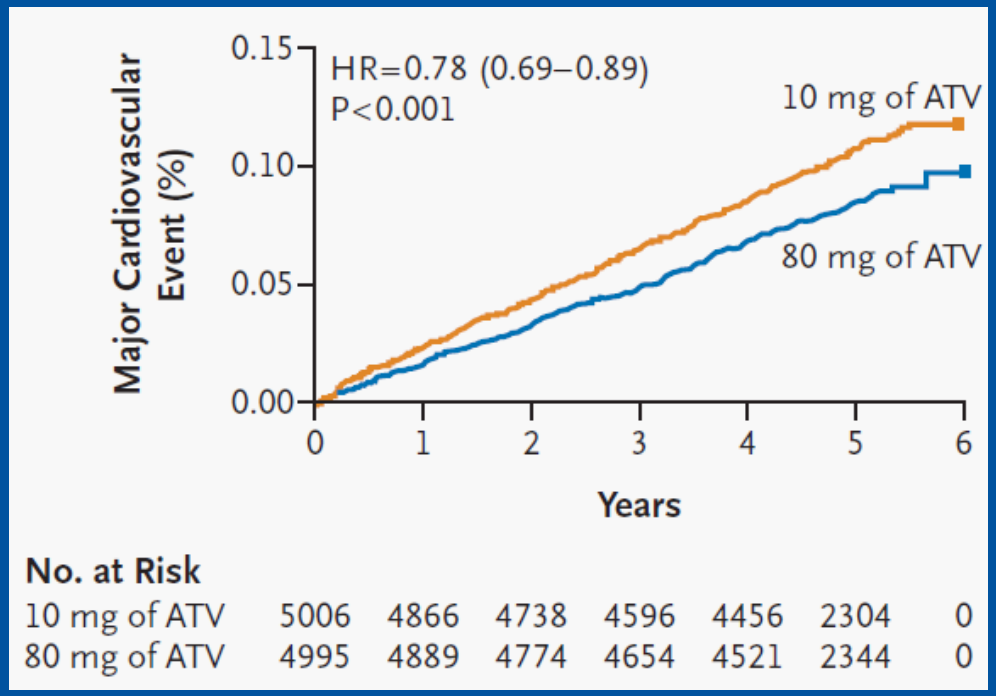
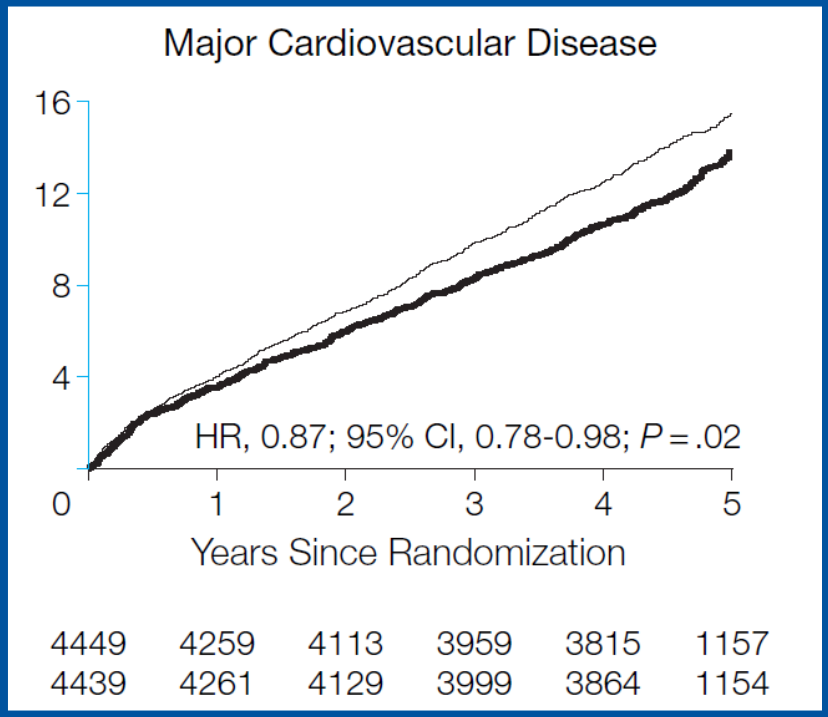
TNT



N Engl J Med 2005;352:1425-35.

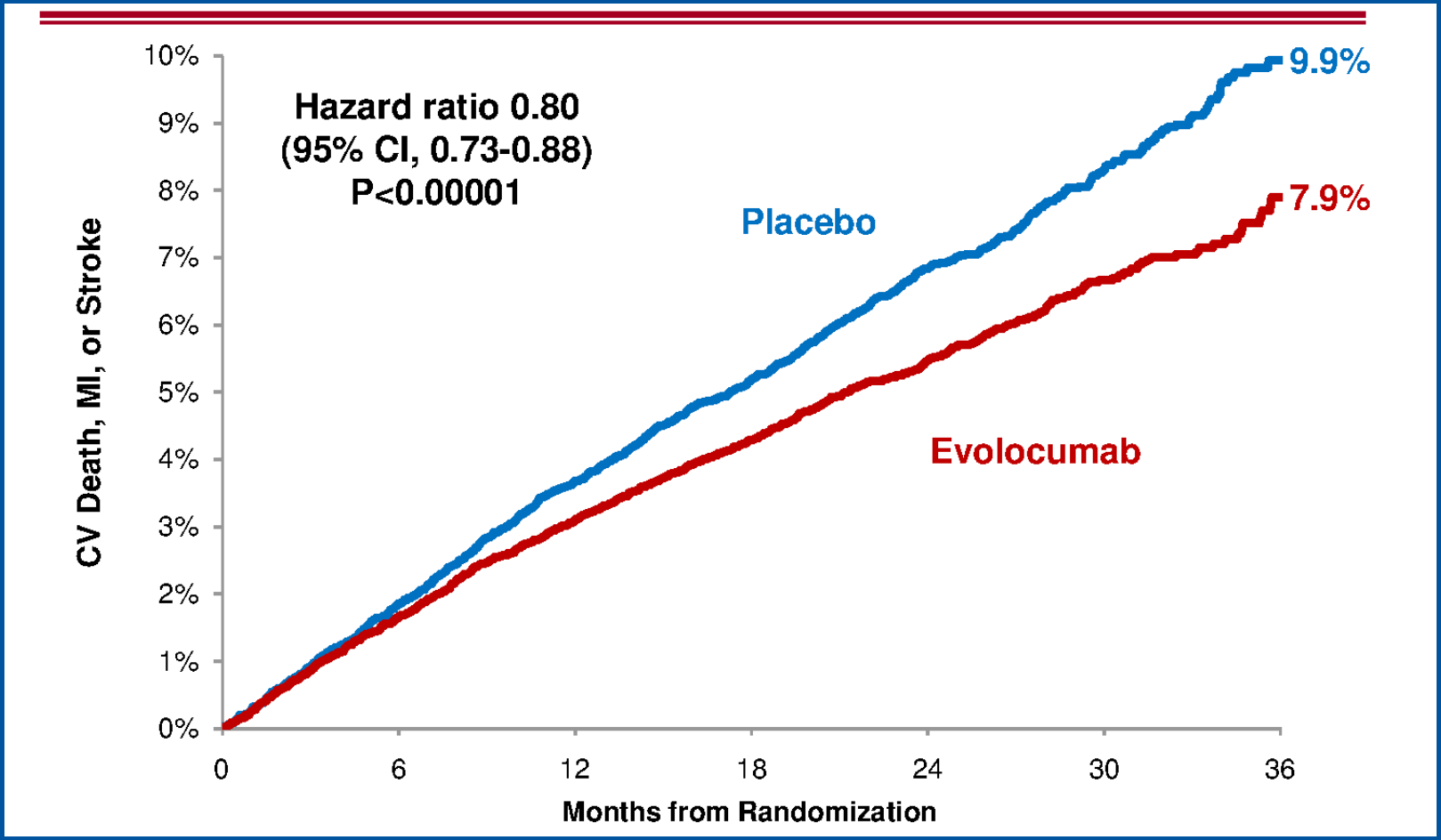
IDEAL



JAMA 2005;294:2437-45.

PCSK9-i in CV patients on top of standard of care lipid-lowering

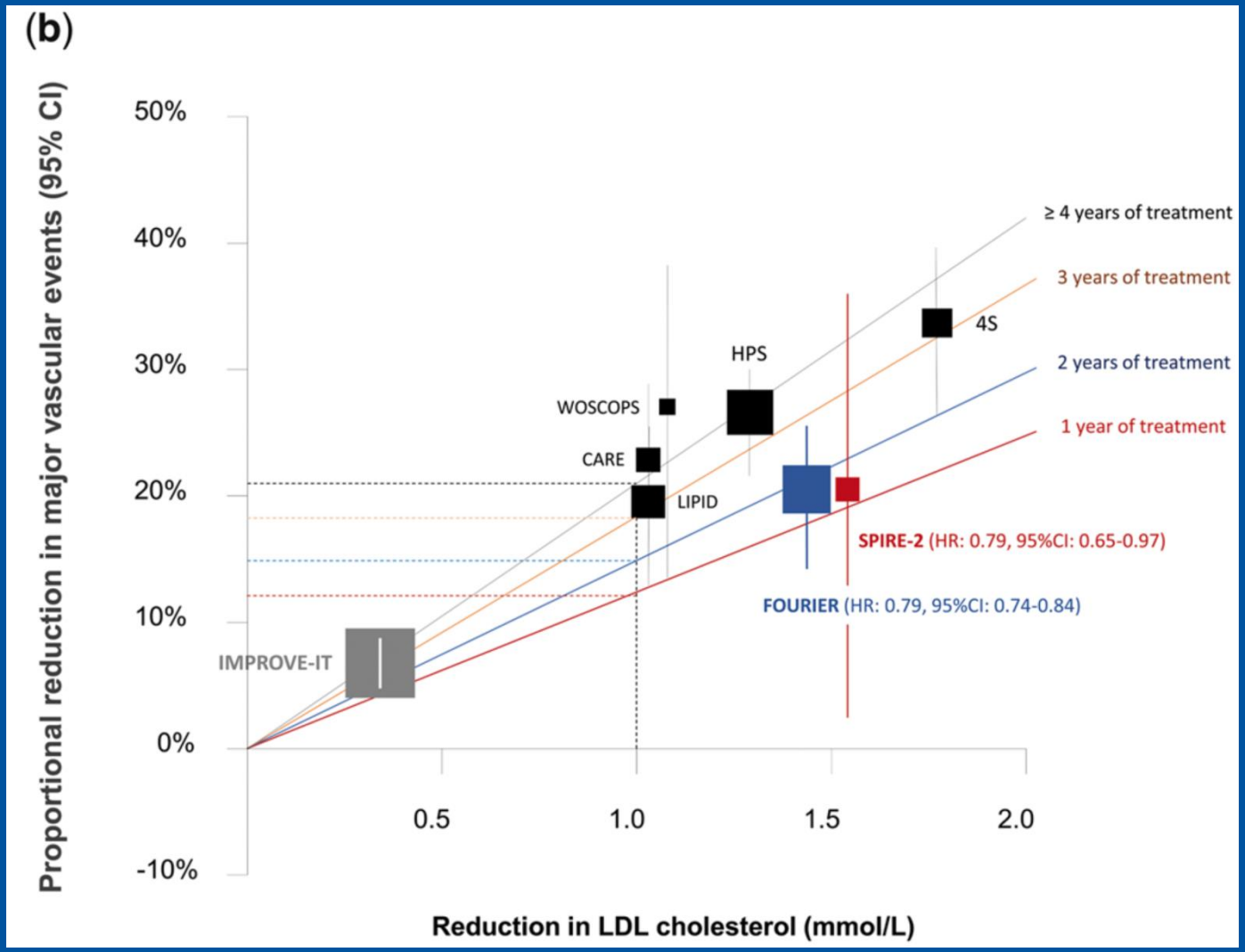
University Medical Center Utrecht



NEJM 2017;376:1713-1722

LDL-c reduction and CV risk reduction by various lipid-lowering strategies

University Medical Center Utrecht



Eur Heart J 2017; Aug 14 epub

II. Lipid-lowering: the guidelines

University Medical Center Utrecht

- ESC guidelines on CV prevention in clinical practice
- National guidelines
- What to do with elderly persons/patients?

European Heart Journal (2016) 37, 2315–2381
doi:10.1093/eurheartj/ehw106

JOINT ESC GUIDELINES

University Medical Center Utrecht

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]

Risk categories

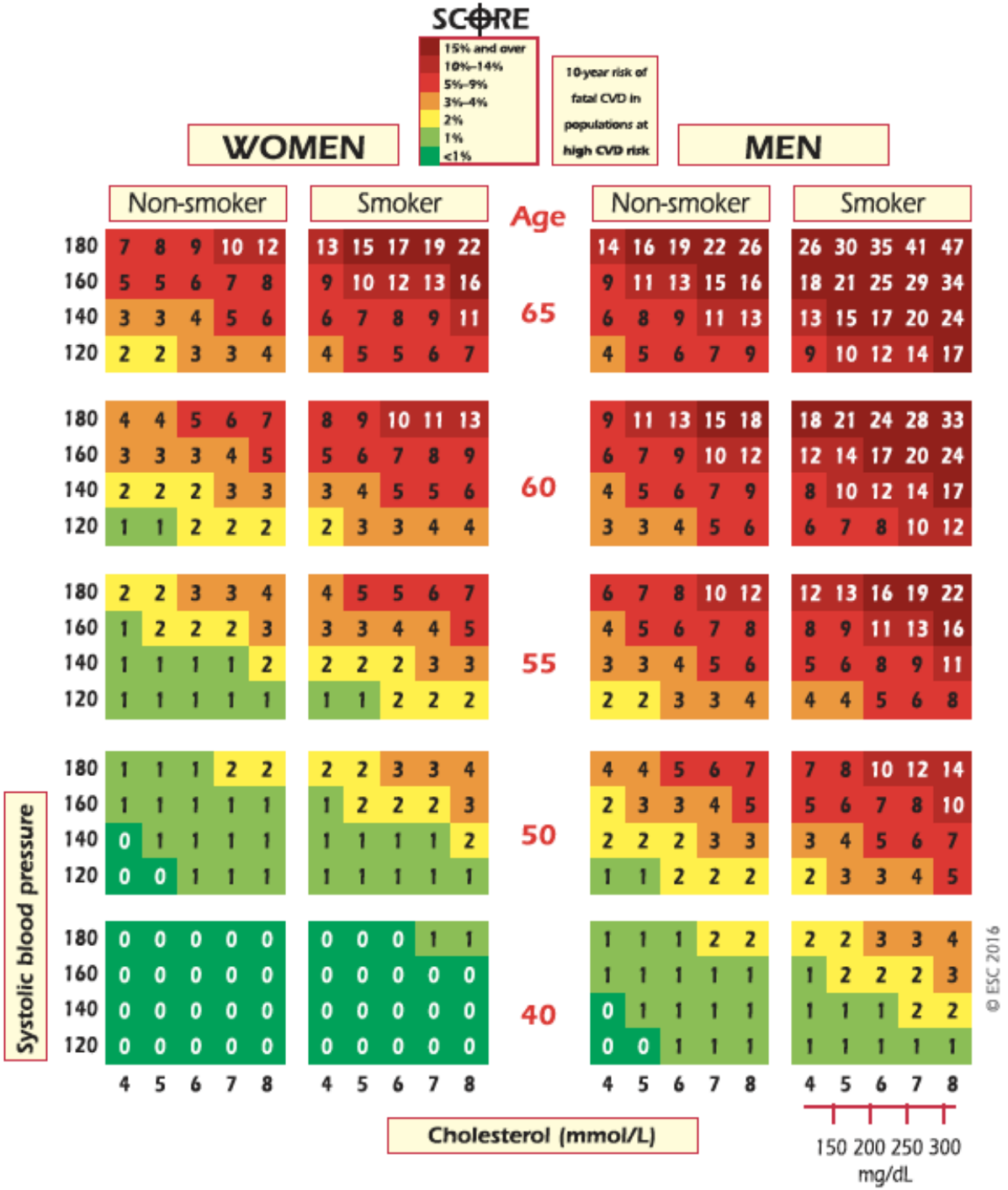
Very high-risk	**Subjects with any of the following:** • **Documented CVD, clinical or unequivocal on imaging. Documented clinical CVD includes previous AMI, ACS, coronary revascularization and other arterial revascularization procedures, stroke and TIA, aortic aneurysm and PAD. Unequivocally documented CVD on imaging includes significant plaque on coronary angiography or carotid ultrasound. It does NOT include some increase in continuous imaging parameters such as intima–media thickness of the carotid artery.** • **DM with target organ damage such as proteinuria or with a major risk factor such as smoking or marked hypercholesterolaemia or marked hypertension.** • **Severe CKD (GFR <30 mL/min/1.73 m^2).** • **A calculated SCORE ≥10%.**
High-risk	**Subjects with:** • **Markedly elevated single risk factors, in particular cholesterol >8 mmol/L (>310 mg/dL) (e.g. in familial hypercholesterolaemia) or BP ≥180/110 mmHg.** • **Most other people with DM (with the exception of young people with type 1 DM and without major risk factors that may be at low or moderate risk).** • **Moderate CKD (GFR 30–59 mL/min/1.73 m^2).** • **A calculated SCORE ≥5% and <10%.**
Moderate-risk	**SCORE is ≥1% and <5% at 10 years. Many middleaged subjects belong to this category.**
Low-risk	**SCORE <1%.**

Treatment goals for low-density lipoprotein-cholesterol

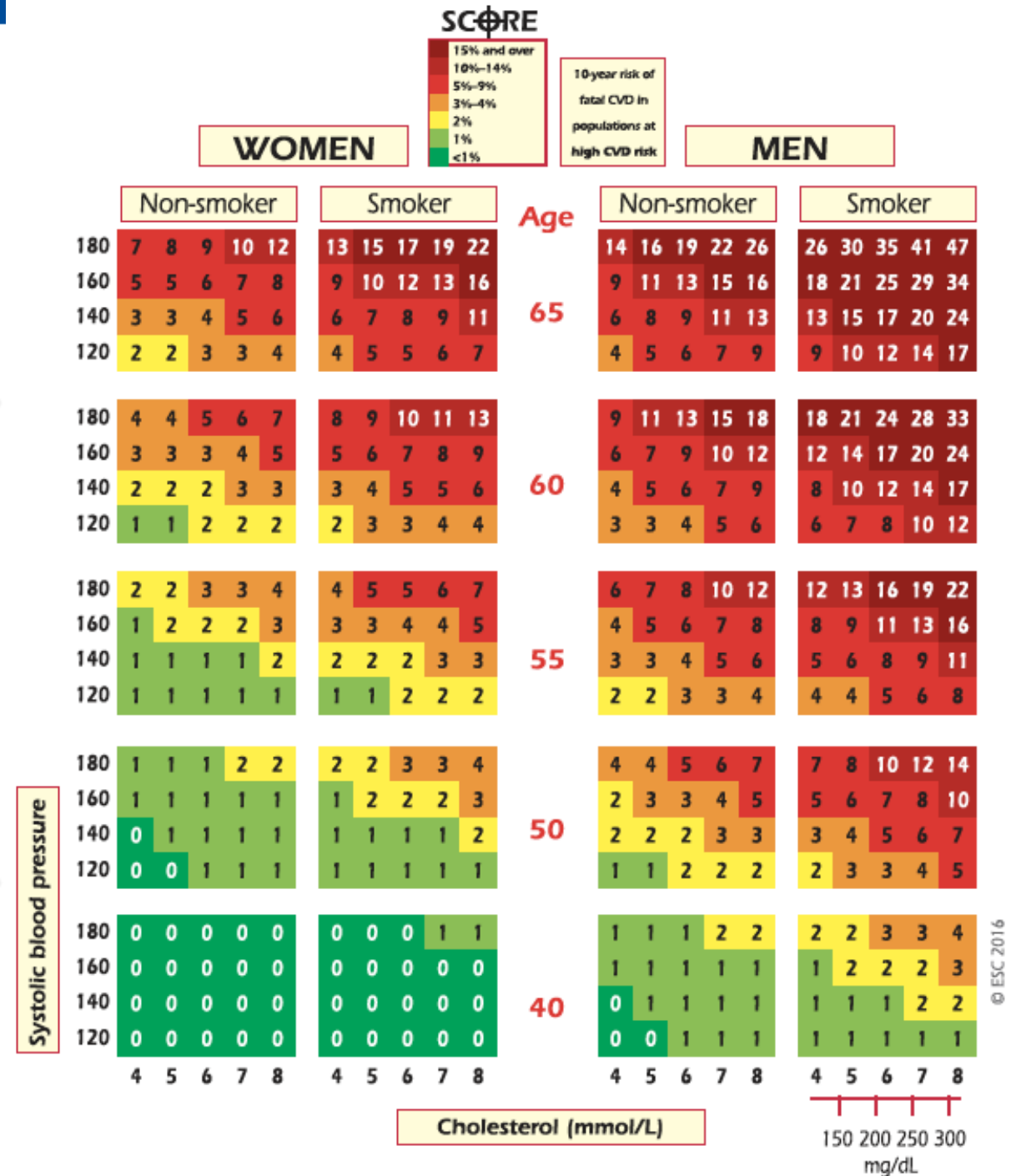
Recommendations	Class	Level
In patients at VERY HIGH CV risk, an LDL-C goal of <1.8 mmol/L (70 mg/dL) or a reduction of at least 50% if the baseline LDL-C is between 1.8 and 3.5 mmol/L (70 and 135 mg/dL) is recommended.	I	B
In patients at HIGH CV risk, an LDL-C goal of <2.6 mmol/L (100 mg/dL), or a reduction of at least 50% if the baseline LDL-C is between 2.6 and 5.2 mmol/L (100 and 200 mg/dL) is recommended.	I	B
In subjects at LOW or MODERATE risk an LDL-C goal of <3.0 mmol/L (<115 mg/dL) should be considered.	IIa	C

Pharmacological treatment of hypercholesterolaemia

Recommendations	Class	Level
Prescribe statin up to the highest recommended dose or highest tolerable dose to reach the goal.	I	A
In the case of statin intolerance, ezetimibe or bile acid sequestrants, or these combined, should be considered.	IIa	C
If the goal is not reached, statin combination with a cholesterol absorption inhibitor should be considered.	IIa	B
If the goal is not reached, statin combination with a bile acid sequestrant may be considered.	IIb	C
In patients at very high-risk, with persistent high LDL-C despite treatment with maximal tolerated statin dose, in combination with ezetimibe or in patients with statin intolerance, a PCSK9 inhibitor may be considered.	IIb	C



All elderly at very high risk???

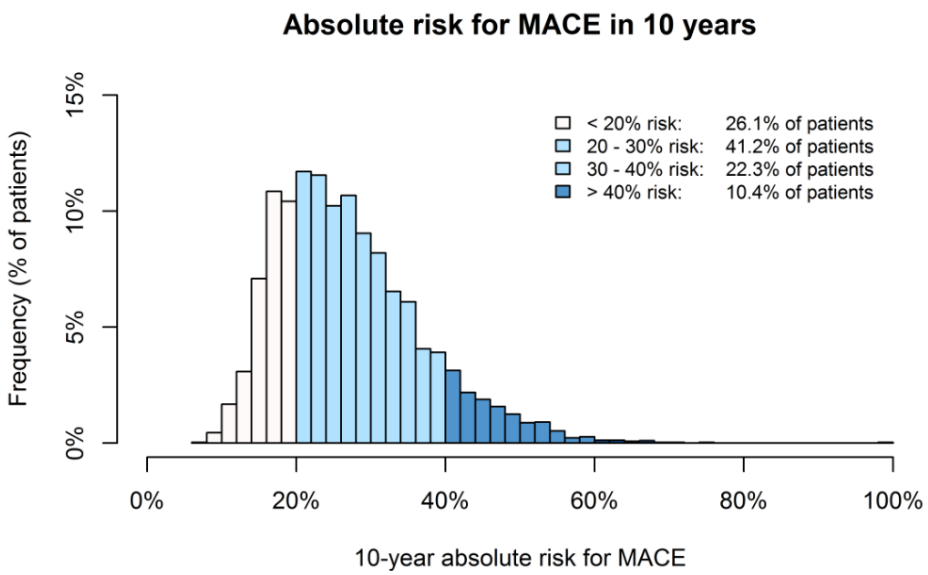


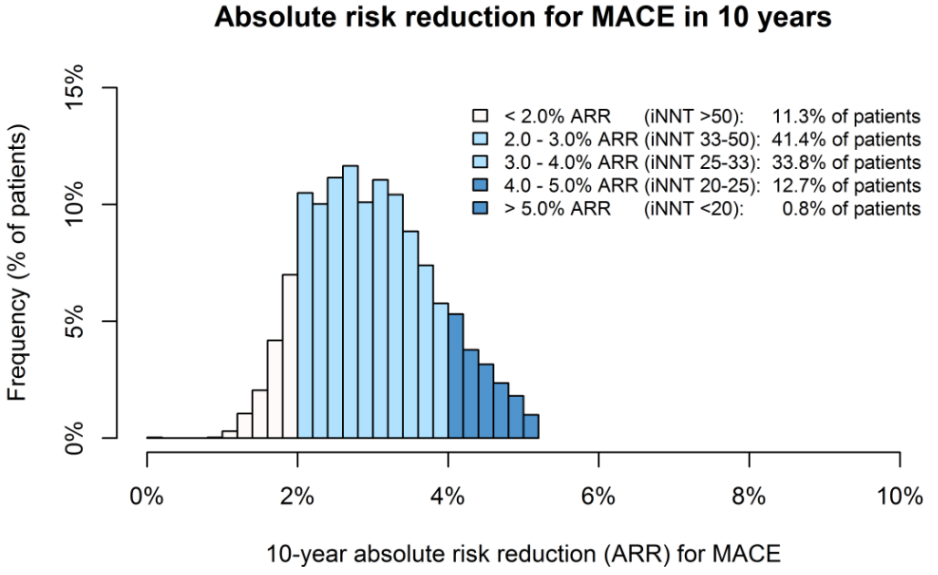
problem

OK

problem

CV risk in elderly (patients) without vascular disease





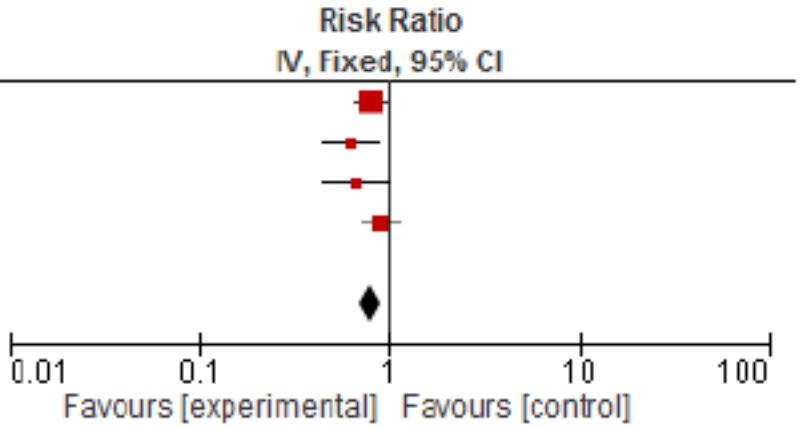
Clin Res in Cardiol. 2017 Jan;106(1):58-68

Lipid-lowering in elderly and risk of myocardial infarction

Study or Subgroup	log[Risk Ratio]	SE	Weight	Risk Ratio IV, Fixed, 95% CI
ALLHAT, 2002	-0.2107	0.0968	45.8%	0.81 [0.67, 0.98]
Collier, 2011	-0.462	0.1717	14.5%	0.63 [0.45, 0.88]
Glynn, 2010	-0.3857	0.2106	9.7%	0.68 [0.45, 1.03]
Shepherd, 2002	-0.0943	0.1195	30.0%	0.91 [0.72, 1.15]
Total (95% CI)			**100.0%**	**0.80 [0.70, 0.90]**

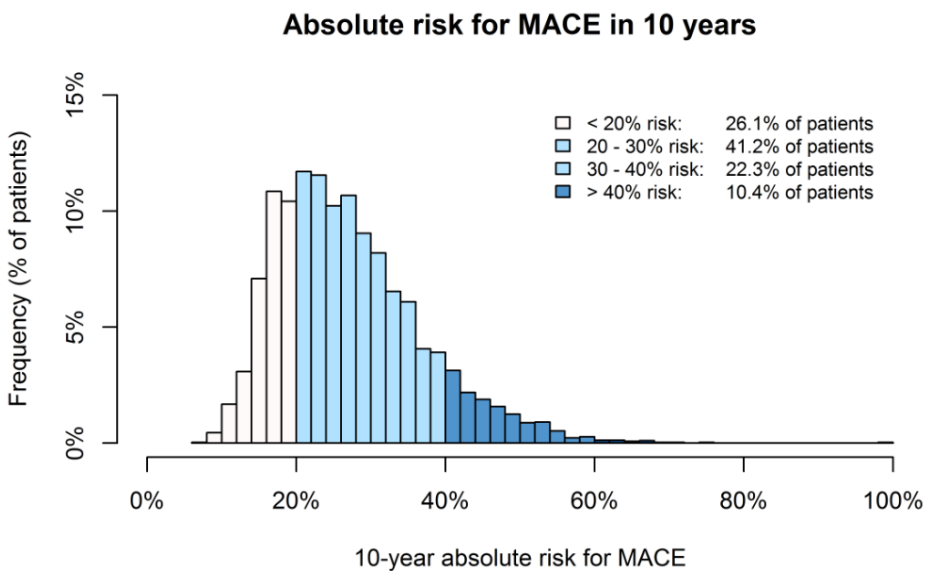
Heterogeneity: Chi² = 3.70, df = 3 (P = 0.30); I² = 19%

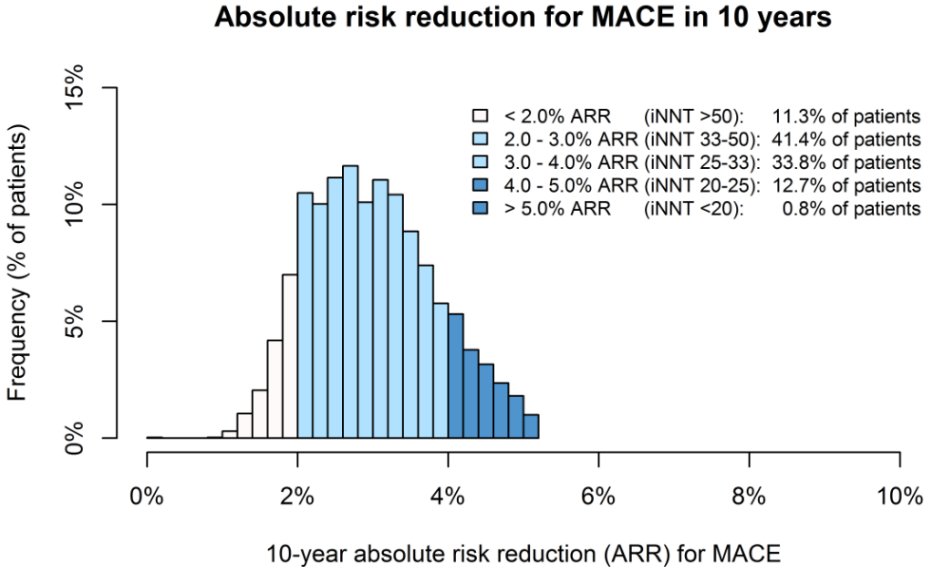
Test for overall effect: Z = 3.50 (P = 0.0005)



On average 20% CV risk reduction by lipid-lowering in elderly

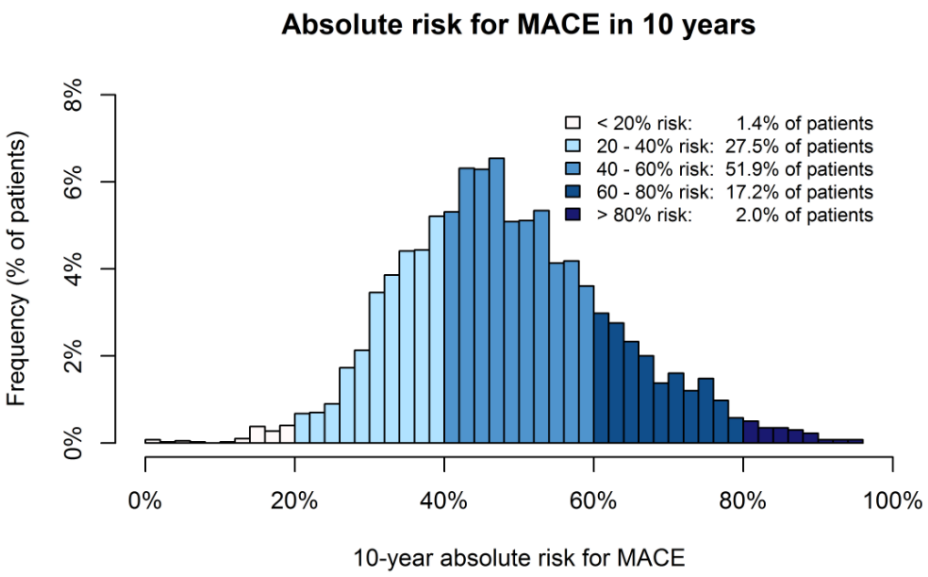
CV risk in elderly (patients) without vascular disease

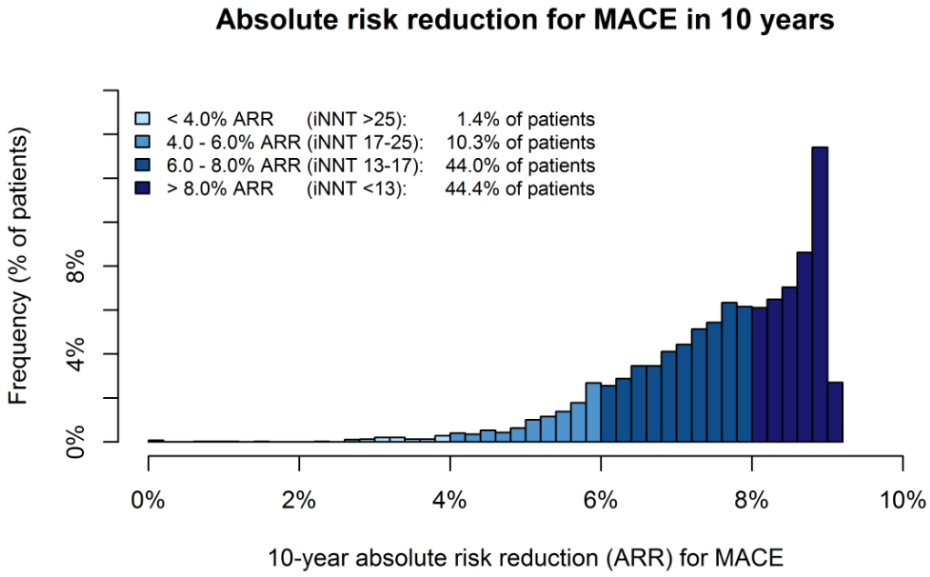




Clin Res in Cardiol. 2017 Jan;106(1):58-68

CV risk in elderly patients with vascular disease





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Moderate-risk	**SCORE is ≥1% and <5% at 10 years. Many middleaged subjects belong to this category.**
Low-risk	**SCORE <1%.**

III. Lipid-lowering: the clinical reality

University Medical Center Utrecht

Reaching LDL-c treatment goals is a problem

Adherence to statins is a problem

How to deal with statin intolerance?

Statins in the media

Shared decision making by individualized risk estimation and risk prediction

Statin adherence in CAD patients in Europe: (EUROASPIRE-4)

University Medical Center Utrecht

Table 1
Statin use at discharge and at interview.

Centre	N	Statin class at discharge			Statin class at interview		
		No %(N)	Low/mod %(N)	High %(N)	No %(N)	Low/Mod %(N)	High %(N)
Belgium	317	10.7(34)	64.0(203)	25.2 (80)	6.0 (19)	62.5 (198)	31.5 (100)
Bosnia Herzegovina	82	22.0(18)	72.0 (59)	6.1 (5)	19.5 (16)	72.0 (59)	8.5 (7)
Bulgaria	101	10.9(11)	77.2 (78)	11.9 (12)	24.8 (25)	67.3 (68)	7.9 (8)
Croatia	373	8.0 (30)	18.5 (69)	73.5 (274)	19.8 (74)	29.0 (108)	51.2 (191)
Cyprus	64	1.6 (1)	90.6 (58)	7.8 (5)	3.1 (2)	85.9 (55)	10.9 (7)
Czech Republic	454	10.8(49)	47.6(216)	41.6 (189)	7.3 (33)	54.8 (249)	37.9 (172)
Finland	438	13.5(59)	69.9(306)	16.7 (73)	18.3 (80)	57.3 (251)	24.4 (107)
France	332	6.9 (23)	36.1(120)	56.9 (189)	4.5 (15)	47.3 (157)	48.2 (160)
Germany	490	11.2(55)	84.9(416)	3.9 (19)	16.7 (82)	76.1 (373)	7.1 (35)
Greece	44	13.6 (6)	52.3 (23)	34.1 (15)	4.5 (2)	63.6 (28)	31.8 (14)
Ireland	189	5.3 (10)	19.6 (37)	75.1 (142)	6.9 (13)	18.0 (34)	75.1 (142)
Latvia	263	4.2 (11)	14.1 (37)	81.7 (215)	6.5 (17)	25.5 (67)	68.1 (179)
Lithuania	423	16.8(71)	73.3(310)	9.9 (42)	27.0(114)	60.8 (257)	12.3 (52)
Netherlands	194	23.2(45)	70.1(136)	6.7 (13)	9.8 (19)	73.2 (142)	17.0 (33)
Poland	349	5.2 (18)	47.0(164)	47.9 (167)	18.3 (64)	46.7 (163)	35.0 (122)
Romania	486	5.6 (27)	31.7(154)	62.8 (305)	12.1 (59)	40.1 (195)	47.7 (232)
Russian Federation	347	7.5 (26)	52.2(181)	40.3 (140)	27.7 (96)	49.0 (170)	23.3 (81)
Serbia	368	8.7 (32)	75.5(278)	15.8 (58)	7.3 (27)	85.6 (315)	7.1 (26)
Slovenia	215	5.1 (11)	29.8 (64)	65.1 (140)	10.2 (22)	33.5 (72)	56.3 (121)
Spain	162	3.7 (6)	6.2 (10)	90.1 (146)	7.4 (12)	12.3 (20)	80.2 (130)
Sweden	323	7.1 (23)	77.7(251)	15.2 (49)	9.3 (30)	64.7 (209)	26.0 (84)
Turkey	199	10.6(21)	45.2 (90)	44.2 (88)	18.6 (37)	52.8 (105)	28.6 (57)
Ukraine	229	11.8(27)	75.1(172)	13.1 (30)	20.5 (47)	73.4 (168)	6.1 (14)
United Kingdom	206	12.6(26)	35.9 (74)	51.5 (106)	13.1 (27)	37.4 (77)	49.5 (102)
Gender							
Men	5029	8.9(450)	52.7(2649)	38.4(1930)	13.3(671)	53.2 (2674)	33.5(1684)
Women	1619	11.7 (190)	52.9 (857)	35.3 (572)	16.1(261)	53.5 (866)	30.4 (492)
Recruiting event							
CABG	816	12.9 (105)	61.3 (500)	25.9 (211)	11.2 (91)	61.9 (505)	27.0 (220)
PTCA	3693	8.5 (314)	53.3 (1967)	38.2 (1412)	12.9(477)	53.8 (1985)	33.3 (1231)
AMI	1451	9.6 (140)	44.3 (643)	46.0 (668)	15.0(218)	47.3 (686)	37.7 (547)
ISCHAEMIA	688	11.8 (81)	57.6 (396)	30.7 (211)	21.2(146)	52.9 (364)	25.9 (178)
All	**6648**	**9.6 (640)**	**52.7 (3506)**	**37.6 (2502)**	**14.0(932)**	**53.2 (3540)**	**32.7 (2176)**

Atherosclerosis 2016;246:243-250

Proportion of CAD patients at LDL-c goal (EUROASPIRE-4)

University Medical Center Utrecht

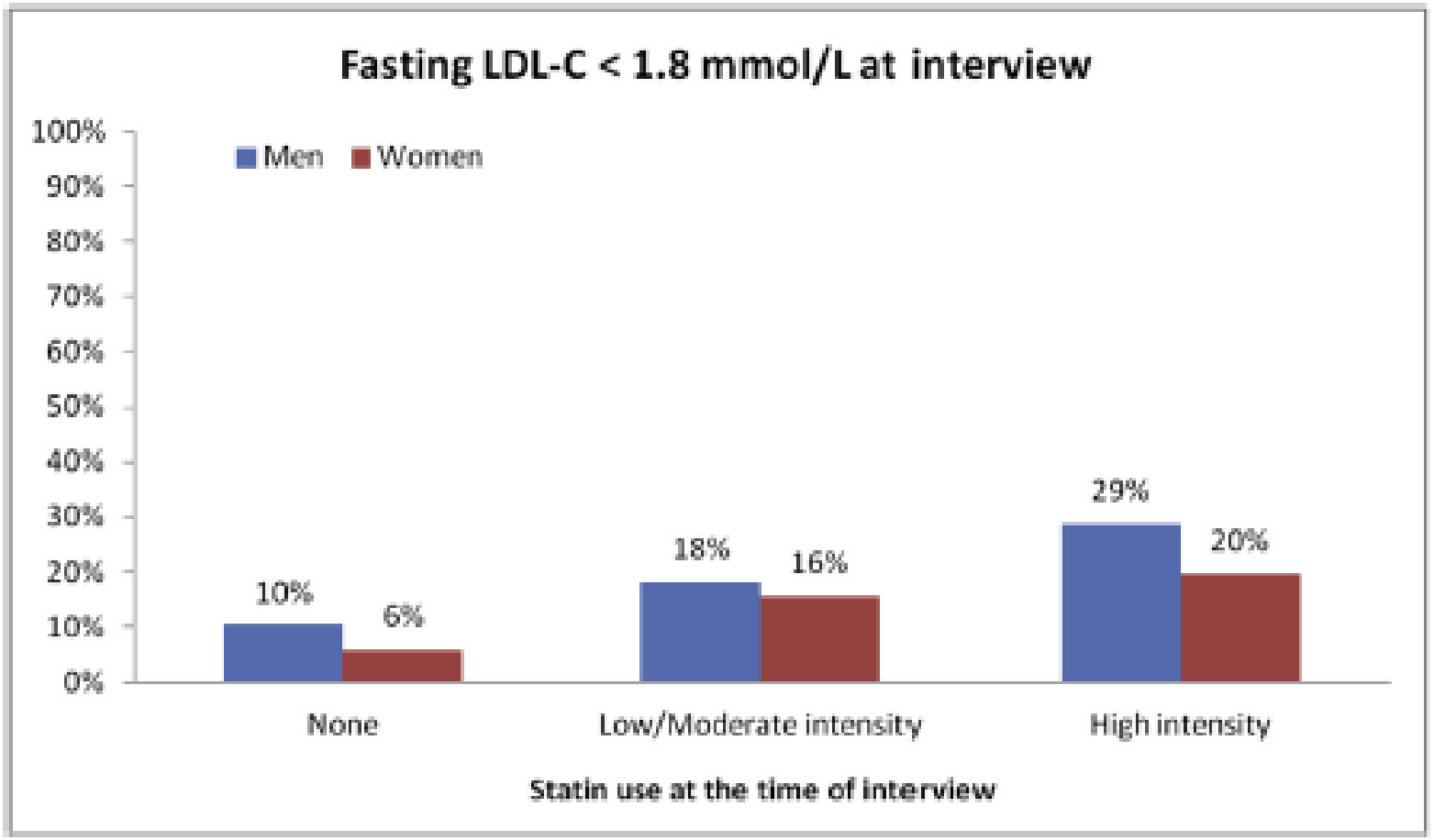


Fig. 1. Proportions of men and women who achieved LDL-C < 1.8 mmol/L at the time of the interview by statin class.

Atherosclerosis 2016;246:243-250

University Medical Center
Utrecht

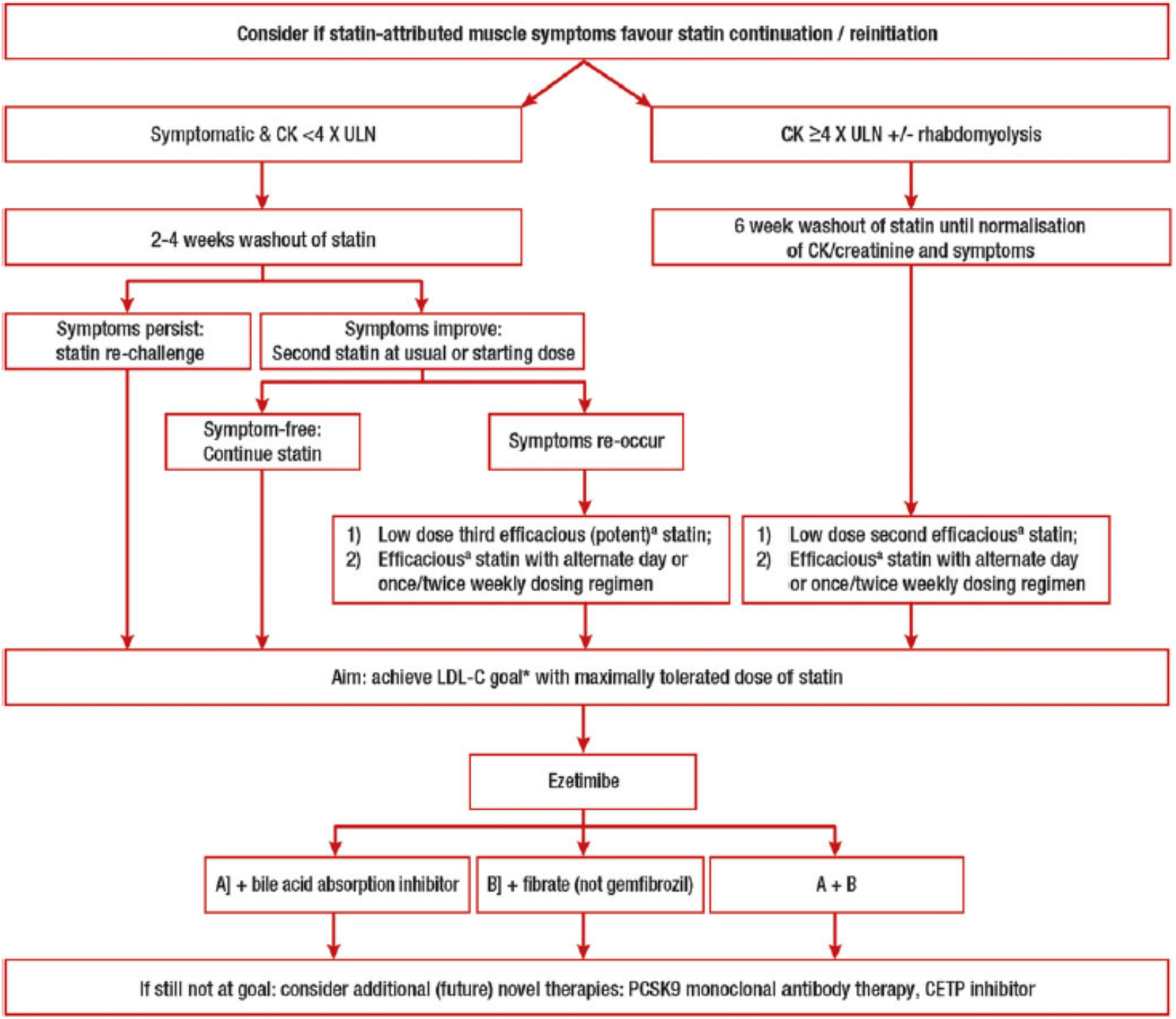
European Heart Journal (2015) **36**, 1012–1022
doi:10.1093/eurheartj/ehv043

REVIEW

Clinical update

Statin-associated muscle symptoms: impact on statin therapy—European Atherosclerosis Society Consensus Panel Statement on Assessment, Aetiology and Management

Erik S. Stroes[1]*, Paul D. Thompson[2], Alberto Corsini[3], Georgirene D. Vladutiu[4], Frederick J. Raal[5], Kausik K. Ray[6], Michael Roden[7], Evan Stein[8], Lale Tokgözoğlu[9], Børge G. Nordestgaard[10], Eric Bruckert[11], Guy De Backer[12], Ronald M. Krauss[13], Ulrich Laufs[14], Raul D. Santos[15], Robert A. Hegele[16], G. Kees Hovingh[17], Lawrence A. Leiter[18], Francois Mach[19], Winfried März[20], Connie B. Newman[21], Olov Wiklund[22], Terry A. Jacobson[23], Alberico L. Catapano[3], M. John Chapman[24], and Henry N. Ginsberg[25], European Atherosclerosis Society Consensus Panel[†]


Consider if statin-attributed muscle symptoms favour statin continuation / reinitiation
Symptomatic & CK <4 X ULN
CK ≥4 X ULN +/- rhabdomyolysis
2-4 weeks washout of statin
6 week washout of statin until normalisation of CK/creatinine and symptoms
Symptoms persist: statin re-challenge
Symptoms improve: Second statin at usual or starting dose
Symptom-free: Continue statin
Symptoms re-occur
1) Low dose third efficacious (potent)[a] statin;
2) Efficacious[a] statin with alternate day or once/twice weekly dosing regimen
1) Low dose second efficacious[a] statin;
2) Efficacious[a] statin with alternate day or once/twice weekly dosing regimen
Aim: achieve LDL-C goal* with maximally tolerated dose of statin
Ezetimibe
A] + bile acid absorption inhibitor
B] + fibrate (not gemfibrozil)
A + B
If still not at goal: consider additional (future) novel therapies: PCSK9 monoclonal antibody therapy, CETP inhibitor

After discontinuation, re-starting a statin usually is successful!

University Medical Center Utrecht

Results—Statins were discontinued at least temporarily for 57,292 out of 107,835 patients. Statin-related events were documented for 18,778 (17.4%) patients. Statins were discontinued at least temporarily by 11,124 of these patients, 6,579 (59.1%) of whom were rechallenged with a statin over the subsequent 12 months. Most patients who were rechallenged (92.2%) were still taking a statin 12 months after the statin-related event. Among the 2,721 patients who were rechallenged with the same statin to which they had a statin-related event, 1,295 (47.6%) were on the same statin 12 months later, including 996 on the same or higher dose.

Ann Intern Med 2013;158:526-534

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Conclusion—Statin-related events are commonly reported and often lead to their discontinuation. However, most patients who are rechallenged can tolerate statins long-term. This suggests that many of the statin-related events may have other etiologies, are tolerable or may be specific to individual statins rather than the entire drug class.

Ann Intern Med 2013;158:526-534

BEHIND THE SCENES AT DOWNTON ABBEY
SUNDAY EXPRESS
FREE ICE CREAM SUNDAE
FREE DOG FOOD
STATINS AGE YOU FASTER
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HELP FIND BRUTES WHO BEAT UP WIDOW, 89
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COWELL: I'VE BEEN TOO ARROGANT
HOW STATINS BEAT CANCER
Daily dose of heart pill will save thousands
CRUISE CAPTAIN WAS FLIRTING WITH BLONDE WHEN SHIP CRASHED

OPEN ACCESS

Impact of statin related media coverage on use of statins: interrupted time series analysis with UK primary care data

Anthony Matthews,[1] Emily Herrett,[1] Antonio Gasparrini,[2] Tjeerd Van Staa,[3,4] Ben Goldacre,[1] Liam Smeeth,[1] Krishnan Bhaskaran[1]

European Heart Journal (2016) **37**, 908–916
doi:10.1093/eurheartj/ehv641

CLINICAL RESEARCH
Prevention and epidemiology

Negative statin-related news stories decrease statin persistence and increase myocardial infarction and cardiovascular mortality: a nationwide prospective cohort study

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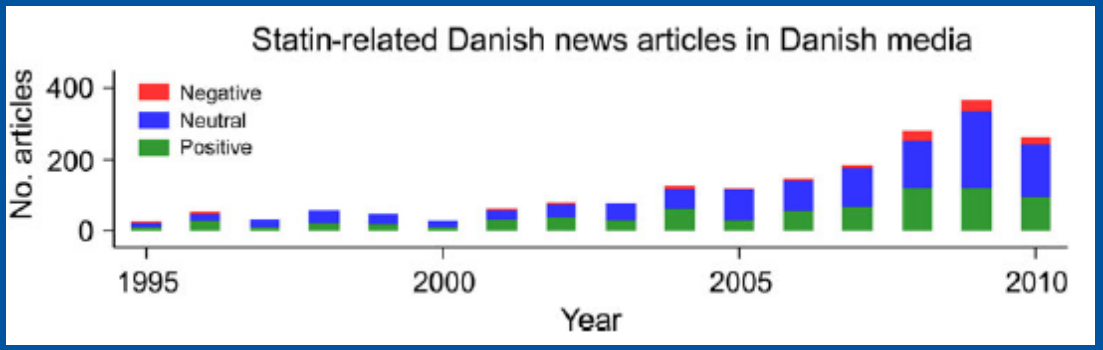
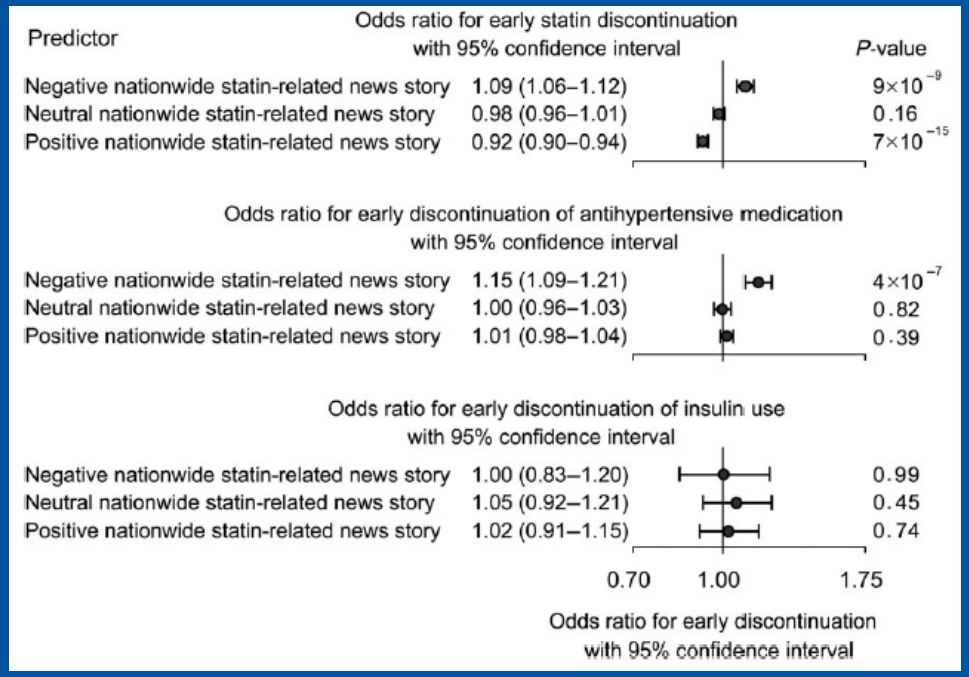
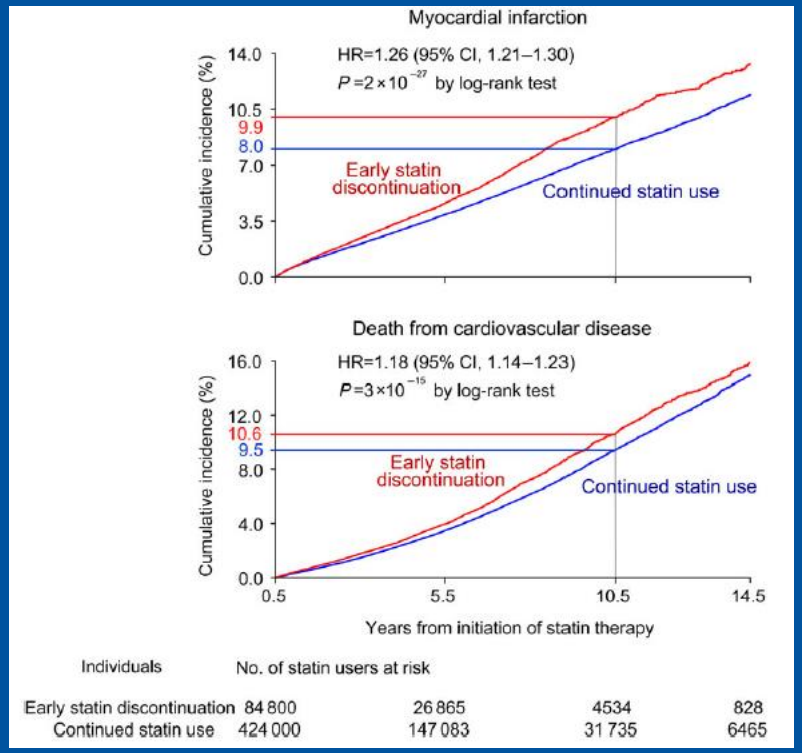
Received 10 June 2015; revised 22 September 2015; accepted 6 November 2015; online publish-ahead-of-print 1 December 2015

Statin-related news stories and cessation of statins and risk of CV events

University Medical Center Utrecht







Eur Heart J 2016;37:908-916

Precision medicine in clinical practice?

University Medical Center Utrecht

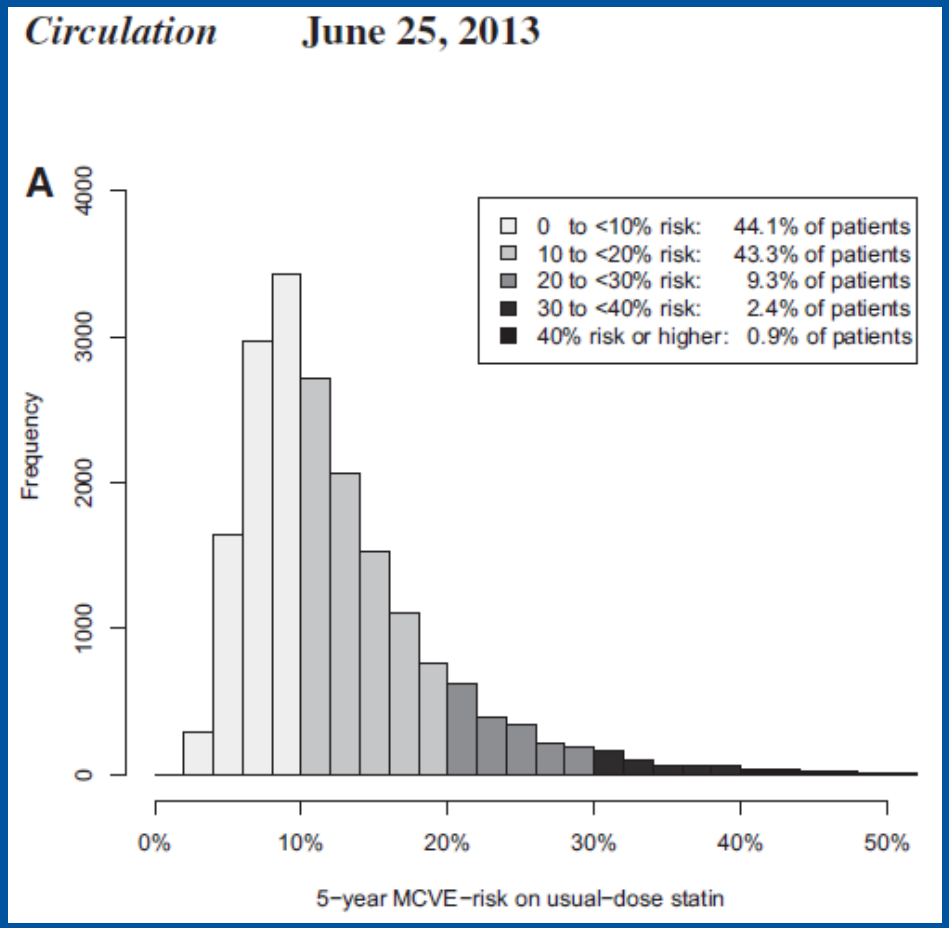
Last year I had an acute coronary syndrome. What is the effect of intensying cholesterol-lowering to prevent a next CV event?

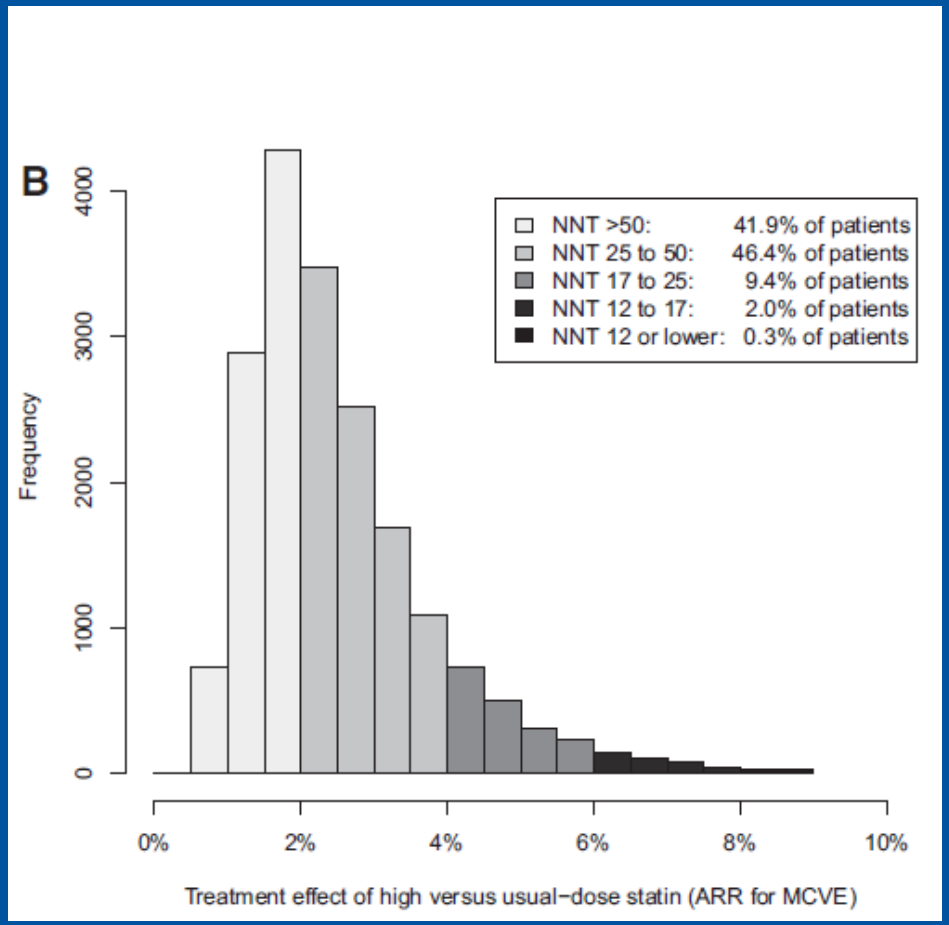
Research shows that on average patients with a heart attack or stroke, on average, benefit from more intensive cholesterol-lowering!

What would my benefit be?

Distribution of baseline risk and predicted absolute treatment effect of intensive vs. moderate lipid-lowering (TNT / IDEAL)

University Medical Center Utrecht





Baseline risk

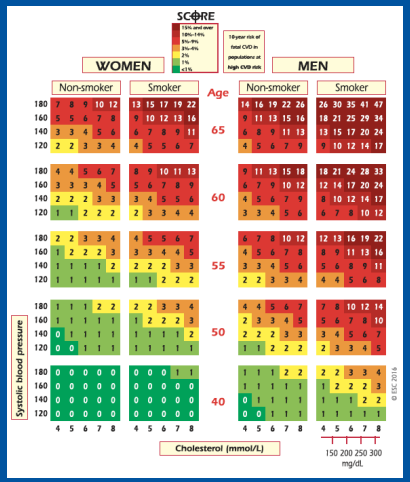
Treatment effect

Dorresteijn et al. Circulation 2013;127:2485-2493

Precision medicine in clinical practice; coming soon!

University Medical Center Utrecht

- Risk estimating not only in ‘primary prevention’ but also in patients with:
  - *Diabetes Mellitus*
  - *Vascular diseases*
  - *Elderly*

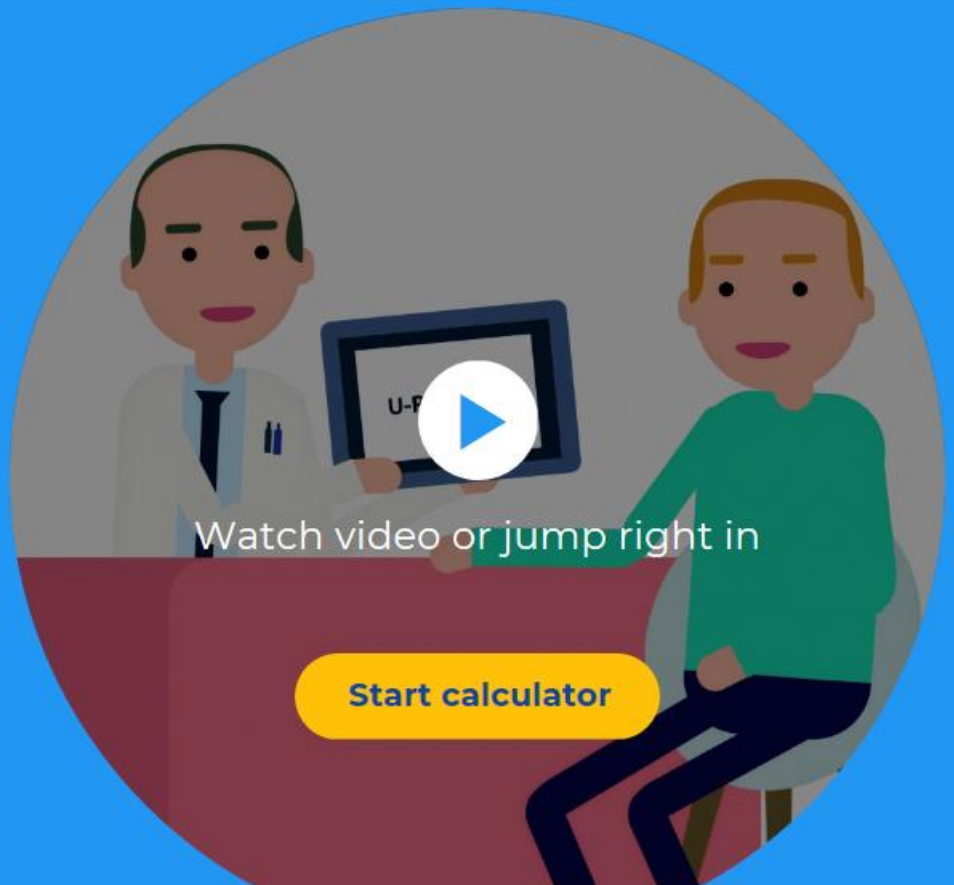


- Estimating <u>life-time risk</u>

- Estimating <u>life-time benefit</u> of (lipid-lowering) treatment expressed as <u>disease-free life years gained</u>

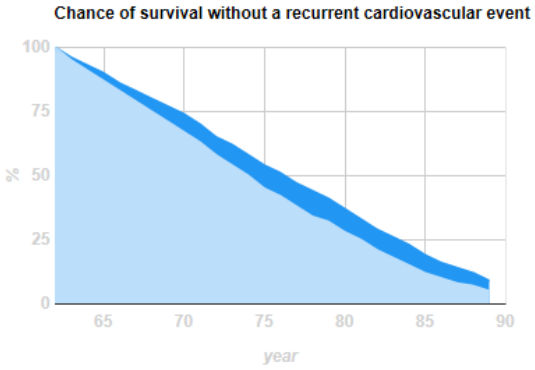
U-Prevent you are in control

We provide tools for personalized Vascular Medicine. Get more insights by calculating individual cardiovascular risk and the effect of preventive treatment.



Slice-galerie
Aanbevolen websites

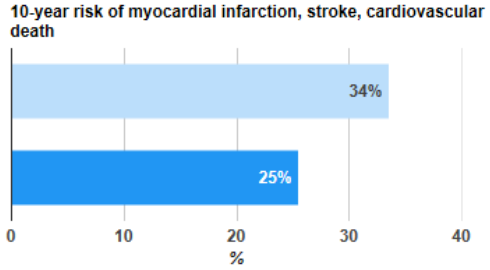
Patient Group	Calculate 5 or 10-year cardiovascular risk'	Calculate lifetime treatment effect
Previous cardiovascular disease	SMART risk score	SMART-REACH model
Type 2 Diabetes Mellitus	ADVANCE risk score	DIABETES model
< 70 years No previous cardiovascular disease or type 2 diabetes mellitus	SCORE/ ASVCD	HEALTHY PEOPLE model
≥ 70 years	ELDERLY risk score	USE ONE of the above



Treatment start age
62

CVD-free years gain
2.3

Expected CVD-free survival
76



Current risk
34%

Change with treatment
-8%

Number needed to treat
12

Print results

Copy to Clipboard

Intended treatment

Statin

Atorvastatin 40 mg

Ezetimibe

PCSK9-inhibitor

Systolic blood pressure

No treatment target

Anticoagulants

Aspirin or equivalent

Intervention Start age

62

Show profile

Thoughts and Conclusions

University Medical Center Utrecht

- Overwhelming evidence for the benefit and safety of lipid-lowering therapy in various groups of patients:
- The lower LDL-c the lower CV risk
- Guidelines have incorporated most lipid evidence
- Various lipid-lowering drugs work! It is all about LDL-c reduction

Thoughts and Conclusions

University Medical Center Utrecht

- The incidence of ‘real‘ statin-associated muscle symptoms is low. Options to deal with it: temporarily discontinue (and re-start), lower dose (and add ezetimibe) or switch to other statin.

- My personal addition to the above to deal with (presumed) statin-associated muscle symptoms: calculate what the absolute (lifetime) benefit is for this particular patient.

- Use media to report positively about lipid-lowering

Thoughts and Conclusions

University Medical Center Utrecht

- Decisions to treat elderly could (should) be based on risk prediction
- Translation (and communication) of group-level evidence to individual patients in clinical practice by inidividualized prediction of risk and treatment effects!

Thank you