Quelle prise en charge du haut risque métabolique?

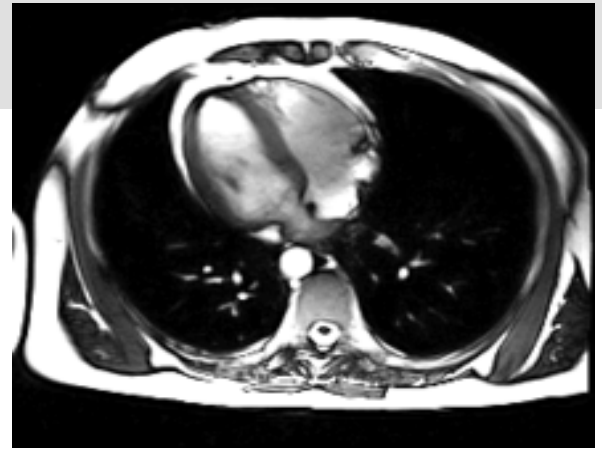
Journée d'actualités thérapeutiques

Amicale des Cardiologues de la Côte d'Azur
Samedi 30 Mars 2019
09h45-10h15
Novotel, Nice , Arénas

Dr François Diévart

Elsan, Clinique Villette
Dunkerque

Conflits d'intérêts



Alliance BMS-Pfizer, Amgen, Astra-Zeneca, Bayer Pharma, BMS, Boehringer-Ingelheim, Daiichi-Sankyo, Ménarini, MSD, Novartis, Novo-Nordisk, Pfizer, sanofi-aventis france, Servier, Takeda

Patient à haut risque métabolique

- 74 ans
- 98 kilos, 1m73
- Diabète de type 2, sulfamide (car intolérance métformine)
- LDL : 0,82 g/l, HDL : 0,70 g/l,
- TG : 2,10 g/l
- PA : 105/70 sous IEC, Calcique, diurétique
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- **EVALUER LE RISQUE : IA IA IA**
- **Sport et régime : oui : 1A**
- **Cible HbA1c: < 7 % : IA**
- **Cible LDL: < 0,7 ou 1g/l: IA**
- **Cible HDL : > 0,50 àu 0,60 g/l : IB**
- **Cible de TG: < 1,50 g/l : IB**
- **Oméga 3 : IIa**
- **PA cible: < 130 mm Hg : IA**
- **Aspirine : si haut risque: IIA**

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Quelle espérance de vie
(INSEE, tables de viager)

- A la naissance en 2019 :
  - Homme : 78,1 ans
  - Femme : 84,8 ans

Différence : 6,7 ans

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(INSEE, tables de viager)

- A la naissance en 2019 :
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  - Femme : 84,8 ans

Différence : 6,7 ans

- **À 74 ans en 2019 :**
  - Homme : **12 ans** et 8 mois (12,69) soit 86 à 87 ans
  - Femme : **15 ans** et 6 mois (15,53) soit 89 à 90 ans

Différence : 3 ans

Mais, le risque CV ?

ESC European Society of Cardiology
European Heart Journal (2019) **40**, 621–631
doi:10.1093/eurheartj/ehy653

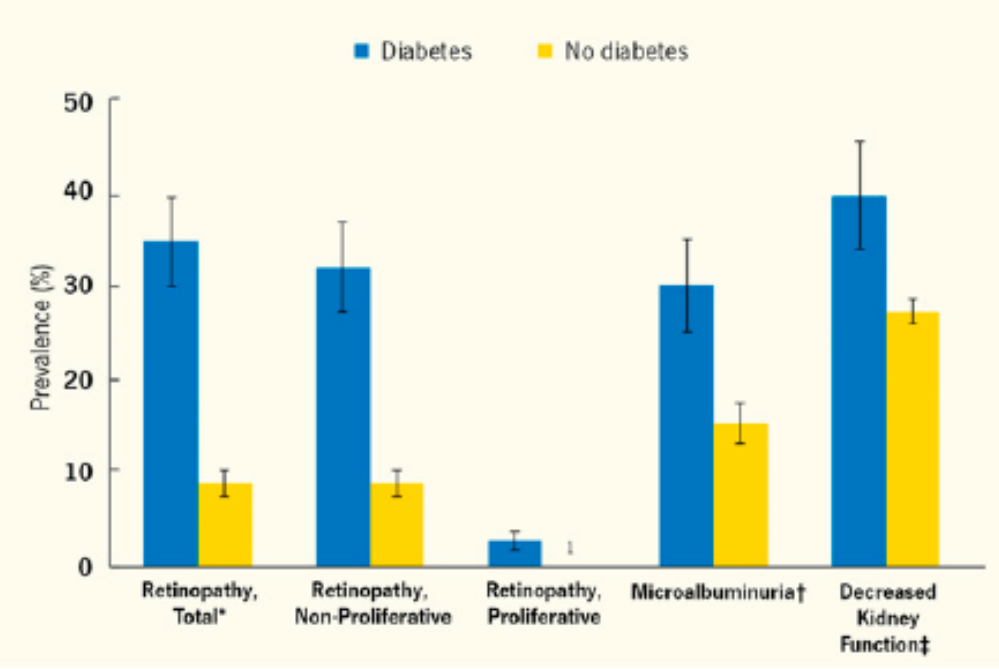
CLINICAL RESEARCH
Prevention and epidemiology

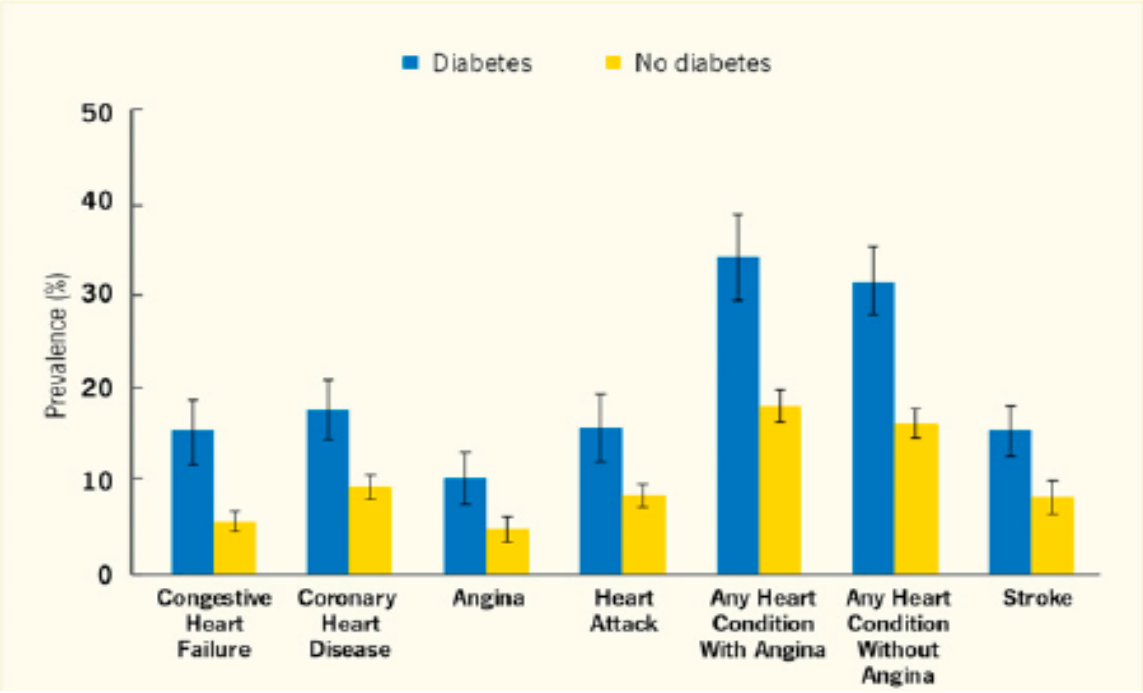
Equalization of four cardiovascular risk algorithms after systematic recalibration: individual-participant meta-analysis of 86 prospective studies

Using individual-participant data on 360 737 participants without CVD at baseline in 86 prospective studies from 22 countries, we compared the Framingham risk score (FRS), Systematic COronary Risk Evaluation (SCORE), pooled cohort equations (PCE), and Reynolds risk score (RRS). We calculated measures of risk discrimination and

lations. The four algorithms had similar risk discrimination. Before recalibration, FRS, SCORE, and PCE over-predicted CVD risk on average by 10%, 52%, and 41%, respectively, whereas RRS under-predicted by 10%.

Prévalence de certaines maladies après 65 ans selon qu'il y a ou pas un diabète, aux USA





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Diététique

Le drame… de l’étude LOOK AHEAD

ORIGINAL ARTICLE

Cardiovascular Effects of Intensive Lifestyle Intervention in Type 2 Diabetes

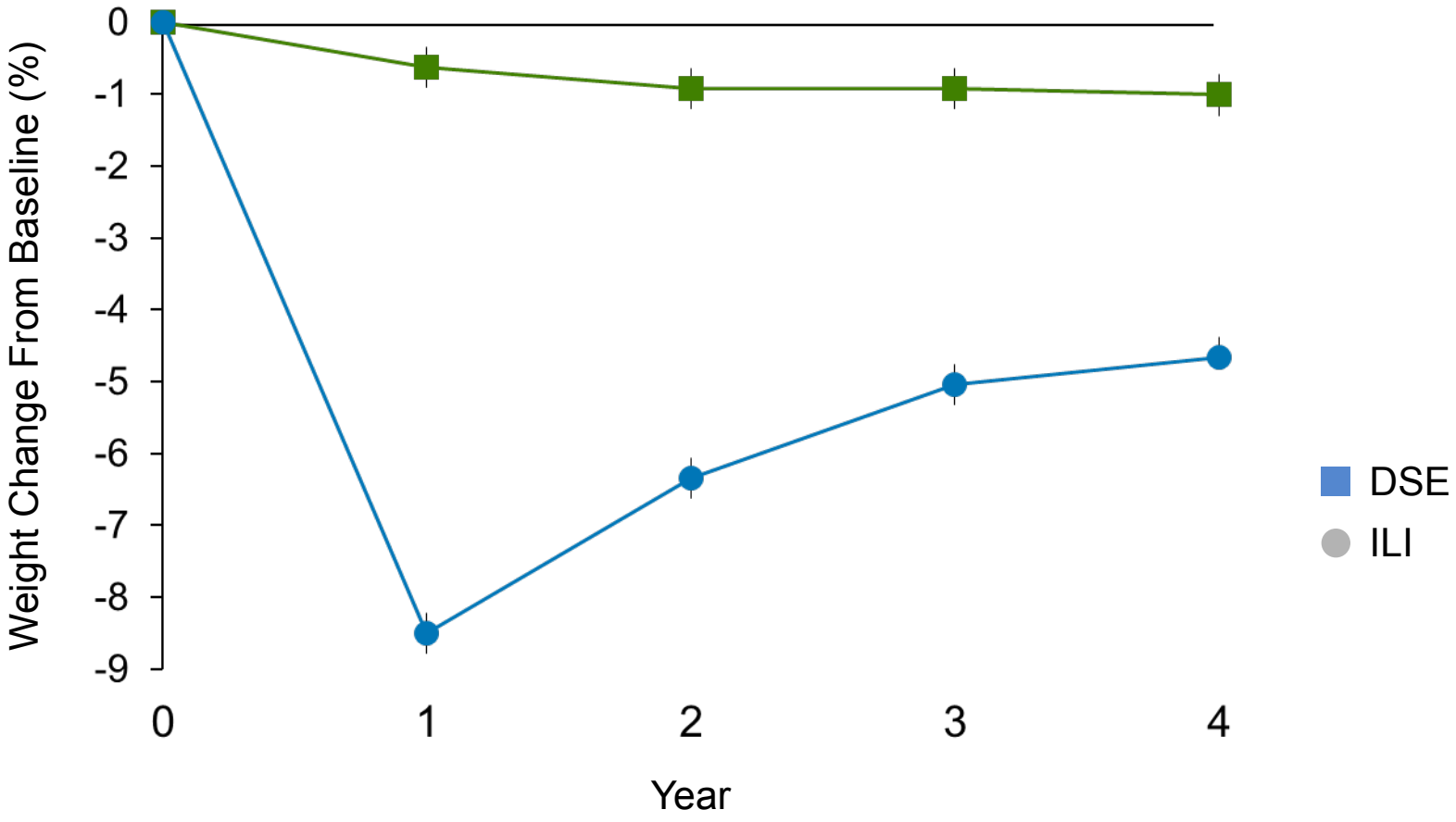
The Look AHEAD Research Group*

METHODS

In 16 study centers in the United States, we randomly assigned 5145 overweight or obese patients with type 2 diabetes to participate in an intensive lifestyle intervention that promoted weight loss through decreased caloric intake and increased physical activity (intervention group) or to receive diabetes support and education (control group). The primary outcome was a composite of death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for angina during a maximum follow-up of 13.5 years.

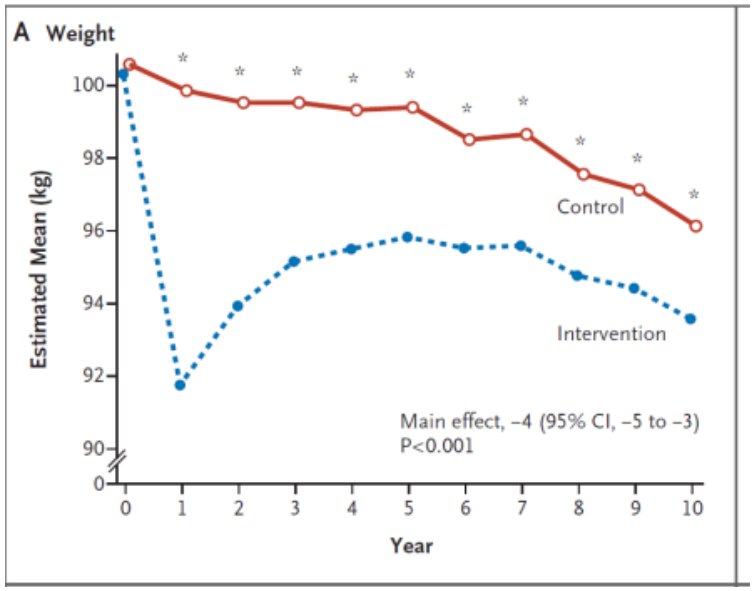
N Engl J Med 2013.
DOI: 10.1056/NEJMoa1212914

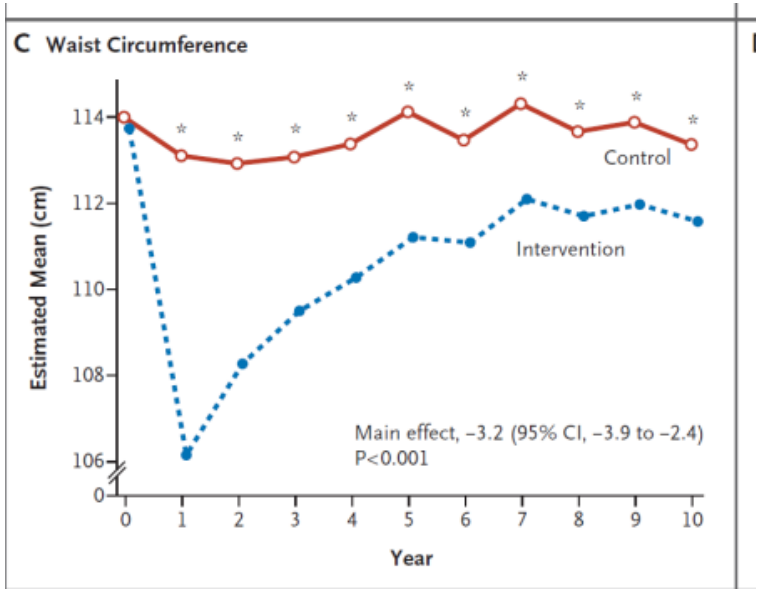
Perte de poids à 4 ans dans Look AHEAD

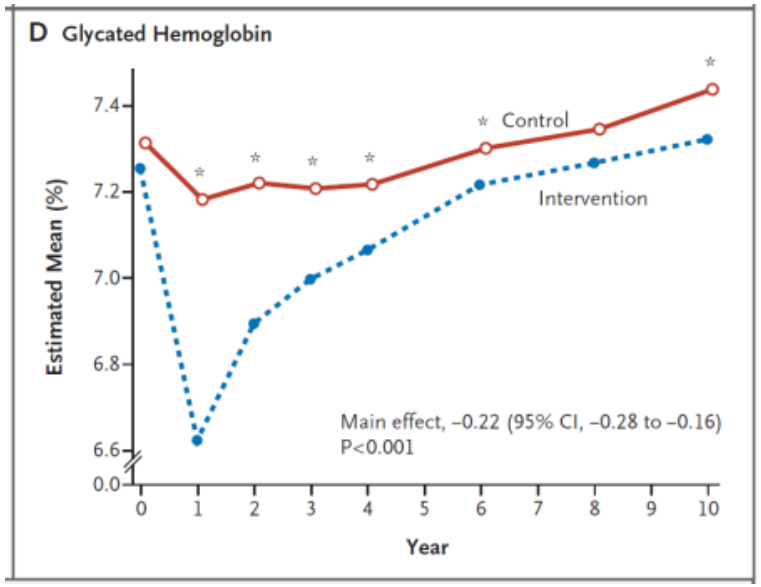


Repeated measures adjusted for clinic and baseline level. *P* value for average effect across all visits: $P < 0.0001$.
DSE, diabetes support and education; ILI , intensive lifestyle intervention.
Look AHEAD Research Group, Wing RR. *Arch Intern Med.* 2010;170(17):1566–1575.

Résultats à 10 ans de Look AHEAD







Poids **Tour de taille** **HbA1c**

Evolution en 10 ans

Résultats à 10 ans de Look AHEAD

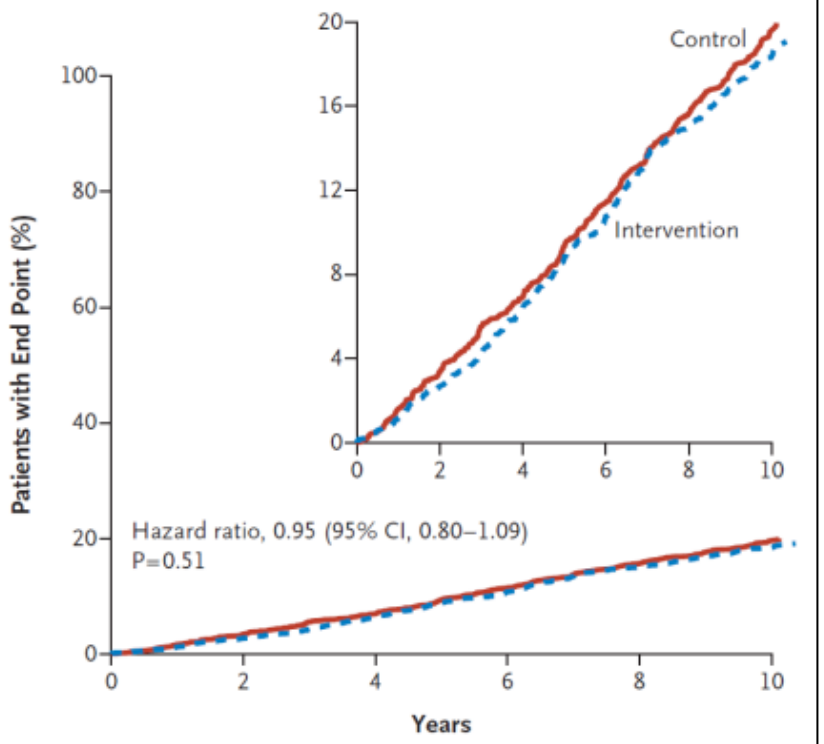


Figure 2. Cumulative Hazard Curves for the Primary Composite End Point.

Table 2. Primary and Secondary Outcomes and Other Cardiovascular Outcomes.*

Outcome	Patients with Event	Control Group	Intervention Group	Hazard Ratio (95% CI)	P Value
	no.	*no. of events (rate/100 person-yr)*			
Primary outcome					
Death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for angina	821	418 (1.92)	403 (1.83)	0.95 (0.83–1.09)	0.51
Secondary outcomes					
Death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke	550	283 (1.25)	267 (1.17)	0.93 (0.79–1.10)	0.42

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Quelle cible d'HbA1C?

CLINICAL PRACTICE GUIDELINE

Treatment of Diabetes in Older Adults: An Endocrine Society* Clinical Practice Guideline

Derek LeRoith,[1] Geert Jan Biessels,[2] Susan S. Braithwaite,[3,4] Felipe F. Casanueva,[5] Boris Draznin,[6] Jeffrey B. Halter,[7,8] Irl B. Hirsch,[9] Marie E. McDonnell,[10] Mark E. Molitch,[11] M. Hassan Murad,[12] and Alan J. Sinclair[13]

(*J Clin Endocrinol Metab* 104: 1–55, 2019) First Published Online 23 March 2019

Quelle cible d'HbA1C?

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Objective: The objective is to formulate clinical practice guidelines for the treatment of diabetes in older adults.

Conclusions: Diabetes, particularly type 2, is becoming more prevalent in the general population, especially in individuals over the age of 65 years. The underlying pathophysiology of the disease in

(*J Clin Endocrinol Metab* 104: 1–55, 2019) First Published Online 23 March 2019

Quelle cible d'HbA1C?

Technical remark: Although evidence for specific targets is lacking, glycemic targets should be tailored to overall health and management strategies (*e.g.*, whether a medication that can cause hypoglycemia is used) (see Table 3).

(*J Clin Endocrinol Metab* 104: 1–55, 2019) First Published Online 23 March 2019

Overall Health Category		Group 1: Good Health	Group 2: Intermediate Health	Group 3: Poor Health
Patient characteristics		No comorbidities **or** 1-2 non-diabetes chronic illnesses* **and** No ADL€ impairments and ≤1 IADL impairment	3 or more non-diabetes chronic illnesses* **and/or** Any one of the following: mild cognitive impairment or early dementia ≥2 IADL impairments	Any **one** of the following: End-stage medical condition(s)** Moderate to severe dementia ≥2 ADL impairments Residence in a long-term nursing facility
		Reasonable glucose target ranges and HbA1c by group Shared decision-making: individualized goal may be lower or higher		
Use of drugs that may cause hypoglycemia (e.g., insulin, sulfonylurea, glinides)	No	Fasting: 90-130 mg/dL Bedtime: 90-150 mg/dL <7.5%	Fasting: 90-150 mg/dL Bedtime: 100-180 mg/dL <8%	Fasting: 100-180 mg/dL Bedtime: 110-200 mg/dL <8.5%¥
	Yes£	Fasting: 90-150 mg/dL Bedtime: 100-180 mg/dL ≥7.0 and <7.5%	Fasting: 100-150 mg/dL Bedtime: 150-180 mg/dL ≥7.5 and <8.0%	Fasting: 100-180 mg/dL Bedtime: 150-250 mg/dL ≥8.0 and <8.5%¥

ADL : actual daily activity

HbA1c: quelle cible ?

Summary of Hgb A1C Guidelines for non-pregnant Adults with Type II DM

Sponsor	Target Hgb A1C	Lifespan < 10 years, risk of hypoglycemia or multiple co-morbidities
ACP	7-8%	Treat to minimize symptoms
AACE/ACE	≤6.5%	7-8%
ADA	<7%	<8%
ICSI	< 7% to < 8%	<8%
NICE	6.5%	7%
SIGN	7%	Balance benefits vs harms
VA/DoD	6.0-7.0%	7-8% 10 yr. life span 8-9% 5 yr. life span with comorbidities

ACP= American College of Physicians, AACE/ACE = American Association of Clinical Endocrinologists and American College of Endocrinology, ADA = American Diabetes Association, ICSI = Institute for Clinical Systems Improvement, NICE = National Institute for Health and Care Excellence, SIGN = Scottish Intercollegiate Guidelines Network, VA/DoD = U.S. Department of Veterans Affairs and Department of Defense.

ACP American College of Physicians℠
Leading Internal Medicine, Improving Lives

CLINICAL GUIDELINE

Hemoglobin A_{1c} Targets for Glycemic Control With Pharmacologic Therapy for Nonpregnant Adults With Type 2 Diabetes Mellitus: A Guidance Statement Update From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Devan Kansagara, MD, MCR; Carrie Horwitch, MD, MPH; Michael J. Barry, MD; and Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians*

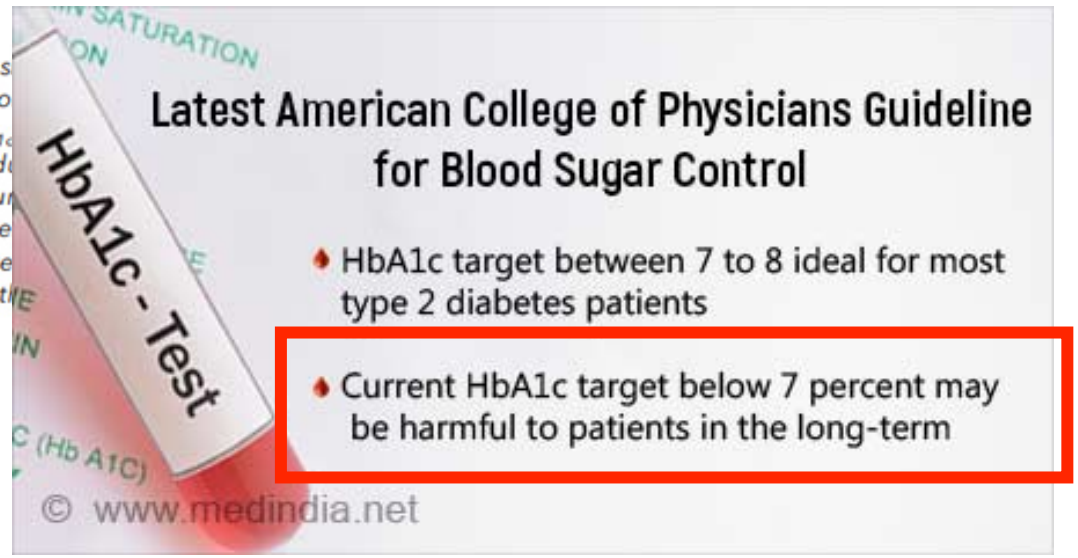
Description: The American College of Physicians developed this guidance statement to guide clinicians in selecting targets for pharmacologic treatment of type 2 diabetes.

Methods: The National Guideline Clearinghouse and the Guidelines International Network library were searched (May 2017) for national guidelines, published in English, that addressed hemoglobin A_{1c} (HbA_{1c}) targets for treating type 2 diabetes in nonpregnant outpatient adults. The authors identified guidelines from the National Institute for Health and Care Excellence and the Institute for Clinical Systems Improvement. In addition, 4 commonly used guidelines were reviewed, from the American Association of Clinical Endocrinologists and American College of Endocrinology, the American Diabetes Association, the Scottish Intercollegiate Guidelines Network, and the U.S. Department of Veterans Affairs and Department of Defense. The AGREE II (Appraisal of Guidelines for Research and Evaluation II) instrument was used to evaluate the guidelines.

Guidance Statement 2: *Clinicians should aim to achieve an HbA_{1c} level between 7% and 8% in most patients with type 2 diabetes.*

Guidance Statement 3: *Clinicians should consider deintensifying pharmacologic therapy in patients with type 2 diabetes who achieve HbA_{1c} levels less than 6.5%.*

Guidance Statement 4: *Clinicians s type 2 diabetes to minimize sympto cemia and avoid targeting an HbA_{1} life expectancy less than 10 years d years or older), residence in a nu conditions (such as dementia, cance ease, or severe chronic obstructive congestive heart failure) because t benefits in this population.*



Hemoglobin A_{1c} Targets for Nonpregnant Adults With Type 2 Diabetes Mellitus

The full guidance statement is titled "Hemoglobin A_{1c} Targets for Glycemic Control With Pharmacologic Therapy for Nonpregnant Adults With Type 2 Diabetes Mellitus: A Guidance Statement Update From the American College of Physicians." The authors are A. Qaseem, T.J. Wilt, D. Kansagara, C. Horwitch, M.J. Barry, and M.A. Forciea, for the Clinical Guidelines Committee of the American College of Physicians.

This article was published at Annals.org on 6 March 2018.

Who developed these recommendations?
The American College of Physicians (ACP) developed these recommendations. The ACP is a professional organization for internal medicine doctors, who specialize in health care for adults.

What is the problem and what is known about it so far?
Type 2 diabetes is a common disease that makes it difficult for the body to use sugar and store energy from food. Common symptoms include urinating often and increased thirst, but diabetes often has no symptoms. Over time, high blood sugar levels can lead to health problems, including blindness, kidney failure, nerve damage, heart attack, stroke, and the need to amputate certain body parts (such as fingers and toes). Treatment to control blood sugar levels includes eating healthy food, regular exercise, and medicines. Doctors measure sugar with a blood test called hemoglobin A_{1c} (HbA_{1c}) to diagnose and control the disease. Different organizations define good control with different HbA_{1c} levels. The ACP reviewed guidelines for HbA_{1c} targets in nonpregnant adults with type 2 diabetes to develop guidance to help doctors and patients decide what levels to aim for.

How did the ACP develop these recommendations?
The ACP Clinical Guidelines Committee reviewed 6 guidelines to rate their quality. They used this information to develop recommendations for HbA_{1c} targets that ACP believes would be best for nonpregnant adults with type 2 diabetes. An HbA_{1c} level below 7% can reduce the chances of diabetes complications. However, this level can be difficult to achieve and can be associated with weight gain and life-threatening episodes of low blood sugar.

What does the ACP suggest that patients and doctors do?
Doctors and patients should work together to create goals for diabetes control. These goals should consider the benefits and harms of diabetes medicines, patient preferences and general health, and costs of treatment.

For most patients, HbA_{1c} levels should be between 7% and 8%.

Doctors and patients should consider decreasing the dose or stopping diabetes medicines if HbA_{1c} levels fall below 6.5%.

If a patient has type 2 diabetes and is not expected to live longer than 10 years, lower HbA_{1c} levels might cause more harm than benefit. These patients include people older than 80 years; people who live in a nursing home; and people who have serious health conditions, such as dementia, cancer, kidney disease, severe chronic obstructive pulmonary disease, or heart failure.

Questions you may want to ask your doctor

- What is HbA_{1c}, and how often should I have this test?
- How do I measure my blood sugar at home and how often?
- What HbA_{1c} level is best for me?
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ACP | Center for Patient Partnership in Healthcare

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Ann Intern Med. 2018;168:I-18. doi:10.7326/P18-0003

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6.5%.

No trials show that targeting HbA_{1c} levels below 6.5% in diabetic patients improves clinical outcomes, and pharmacologic treatment to below this target has substantial harms. The ACCORD trial, which targeted an HbA_{1c} level less than 6.5% and achieved the lowest level of the included studies (6.4%), was discontinued early because of increased overall and cardiovascular-related death and severe hypoglycemic events (18). The ADVANCE study also failed to find a statistically

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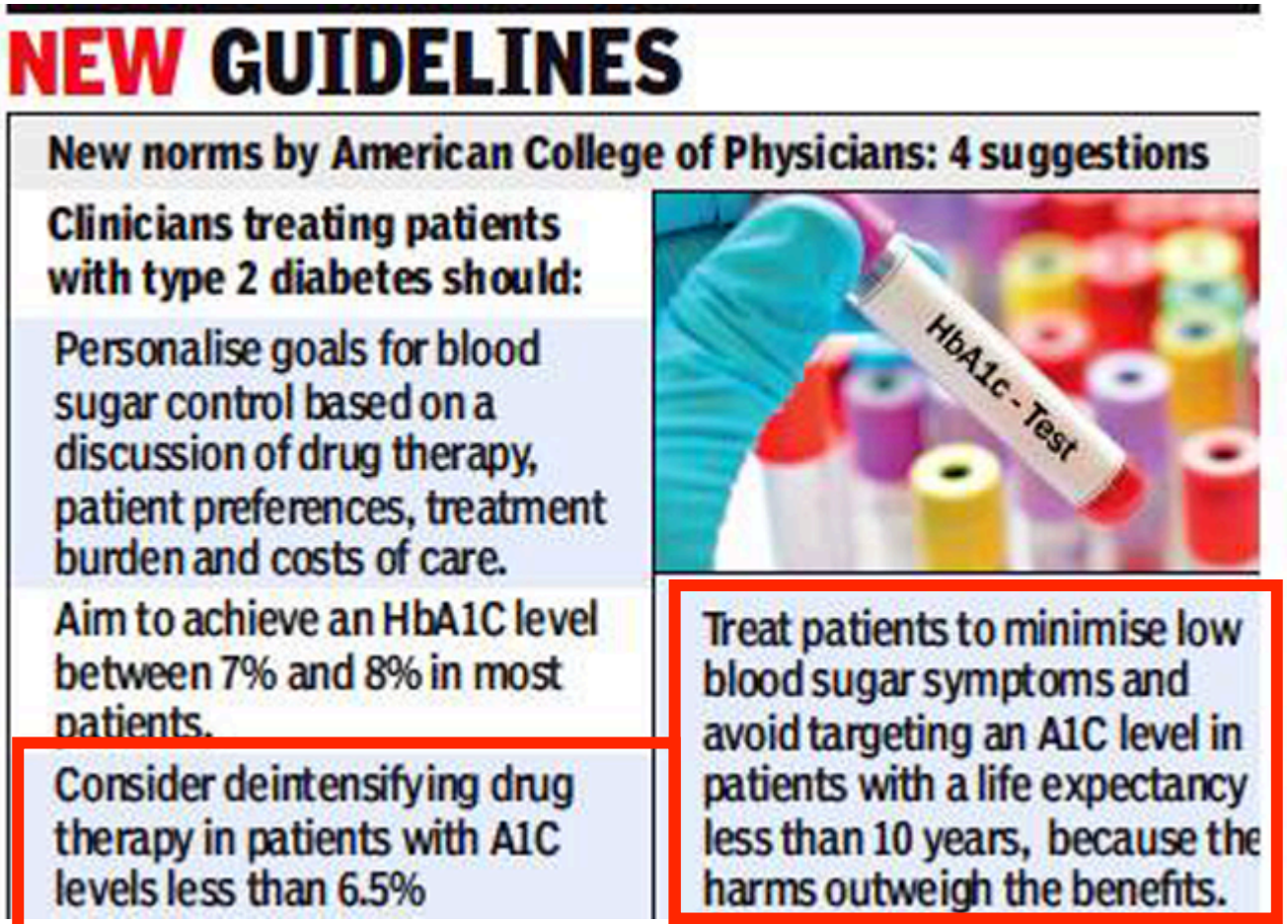

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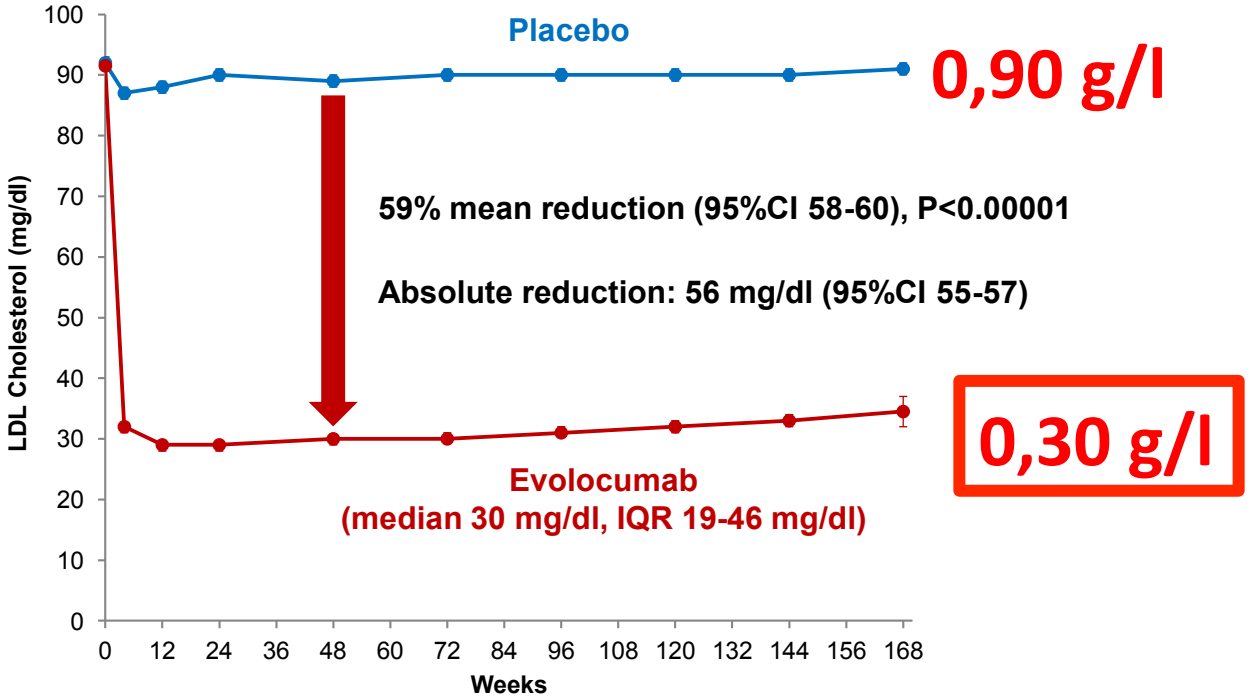
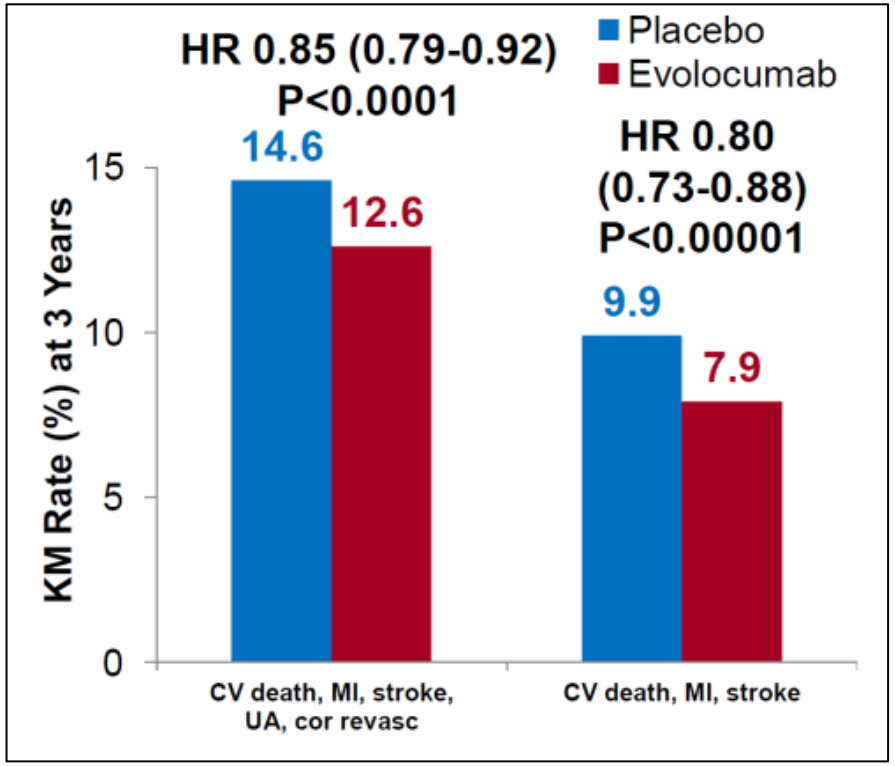
Quelle cible de LDL?

LDL Cholesterol





Sabatine MS et al. *New Engl J Med* 2017;376:1713-22

LDL: as low as you can

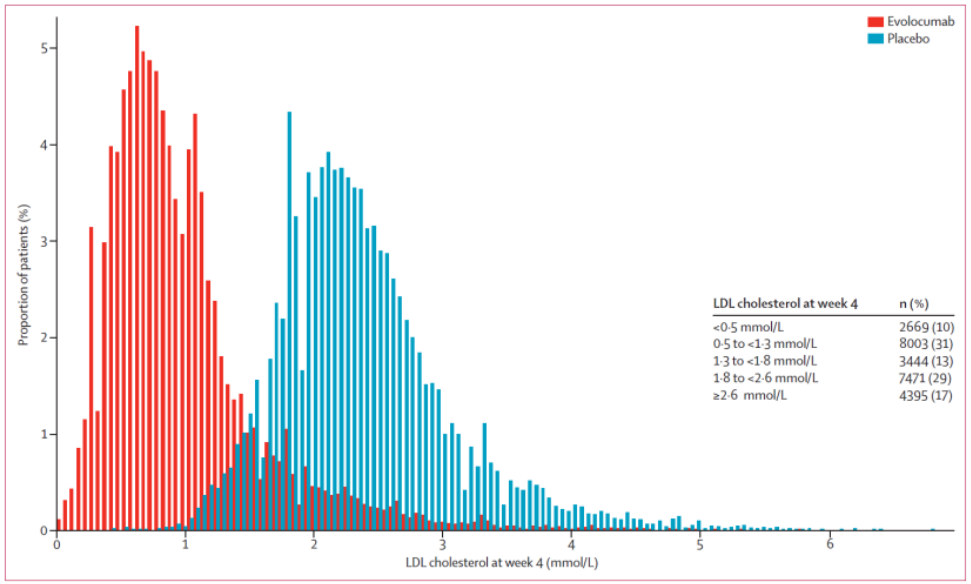


Figure 1: **Distribution of achieved LDL-cholesterol concentrations at 4 weeks in patients who did not have a primary efficacy or prespecified safety event before the study**
Red bars are evolocumab (median 0·8 mmol/L, IQR 0·5–1·2). Blue bars are placebo (median 2·2 mmol/L, IQR 1·9–2·7).

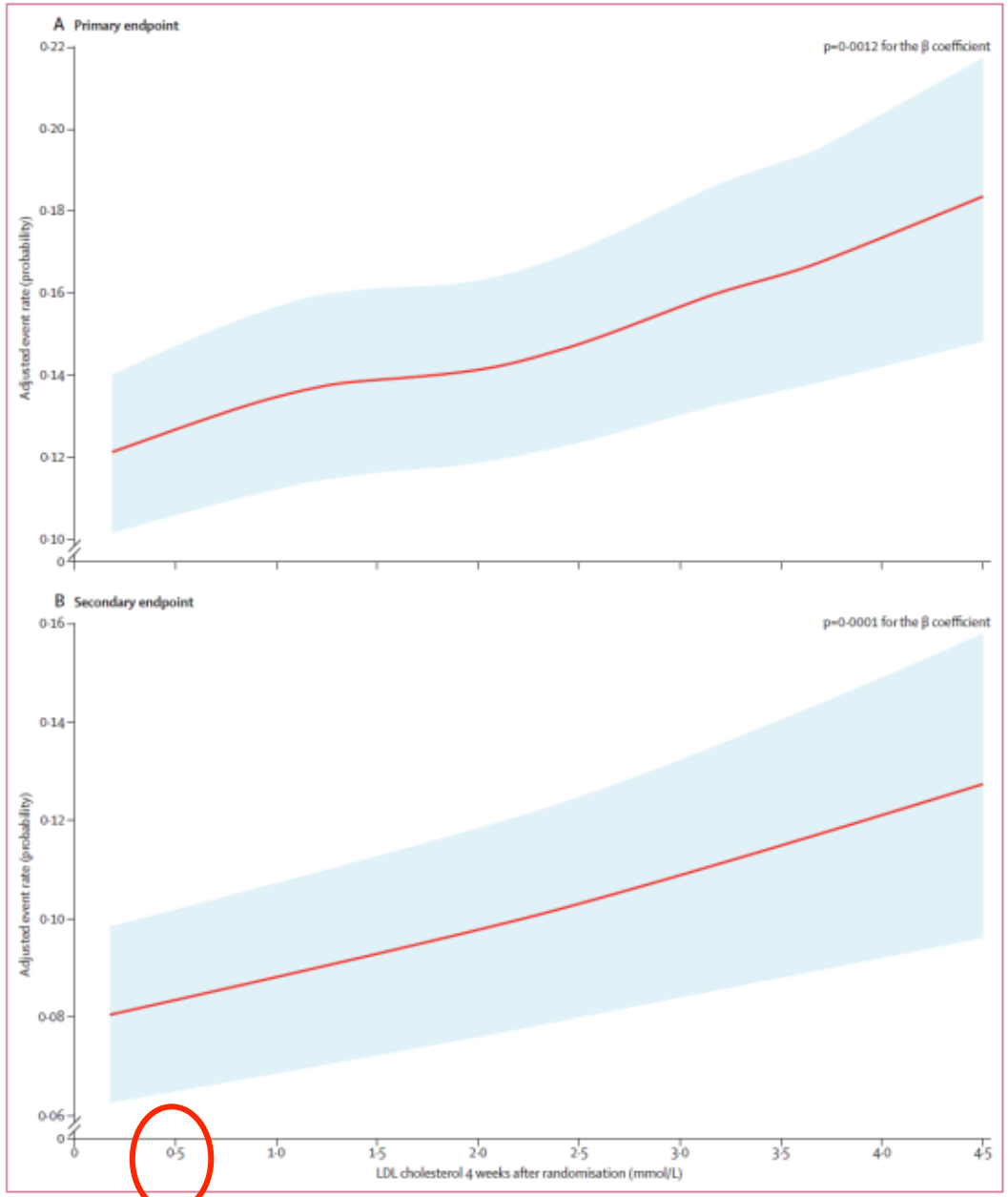
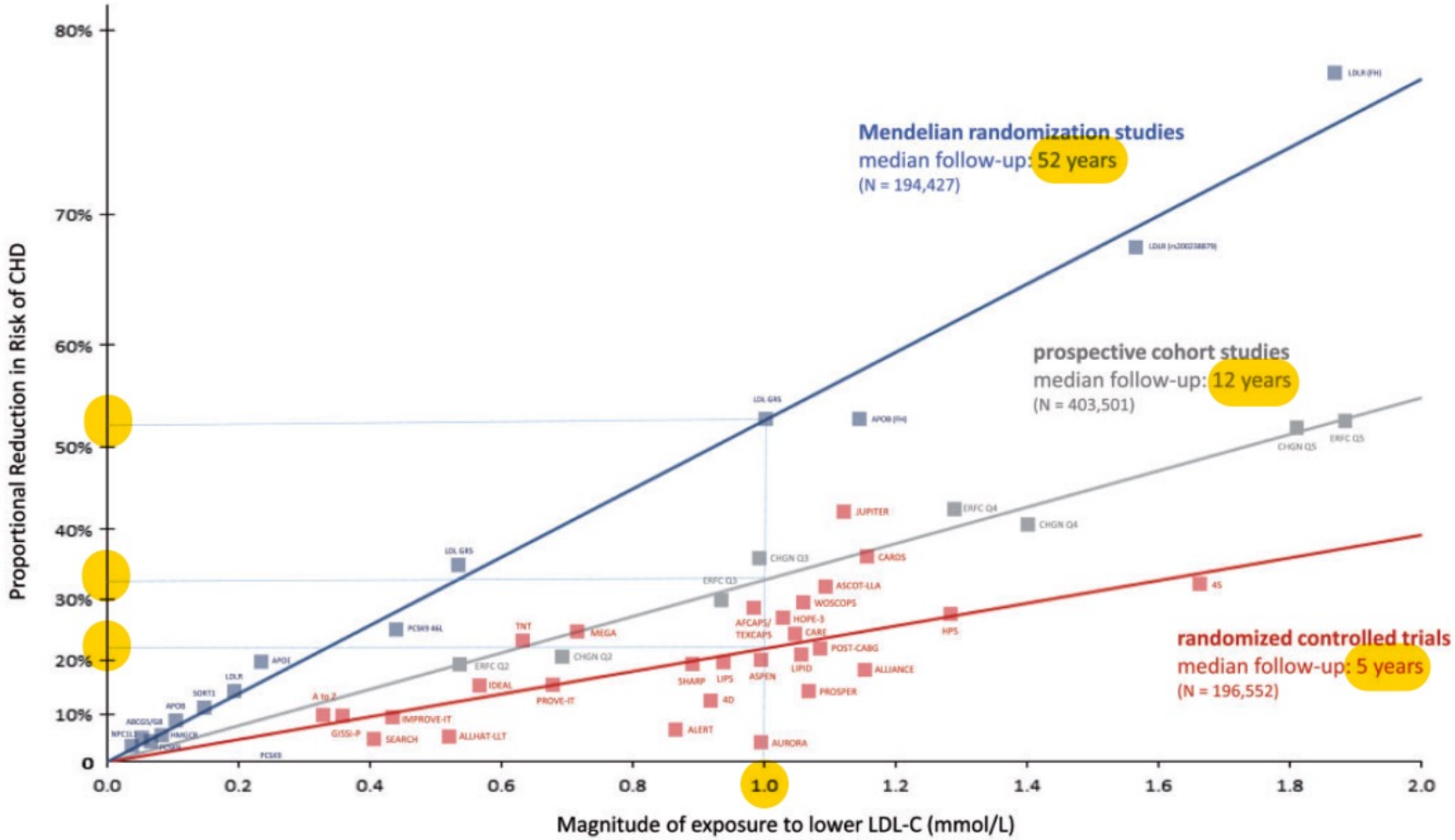


Figure 3: **Relationship between the achieved LDL-cholesterol concentration at 4 weeks and the risk of the primary (A) and key secondary (B) efficacy composite endpoints**
The primary efficacy endpoint was a composite of cardiovascular death, myocardial infarction, stroke, coronary revascularisation, or hospital admission for unstable angina. The key secondary efficacy endpoint was a composite of cardiovascular death, myocardial infarction, or stroke. The red line represents the adjusted probability of an event and blue areas are the 95% CIs of the regression model estimate.

Giugliano RP et al.. Lancet 2017; 390: 1962–71

Benefit grows with time…as long as you can



Ference B et al. European Heart Journal 2017 doi:10.1093/eurheartj/ehx144

Prediction of clinical effect : LDL-c (apoB or non-HDL)

1. **Time**
2. **Basal LDL-c**
3. **Magnitude of LDL reduction**
4. **No adverse event**

- 12 % at 1 year
- 17 % at 2 years
- 20 % at 3 years
- 22 % at 4 years
- 33 % at 12 years
- 54 % at 52 years

Treatment for 4 to 5 years

Basal LDL-c Magnitude of relative reduction of LDL-c	2 g/l = 5,2 mmol	1 g/l = 2,6 mmol/l	0,50 g/l = 1,3 mmol/l
50 %	2,6 mmol/l : **57,2 %**	1,3 mmol/l : **28,6 %**	0,65 mmol/l : **14,3 %**
30 %	1,56 mmol/l : **34,3 %**	0,78 mmol/l : **17,2 %**	0,39 mmol/l : **8,6 %**
15 %	0,78 mmol/l : **17,2 %**	0,39 mmol/l : **8,6 %**	0,20 mmol/l : **4,3 %**

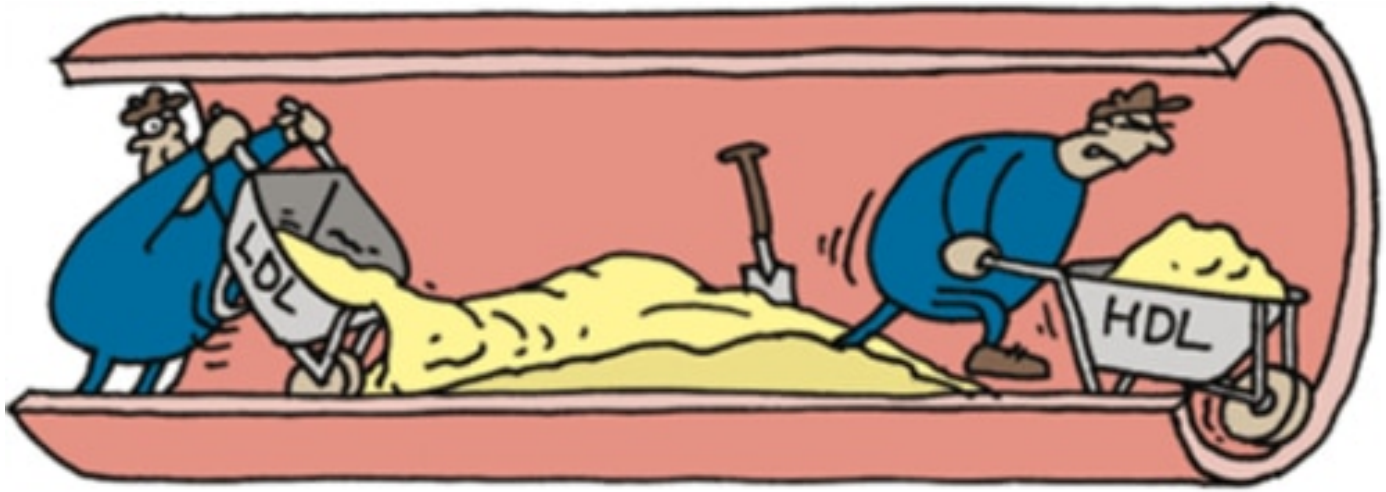
Patient à haut risque métabolique

- 74 ans
- 98 kilos, 1m73
- Diabète de type 2, sulfamide (car intolérance métformine)
- LDL : 0,82 g/l, HDL : 0,70 g/l,
- TG : 2,10 g/l
- PA : 105/70 sous IEC, Calcique, diurétique
- Aspirine

- Quelle espérance de vie?
- Sport et régime?
- Quelle cible d'HbA1c?
- **Quelle cible** de LDL? **de HDL ?** de TG ?
- Oméga 3 ou pas?
- Quelle PA cible?
- Aspirine ou pas?

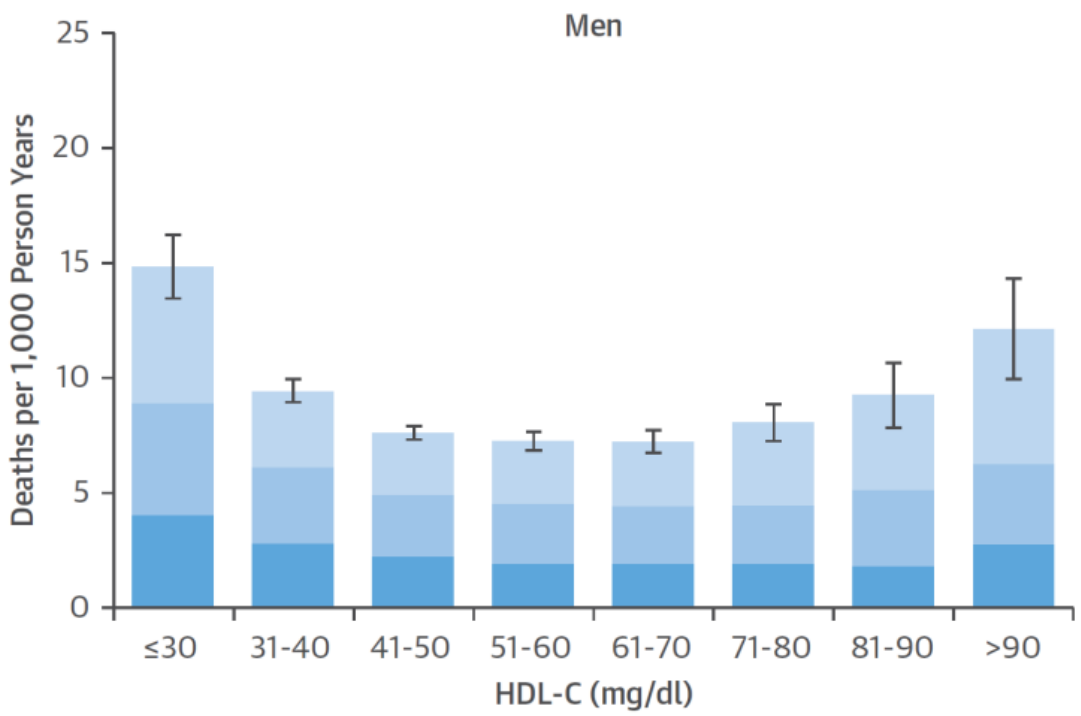
Quelle cible de HDL ?

- Avant 2016
- 2016
- 2017
- **2018**

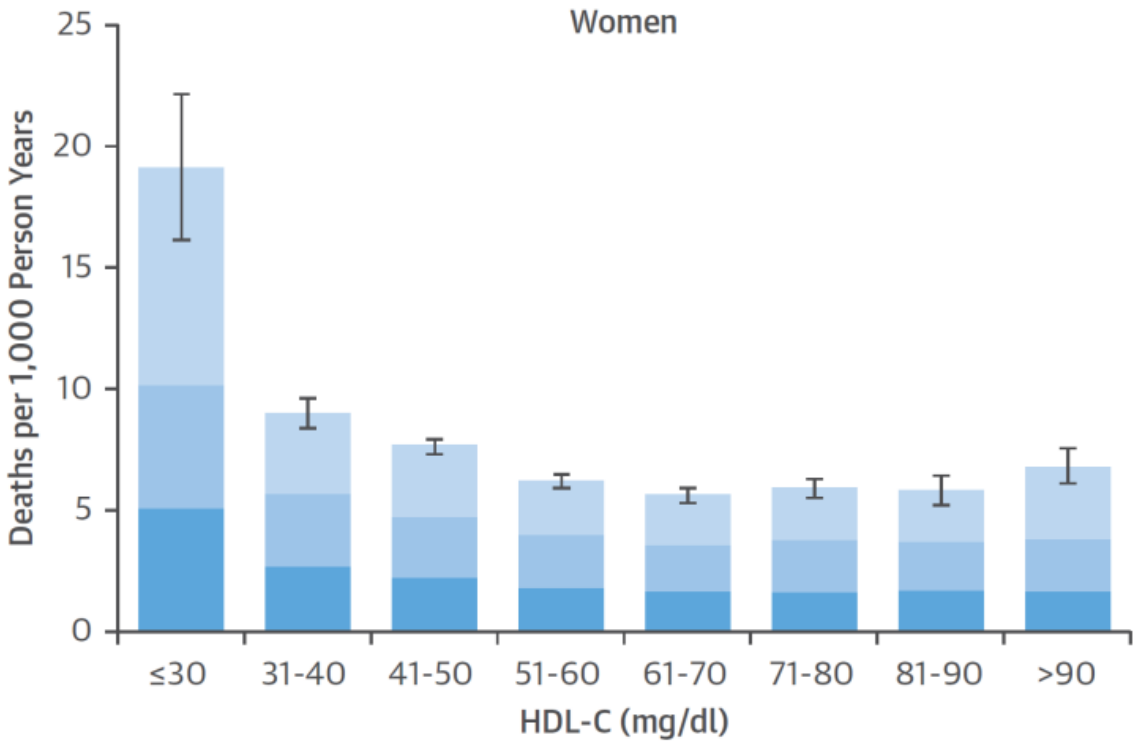


CANHEART HDL : Age-Standardized Cause-Specific Mortality

2016



9 339 deaths



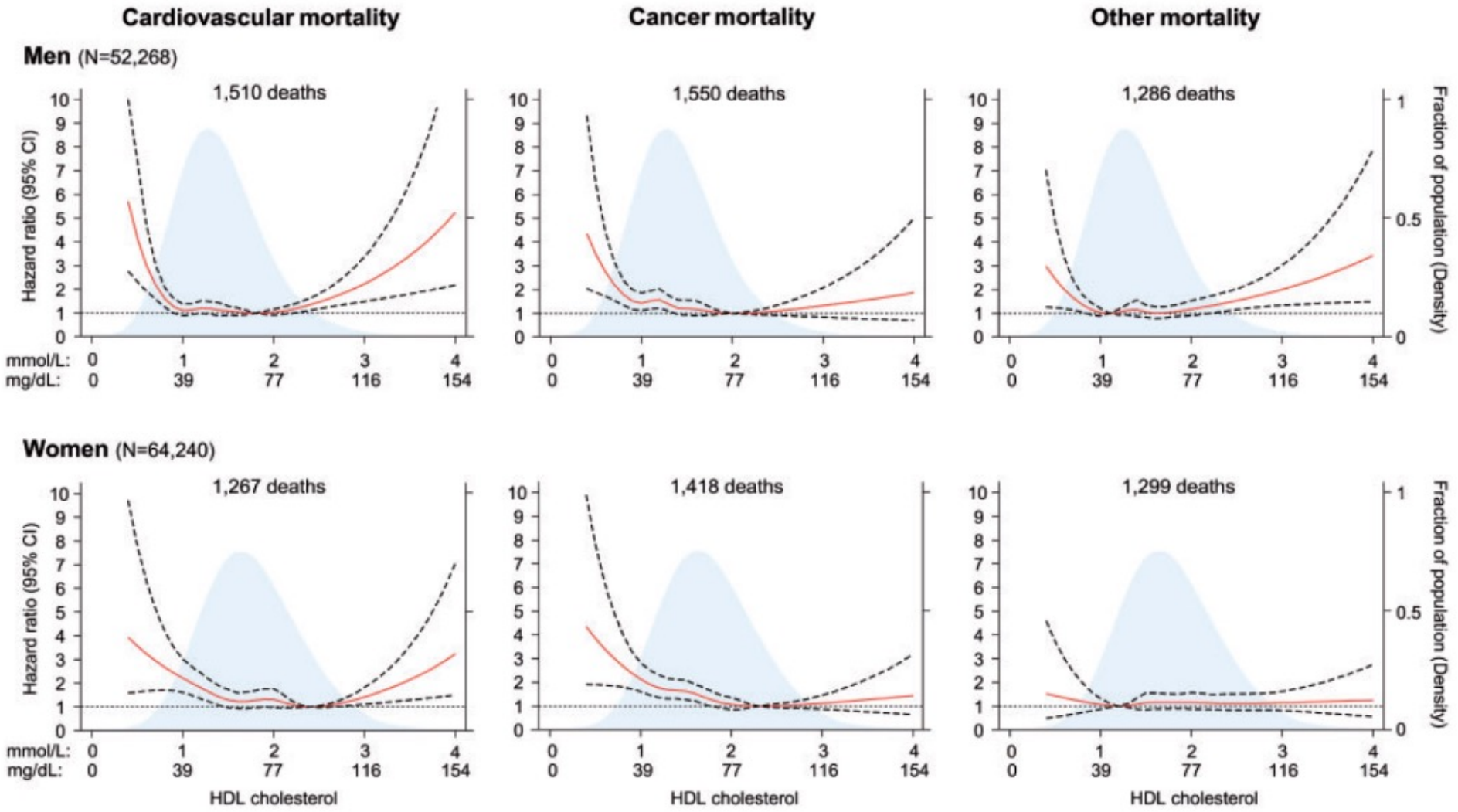
8 613 deaths

CV death Cancer death Other death

Ko, D.T. et al. J Am Coll Cardiol. 2016;68(19):2073–83.

Copenhagen studies : Age-Standardized Cause-Specific Mortality

2017



Madsen CM et al. Eur H J 2017; 38: 2478-2486

2018

Elevated HDL-C is associated with adverse cardiovascular events

Marc Allard-Ratick, MD
Jay Khambhati, MD
Pratik Sandesara, MD
Laurence Sperling, MD, FACC, FAHA, FACP

No sources of funding

Figure 1a: Association between HDL-C and all-cause mortality

▲ Reference HDL-C 45mg/dL

95% confidence interval

*Adjusted for common covariates

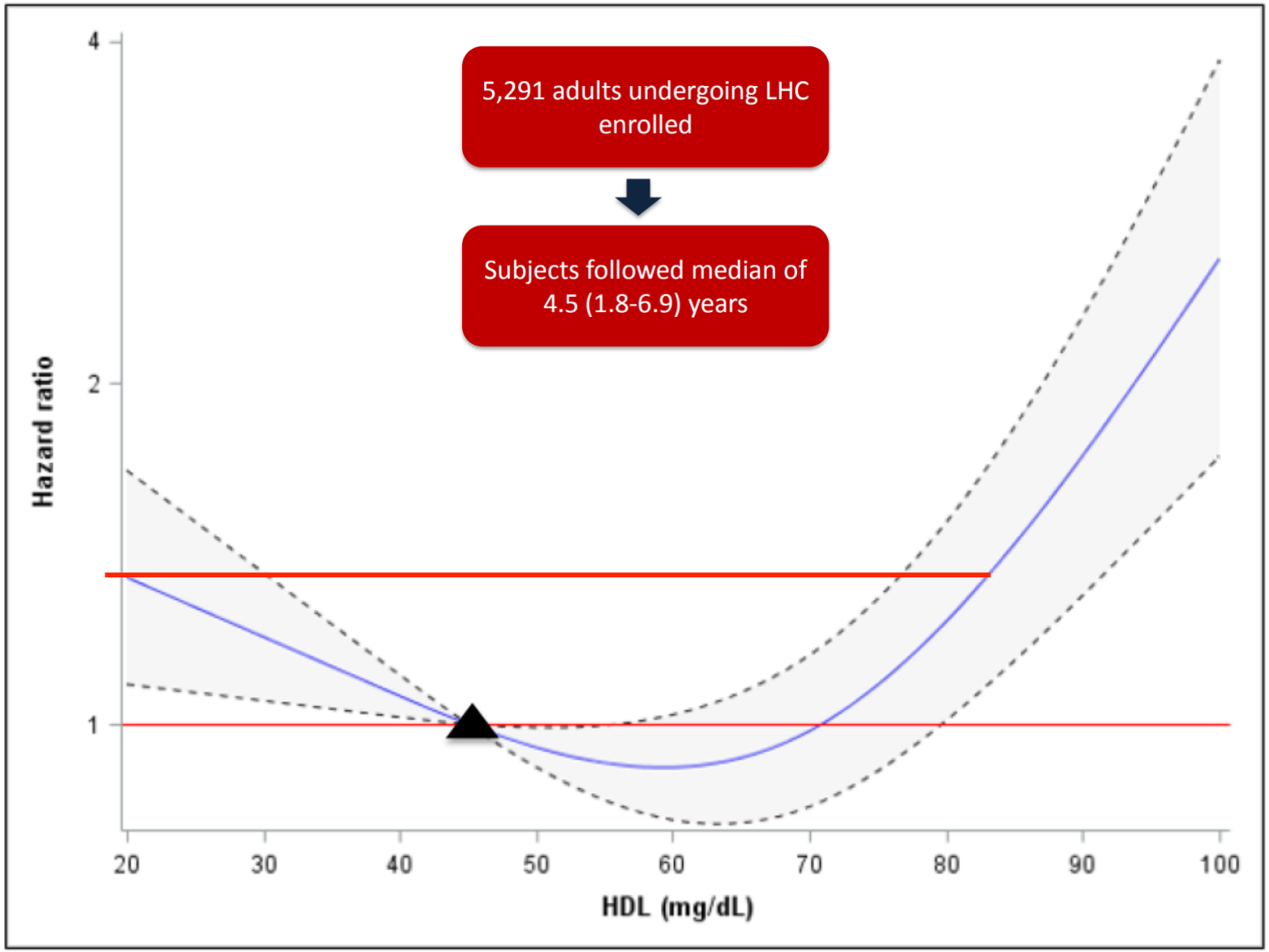


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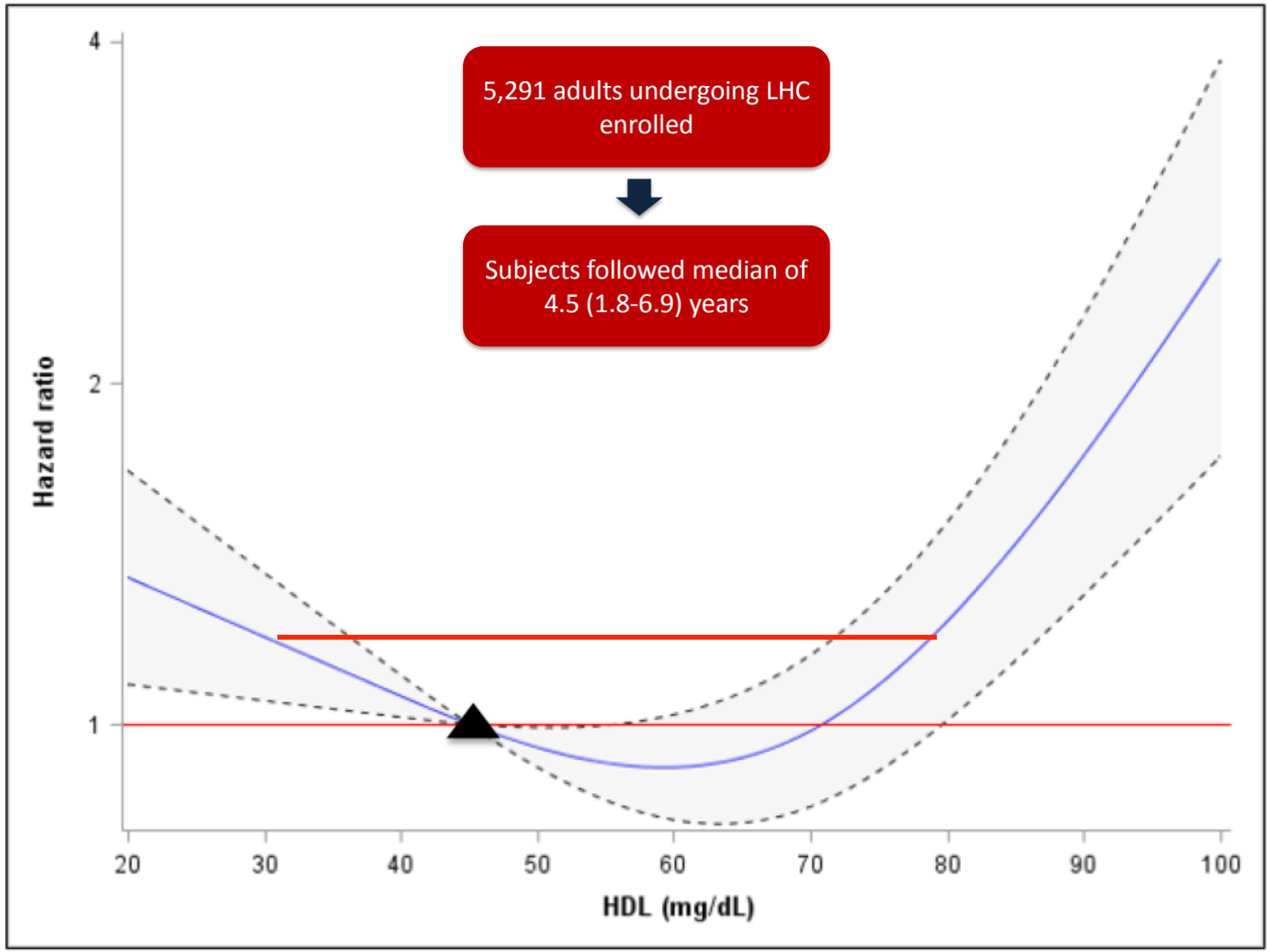
Figure 1a: Association between HDL-C and all-cause mortality

▲ Reference HDL-C 45mg/dL

95% confidence interval

*Adjusted for common covariates



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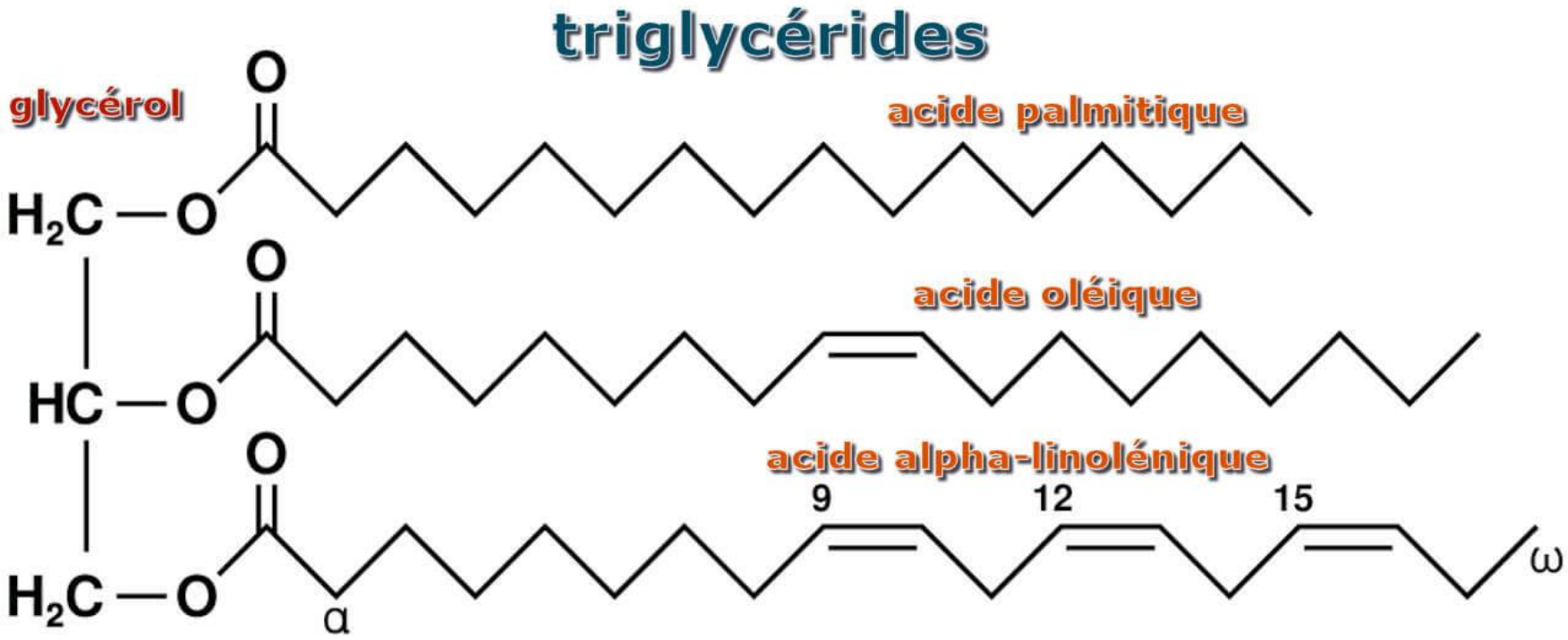
Patient à haut risque métabolique

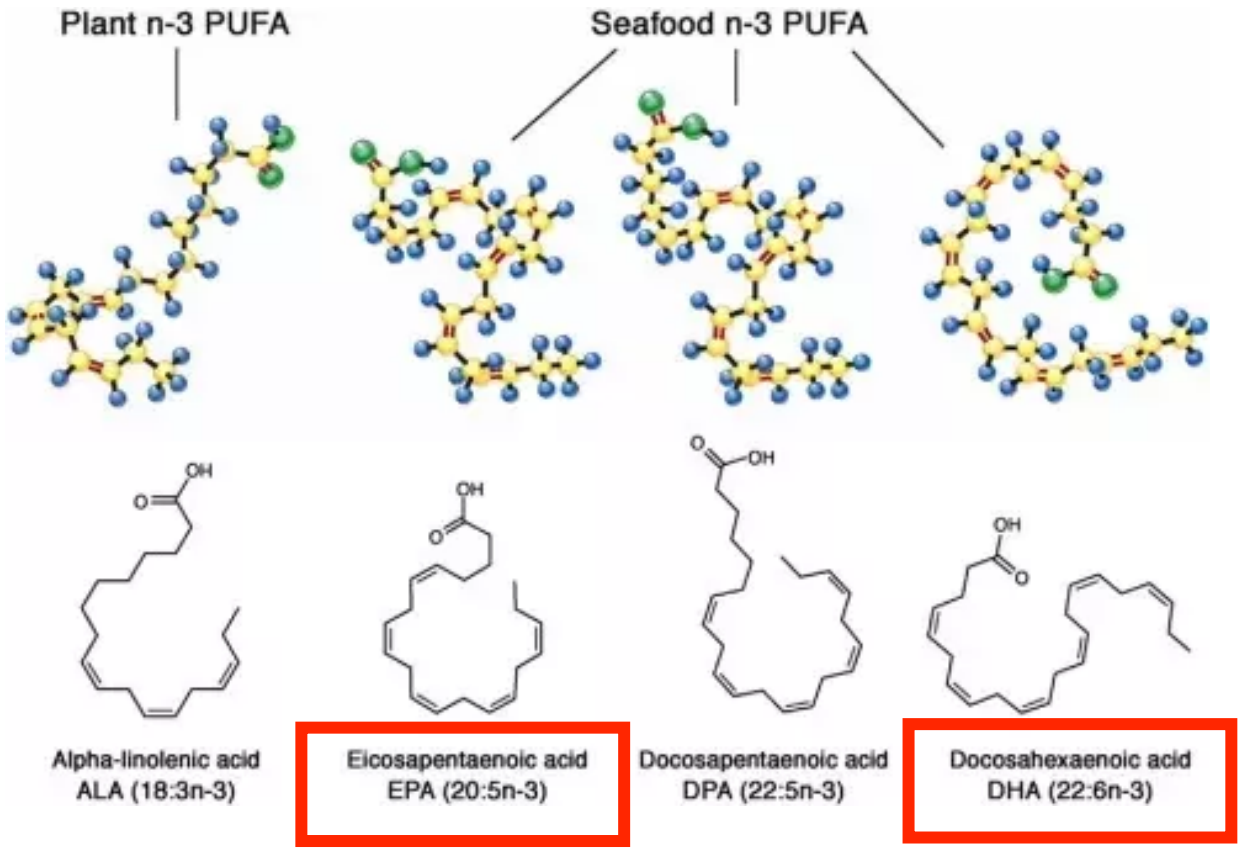
- 74 ans
- 98 kilos, 1m73
- Diabète de type 2, sulfamide (car intolérance métformine)
- LDL : 0,82 g/l, HDL : 0,70 g/l,
- TG : 2,10 g/l
- PA : 105/70 sous IEC, Calcique, diurétique
- Aspirine

- Quelle espérance de vie?
- Sport et régime?
- Quelle cible d'HbA1c?
- **Quelle cible** de LDL? de HDL ? **de TG ?**
- **Oméga 3 ou pas?**
- Quelle PA cible?
- Aspirine ou pas?

Quelle cible de TG ?



Oméga 3 ou pas ?



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Omega-3 fatty acids for the primary and secondary prevention of cardiovascular disease

Article *in* Cochrane Database of Systematic Reviews · July 2018
DOI: 10.1002/14651858.cd003177.pub3

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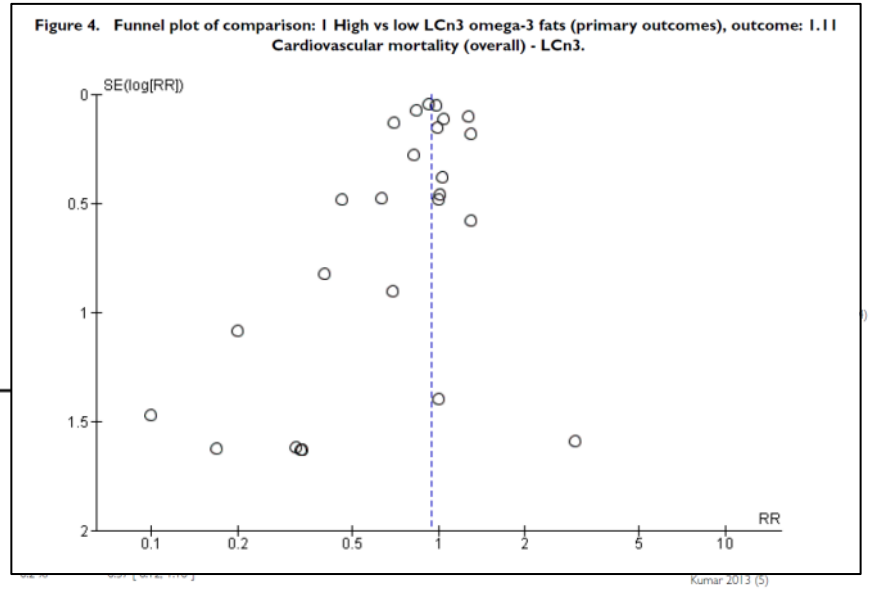
Omega-3 fatty acids for the primary and secondary prevention of cardiovascular disease (Review)

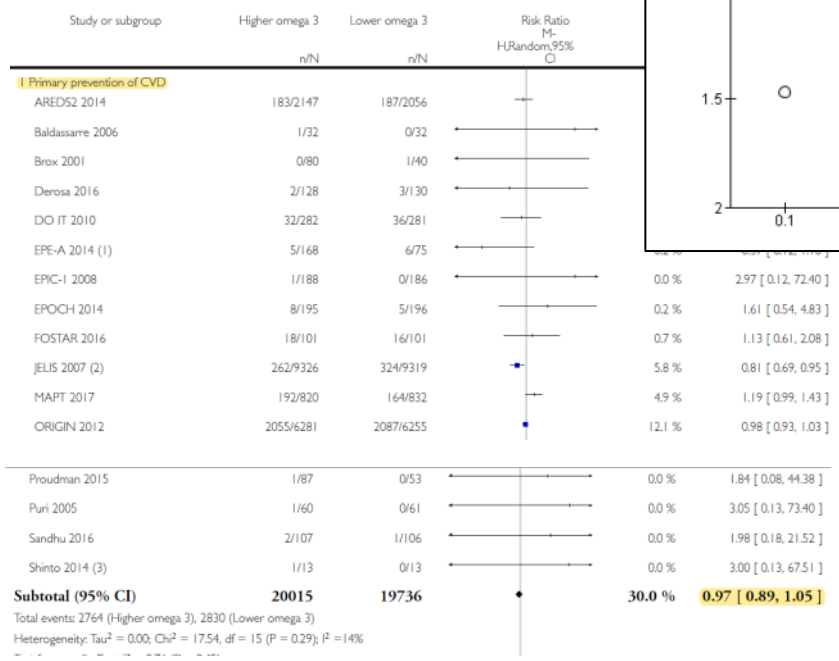
Main results

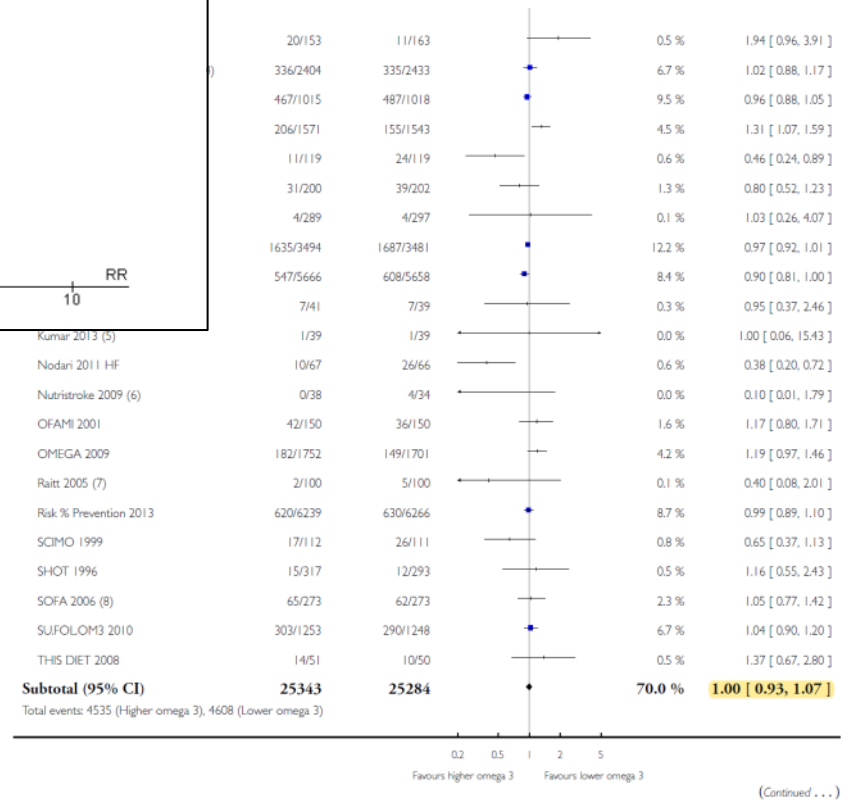
We included 79 RCTs (112,059 participants) in this review update and found that 25 were at low summary risk of bias. Trials were of 12 to 72 months' duration and included adults at varying cardiovascular risk, mainly in high-income countries. Most studies assessed LCn3 supplementation with capsules, but some used LCn3- or ALA-rich or enriched foods or dietary advice compared to placebo or usual diet.

Meta-analysis and sensitivity analyses suggested **little or no effect of increasing LCn3** on **all-cause mortality** (RR 0.98, 95% CI 0.90 to 1.03, 92,653 participants; 8189 deaths in 39 trials, high-quality evidence), **cardiovascular mortality** (RR 0.95, 95% CI 0.87 to 1.03, 67,772 participants; 4544 CVD deaths in 25 RCTs), **cardiovascular events** (RR 0.99, 95% CI 0.94 to 1.04, 90,378 participants; 14,737 people experienced events in 38 trials, high-quality evidence), **coronary heart disease (CHD) mortality** (RR 0.93, 95% CI 0.79 to 1.09, 73,491 participants; 1596 CHD deaths in 21 RCTs), **stroke** (RR 1.06, 95% CI 0.96 to 1.16, 89,358 participants; 1822 strokes in 28 trials) or **arrhythmia** (RR 0.97, 95% CI 0.90 to 1.05, 53,796 participants; 3788 people experienced arrhythmia in 28

Prévention primaire vs prévention secondaire: événements CV majeurs





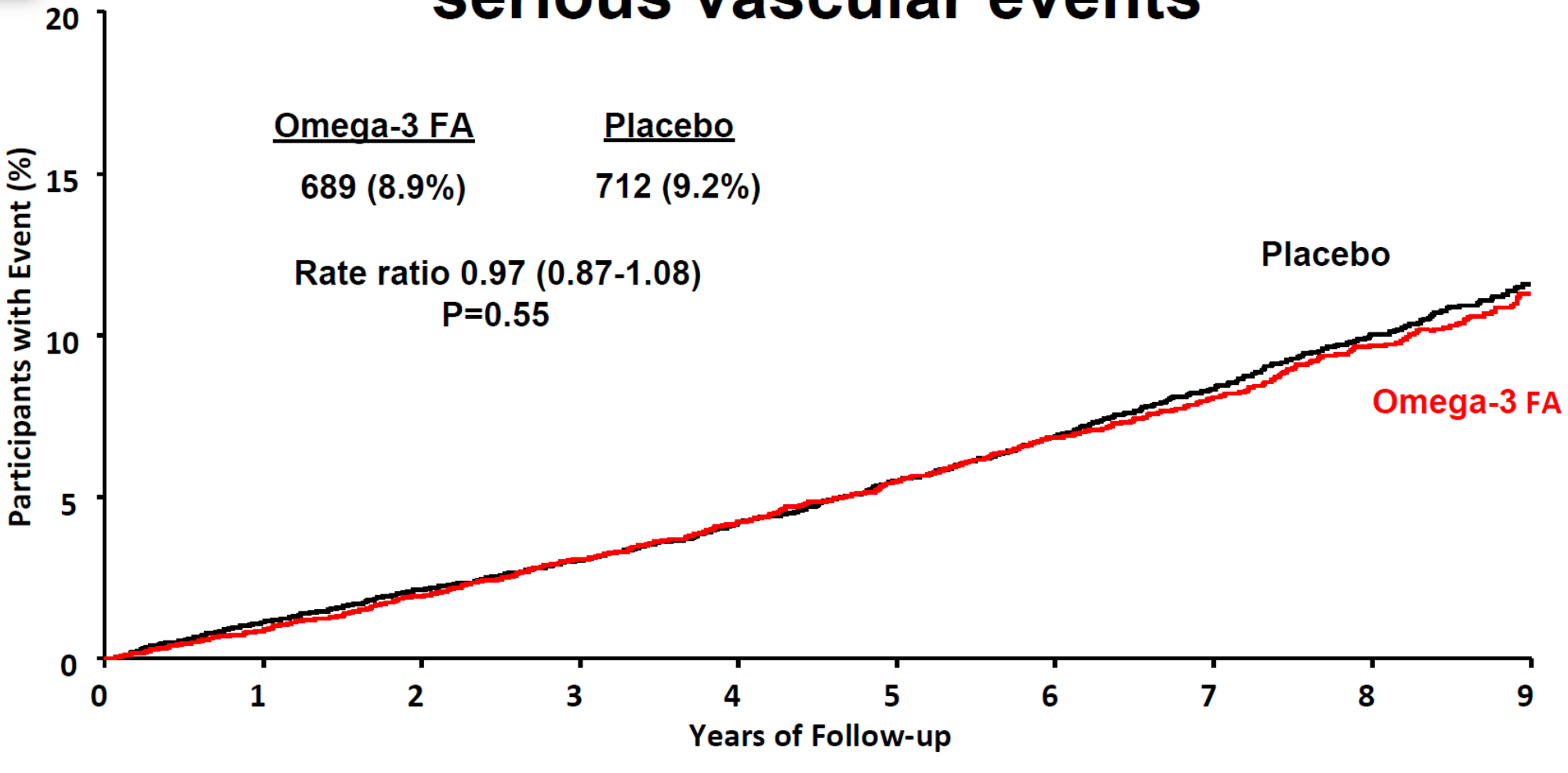


Étude ASCEND : résultats oméga-3 vs placebo, 15 480 pts

ESC Congress Munich 2018
25-29 August
Where the world of cardiology comes together

British Heart Foundation

Effect of omega-3 FA supplements on serious vascular events



Etude VITAL : schéma

VITamin D and OmegA-3 TriaL

Question évaluée : par rapport au placebo, un supplément alimentaire par des oméga-3 et/ou de la vitamine D, peut-il réduire le risque d'événements CV majeurs et de cancers chez des patients à risque CV élevé?

Critères d'inclusion : prévention CV primaire et pas d'antécédent de cancer; hommes ≥ 50 ans; femmes ≥ 55 ans

N = 25 875

R : plan factoriel

	Oméga 3 (840 mg/j huile de poisson EPA + DHA)	**Placebo d'oméga 3**
Vitamine D3 (2000 UI/j cholécalciférol)	6 469	6 469
Placebo de Vitamine D3	6 468	6 469

Critère primaire: tous les cancers à 5 ans, événements CV majeurs à 5 ans (décès CV, IDM, AVC)

EPA : acide eicosapentaénoïque
DHA: acide docosahexaénoïque

Etude VITAL : résultats oméga-3

VITamin D and OmegA-3 TriaL

Événements CV

(Critères primaire e

Evénements CV ma

Evénements CV éla

Tous IDM

Tous AVC

Mortalité CV

Autres critères[c]

Tous cancers invasif

Décès par cancer

Mortalité toutes cau

%I)

1.06)

1.04)

0.90)*

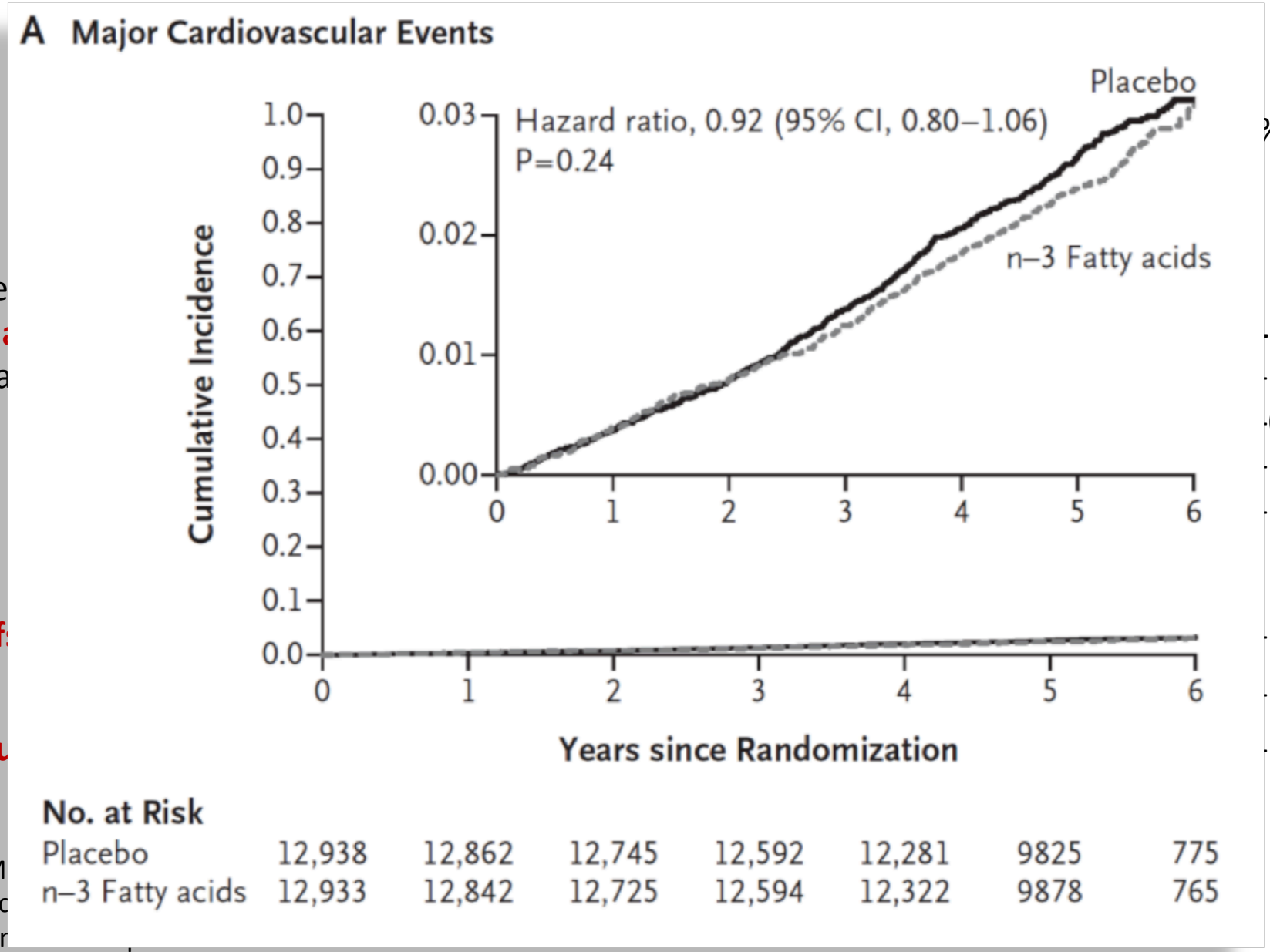
1.31)

1.21)

1.13)

1.20)

1.15)



- Valeur de p <0,05; IDM
  [a] Pcritère primaire : déc
- [C] Non préspécifié comr

Etude VITAL : synthèse, commentaire

VITamin D and OmegA-3 Trial

- Chez des patients à risque CV élevé, un supplément alimentaire par des oméga-3, par rapport au placebo,
  - ne réduit le risque d'événements CV majeurs
  - ne réduit le risque de cancer
- Ce résultat neutre est concordant avec celui d'autres études contre placebo ayant évalué une dose faible à moyenne d'une association d'EPA et de DHA (études ORIGIN et ASCEND)
- Ce résultat neutre n'est **pas concordant avec celui de l'étude REDUCE IT** ayant évalué une forte dose d'EPA exclusivement

EPA : acide eicosapentaénoïque
DHA: acide docosahexaénoïque

reduce-it

Reduction of Cardiovascular Events with Icosapent Ethyl–Intervention Trial

Deepak L Bhatt, MD, MPH, Ph. Gabriel Steg, MD, Michael Miller, MD,

Eliot A. Brinton, MD, Terry A. Jacobson, MD, Steven B. Ketchum, PhD,

Ralph T. Doyle, Jr., BA, Rebecca A. Juliano, PhD, Lixia Jiao, PhD,

Craig Granowitz, MD, PhD, Jean-Claude Tardif, MD, Christie M. Ballantyne, MD,

on Behalf of the REDUCE-IT Investigators

BWH

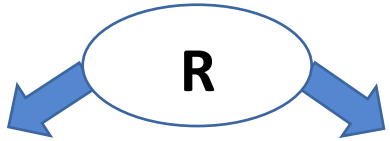
VE RI TAS

Etude REDUCE IT : schéma

Reduction of Cardiovascular Events With EPA – Intervention Trial

Critères d'inclusion : prévention CV secondaire ou diabète et au moins 1 FdR, traitement par statine, LDL entre 0,41 et 1 g/l et élévation des triglycérides entre 1,50 et 4,99 g/l

N = 8 179



Intervention	Contrôle
Omega 3, EPA uniquement (4g/j)	**Placebo**

Critère primaire: décès CV, IDM non fatal, AVC non fatal, revascularisation coronaire ou angor instable justifiant une hospitalisation

Hypothèse: supériorité

Etude REDUCE IT : caractéristiques des patients inclus

Reduction of Cardiovascular Events With EPA – Intervention Trial

	Icosapent Ethyl (N=4089)	Placebo (N=4090)
Age (ans), médiane (Q1-Q3)	64,0 (57,0 – 69,0)	64,0 (57,0 – 69,0)
Femmes, n (%)	1162 (28,4%)	1195 (29,2%)
Catégorie de risque CV, n (%)		
Prévention secondaire	2892 (70,7%)	2893 (70,7%)
Prévention primaire	1197 (29,3%)	1197 (29,3%)
Ezetimibe en cours (%)	262 (6,4%)	262 (6,4%)
Statine, dose, n (%)		
Faible	254 (6,2%)	267 (6,5%)
Modérée	2533 (61,9%)	2575 (63,0%)
Haute	1290 (31,5%)	1226 (30,0%)
Diabète de type 2, n (%)	2367 (57,9%)	2363 (57,8%)
Triglycérides (g/l), médiane (Q1-Q3)	**2,16** (1,76 – 2,72)	**2,16** (1,75 – 2,74)
HDL-C (g/l), médiane (Q1-Q3)	0,40 (0,34 – 0,46)	0,40 (0,35 – 0,46)
LDL-C (g/l), médiane (Q1-Q3)	**0,74** (0,62 – 0,88)	**0,76** (0,63 – 0,89)
Triglycerides repartition, n (%)		
< 1,50 g/l	412 (10,1%)	429 (10,5%)
1,50 à < 2,00 g/l	1193 (29,2%)	1191 (29,1%)
≥ 2,00 g/l	2481 (60,7%)	2469 (60,4%)

Etude REDUCE IT : effets sur les biomarqueurs à 1 an

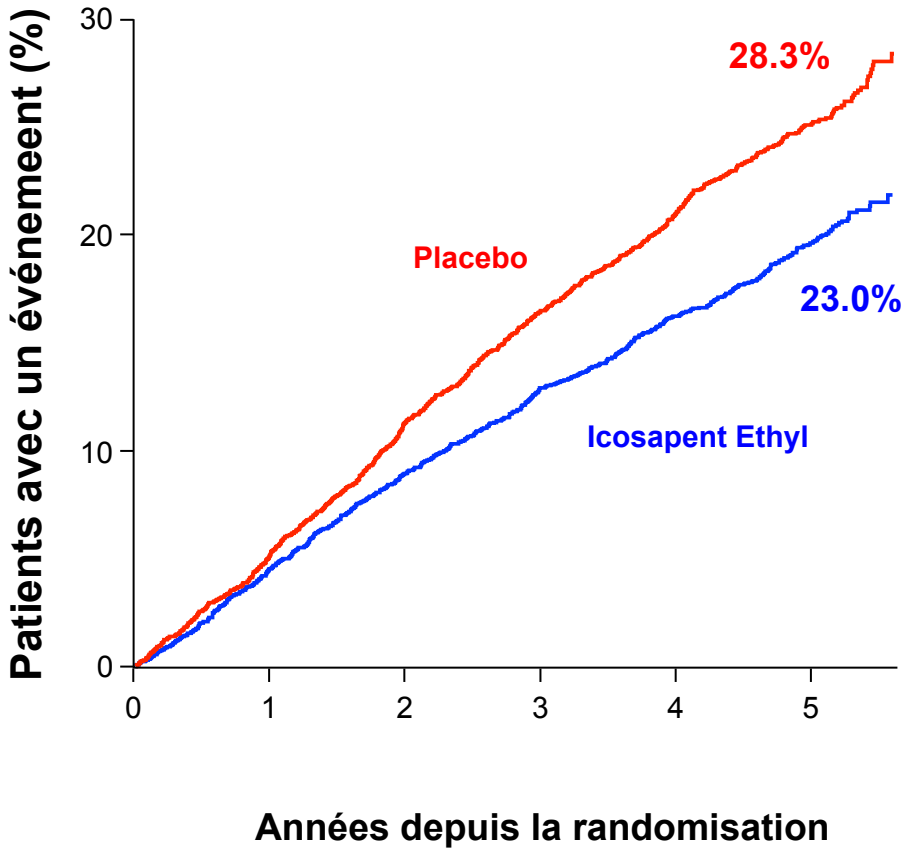
Reduction of Cardiovascular Events With EPA – Intervention Trial

	Icosapent Ethyl (N=4089) Médiane		Placebo (N=4090) Médiane		Différence médiane entre les groups à 1 an		
Biomarqueur*	**Base**	**1 an**	**Base**	**1 an**	**Variation absolue par rapport à la base**	**Variation relative (%) par rapport à la base**	**Valeur de p pour la variation relative**
Triglycerides (g/l)	2,16	1,75	2,16	2,21	- 0,44	**- 19,7**	< 0,0001
Non-HDL-C (g/l)	1,18	1,13	1,18	1,30	- 0,15	- 13,1	< 0,0001
LDL-C (g/l)	0,74	0,77	0,76	0,84	- 0,05	**- 6,6**	< 0,0001
HDL-C (g/l)	0,40	0,39	0,40	0,42	- 0,025	- 6,3	< 0,0001
Apo B (g/l)	0,82	0,80	0,83	0,89	- 0,08	- 9,7	< 0,0001
hsCRP (mg/l)	2.2	1.8	2.1	2.8	- 0,9	- 39,9	< 0,0001
EPA (µg/ml)	26.1	144.0	26.1	23.3	+ 114,9	+ 358,8	< 0,0001

*Apo B et hsCRP ont été mesurées à 2 ans.

Etude REDUCE IT : résultat sur le critère primaire

(décès CV, IDM, AVC, revascularization coronaire, angor instable)



Hazard Ratio: 0,75

(IC 95% : 0,68–0,83)

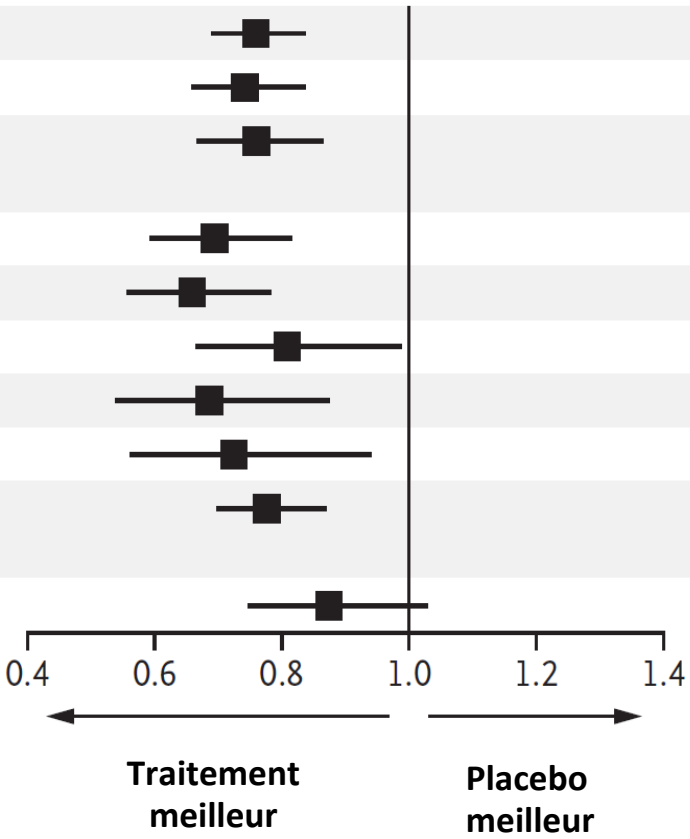
Réduction relative du risque : 24,8%

P=0,00000001

Etude REDUCE IT : résultats

Analyse hiérarchisée des principaux critères évalués

Critère évalué	Icosapent Ethyl (N=4089)	Placebo (N=4090)	HR (IC 95 %)	Valeur de p pour l'interaction
	no. of patients with event (%)			
Critère primaire composé	705 (17.2)	901 (22.0)	0.75 (0.68–0.83)	<0.001
Principal critère secondaire composé	459 (11.2)	606 (14.8)	0.74 (0.65–0.83)	<0.001
Décès CV et IDM non fatals	392 (9.6)	507 (12.4)	0.75 (0.66–0.86)	<0.001
IDM fatals et non fatals	250 (6.1)	355 (8.7)	0.69 (0.58–0.81)	<0.001
Revascularisation en urgence	216 (5.3)	321 (7.8)	0.65 (0.55–0.78)	<0.001
Décès CV	174 (4.3)	213 (5.2)	0.80 (0.66–0.98)	0.03
Hospitalisation pour angor instable	108 (2.6)	157 (3.8)	0.68 (0.53–0.87)	0.002
AVC fatals et non fatals	98 (2.4)	134 (3.3)	0.72 (0.55–0.93)	0.01
Décès toutes causes, IDM et AVC non fatals	549 (13.4)	690 (16.9)	0.77 (0.69–0.86)	<0.001
Décès toutes causes	274 (6.7)	310 (7.6)	0.87 (0.74–1.02)	—



Critère primaire composé : décès CV, infarctus du myocarde non fatals, AVC non fatals, revascularisation coronaire et angor instable
Principal critère secondaire composé: décès CV, infarctus du myocarde non fatals, AVC non fatals.
CV = cardiovasculaire ; IDM =infarctus du myocarde; AVC : accident vasculaire cérébral

Etude REDUCE IT

Analyses en sous-groupe pertinentes (décès CV, IDM, AVC)

Sous-groupe	Hazard Ratio (95% CI)	Icosapent Ethyl n/N (%)	Placebo n/N (%)	HR (IC95%)	Int P Val
Catégorie de risque					0.46
Prévention secondaire		361/2892 (12.5%)	489/2893 (16.9%)	0.72 (0.63–0.82)	
Prévention primaire		98/1197 (8.2%)	117/1197 (9.8%)	0.81 (0.62–1.06)	

Sous-groupe	Hazard Ratio (95% CI)	Icosapent Ethyl n/N (%)	Placebo n/N (%)	HR (IC95%)	Int P Val
Diabète à l'inclusion					0.29
Diabète		286/2394 (11.9%)	391/2393 (16.3%)	0.70 (0.60–0.81)	
Pas de diabète		173/1695 (10.2%)	215/1694 (12.7%)	0.80 (0.65–0.98)	

Sous-groupe	Hazard Ratio (95% CI)	Icosapent Ethyl n/N (%)	Placebo n/N (%)	HR (IC95%)	Int P Val
Triglycerides à l'inclusion ≥ 2,00 vs < 2,00 g/l					0.62
Triglycerides ≥ 2,00 g/l		290/2481 (11.7%)	371/2469 (15.0%)	0.75 (0.65–0.88)	
Triglycerides < 2,00 g/l		169/1605 (10.5%)	235/1620 (14.5%)	0.71 (0.58–0.86)	

Sous-groupe	Hazard Ratio (95% CI)	Icosapent Ethyl n/N (%)	Placebo n/N (%)	HR (IC95%)	Int P Val
Triglycerides à l'inclusion ≥1,50 vs <1,50 g/l					0.68
Triglycerides ≥ 1,50 g/l		421/3674 (11.5%)	546/3660 (14.9%)	0.74 (0.65–0.84)	
Triglycerides < 1,50 g/l		38/412 (9.2%)	60/429 (14.0%)	0.66 (0.44–0.99)	

Etude REDUCE IT : commentaires

Reduction of Cardiovascular Events With EPA – Intervention Trial

- **Profil lipidique** : LDL moyen : 0,75 g/l et TG moyens: 2,16 g/l , tous sous statine
- **Effet lipidique** : diminution de 19 % des TG, sans élévation du LDL ?

  Résultat identique si TG au départ inférieur ou supérieur à 2 g/l

  ou si TG atteints inférieurs ou pas à 1,5 g/l
- **Profil clinique** des patients : prévention secondaire 70 %, diabète 30 % ?
- **Molécule** utilisée: **EPA uniquement** ou acide eicosapentaénoïque sous forme ethyl-esther?
- **Dose** utilisée : **4 g/j** ?
- **Critères évalués** : revascularisation coronaire et angor instable en sus ?
- Effet hasard?...

Etude REDUCE IT
Hémorragies sévères

	Icosapent Ethyl (N=4089)	Placebo (N=4090)	P-value
Hémorragies	111 (2.7%)	85 (2.1%)	0.06
gastrointestinales	62 (1.5%)	47 (1.1%)	0.15
du système nerveux central	14 (0.3%)	10 (0.2%)	0.42
autres	41 (1.0%)	30 (0.7%)	0.19

- Aucune hémorragie fatale durant l'étude
- AVC hémorragique certifié par comité d'adjudication – pas de différence entre les groupes (13 sous icosapent ethyl et 10 sous placebo; p=0,55)

Etude REDUCE IT Effets indésirables les plus fréquents (au moins 5 % des patients) et significatifs

Événements	Icosapent Ethyl (N=4089)	Placebo (N=4090)	P-value
Diarrhée	367 (9.0%)	453 (11.1%)	0.002
Oedèmes périphériques	267 (6.5%)	203 (5.0%)	0.002
Constipation	221 (5.4%)	149 (3.6%)	<0.001
Fibrillation atriale	215 (5.3%)	159 (3.9%)	0.003
Anémie	191 (4.7%)	236 (5.8%)	0.03

Etude REDUCE IT : synthèse, commentaire

Reduction of Cardiovascular Events With EPA – Intervention Trial

- **De l'acide eicosapentaénoïque (EPA) à 4 g/j** réduit le risque d'événements CV majeurs en prévention CV secondaire, et en prévention primaire en cas de diabète ou de syndrome métabolique, chez des patients traités par statine et ayant des triglycérides compris entre 1,5 et 5 g/l

- L'effet clinique **parait indépendant de l'effet obtenu sur les triglycérides**

- **Cet effet clinique n'a jamais été constaté** dans les essais thérapeutiques conduits en double aveugle contre placebo afin d'évaluer des doses modérées d'association d'acide eicosapentaénoïque et d'acide docosahexaénoïque (DHA)

- **Ces éléments suggèrent un effet spécifique de l'EPA à dose élevée**

Etude REDUCE IT vs VITAL oméga-3

Bénéfice clinique net et ample dans REDUCE IT

Pas de bénéfice clinique dans VITAL

- **Molécule** utilisée:
  - acide elcosapentanoïque (EPA) + acide docosahexanoïque (DHA) dans VITAL
  - **EPA uniquement** ou acide eicosapentaénoïque sous forme ethyl-esther dans REDUCE IT

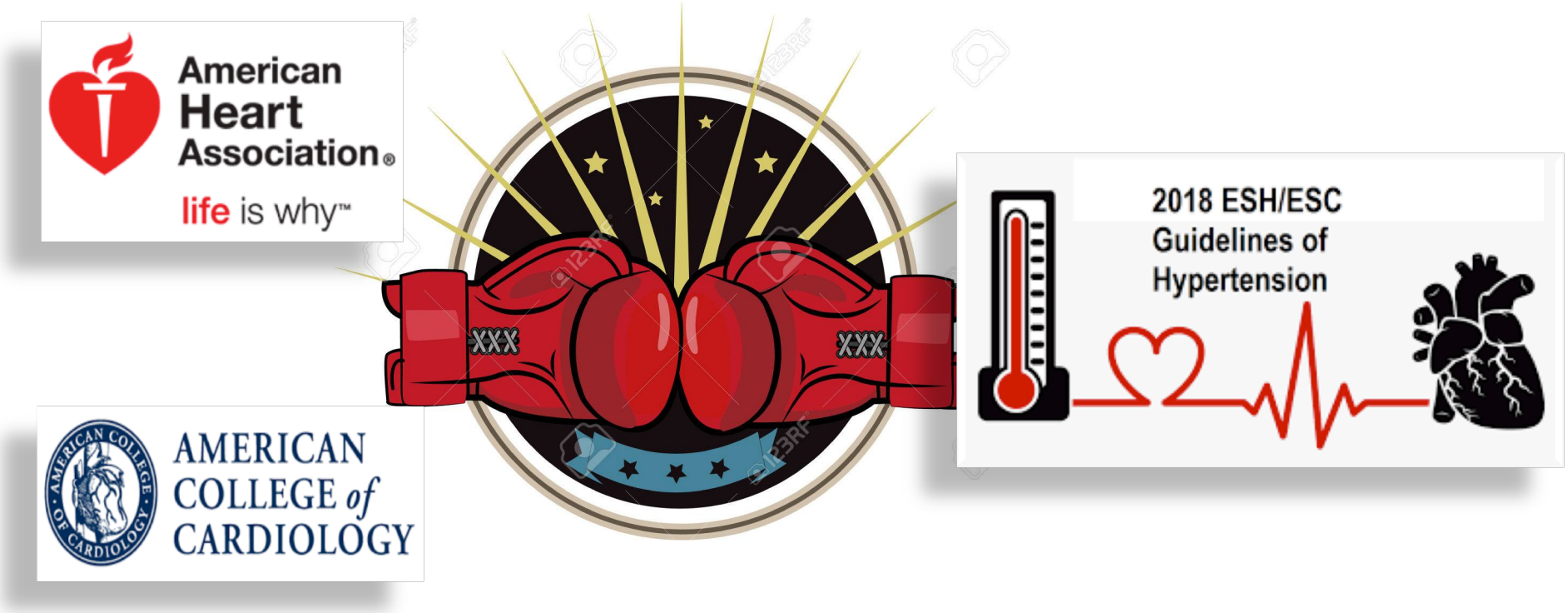
- **Dose** utilisée :
  - esters éthyliques d'acides oméga-3 à 90 % (**1000 mg**) dont EPA à 460 mg et DHA à 380 mg dans VITAL
  - **EPA à 4000 mg/j** dans REDUCE IT

Patient à haut risque métabolique

- 74 ans
- 98 kilos, 1m73
- Diabète de type 2, sulfamide (car intolérance métformine)
- LDL : 0,82 g/l, HDL : 0,70 g/l,
- TG : 2,10 g/l
- PA : 105/70 sous IEC, Calcique, diurétique
- Aspirine

- Quelle espérance de vie?
- Sport et régime?
- Quelle cible d'HbA1c?
- Quelle cible de LDL? de HDL ? de TG ?
- Oméga 3 ou pas?
- **Quelle PA cible?**
- Aspirine ou pas?

Quelle cible de PA ?



Nouvelles recommandations américaines

- **Nouvel élément majeur : changement de cible**

Inférieure à 130/80 mm Hg

American Heart Association®
life is why™

AMERICAN COLLEGE of CARDIOLOGY

Question

Êtes vous d’accord avec cela ?

Billet du mois

Faut-il abaisser la PAS en dessous de 130 mmHg et la PAD en dessous de 80 mmHg ? Ou du dévoiement de l'esprit de recommandations de pratique

"Dans la République des Sciences, la vérité ne se mesure pas au nombre des suffrages."

~ Pline l'Ancien

Parmi les éléments faisant débat dans le domaine de l'hypertension artérielle (HTA), il y a des recommandations récentes nord-américaines proposant que la pression artérielle soit diminuée en dessous de 130 mmHg pour la pression artérielle systolique (PAS) et en dessous de 80 mmHg pour la pression artérielle diastolique (PAD) sous traitement. Cette proposition s'adresse prioritairement aux patients les plus à risque d'événements cardiovasculaires (CV) et donc d'emblée en

BP TREATMENT THRESHOLD AND THE USE OF ASCVD RISK ESTIMATION TO GUIDE DRUG TREATMENT OF HYPERTENSION

Recommendations for BP Treatment Threshold and Use of ASCVD Risk Estimation* to Guide Drug Treatment of Hypertension		
COR	**LOE**	**Recommendations**
I	SBP: A DBP: C-EO	1. Use of BP-lowering medications is recommended for secondary prevention of recurrent CVD events in patients with clinical CVD and an average SBP of 130 mm Hg or higher or an average DBP of 80 mm Hg or higher, and for primary prevention in adults with an estimated 10-year atherosclerotic cardiovascular disease (ASCVD) risk of 10% or higher and an average SBP 130 mm Hg or higher or an average DBP 80 mm Hg or higher.
I	C-LD	2. Use of BP-lowering medication is recommended for primary prevention of CVD in adults with no history of CVD and with an estimated 10-year ASCVD risk <10% and an SBP of 140 mm Hg or higher or a DBP of 90 mm Hg or higher

* ACC/AHA Pooled Cohort Equations to estimate 10-y risk of ASCVD. ASCVD was defined as a first nonfatal MI or CHD death, or fatal or nonfatal stroke among adults free of CVD.

Critiques

Quelle est la définition de l'hypertension artérielle?

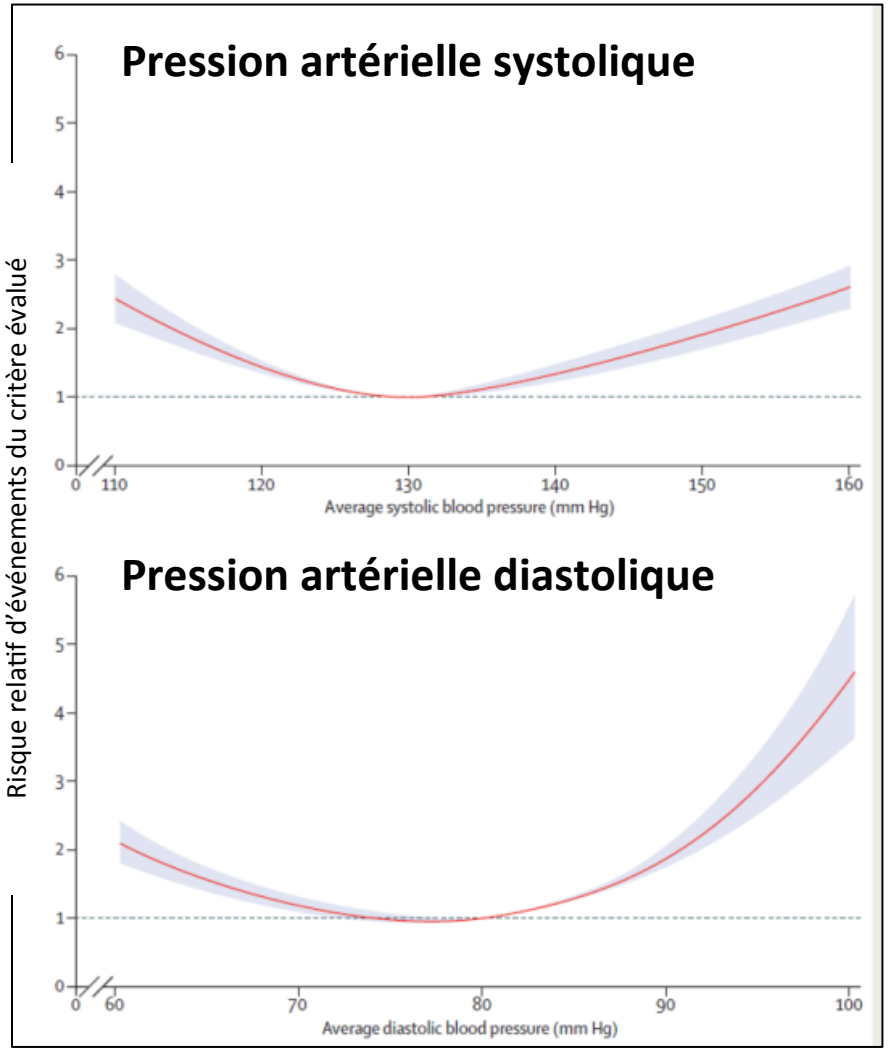
Définition conceptuelle

- Un chiffre tensionnel pour lequel le bénéfice d'une intervention (avec son risque et son coût) est supérieur à celui d'une absence d'intervention

Définition opérationnelle

- La valeur des chiffres tensionnels issue des essais cliniques pertinents : 140 mm Hg

Courbe en J dans la relation entre la pression artérielle sous traitement et le risque de décès CV, d'IDM ou d'AVC chez des coronariens

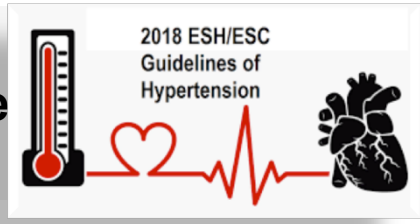


- Registre Clarify
- 22 672 coronariens
- traitement antihypertenseur en cours
- Suivi 5 ans

Référence : Vidal-Petiot E et al. Cardiovascular event rates and mortality according to achieved systolic and diastolic blood pressure in patients with stable coronary artery disease: an international cohort study. Lancet 2016; 388: 2142–52

Recommandations 2018 pour la prise en charge de l'hypertension artérielle de la Société européenne d'hypertension et de la Société européenne de cardiologie

Seuils décisionnels



PA normale haute (130-139/85-89)	HTA grade 1 (140-159/90-99)	HTA grade 2 (160-179/100-109)	HTA grade 3 (≥ 180/110)
Conseils hygiéno-diététiques			
Envisager le traitement pharmacologique **chez les patients à très haut risque** ayant une maladie CV notamment coronaire	Traitement pharmacologique **immédiat chez les patients à très haut risque CV**, ou avec maladie rénale ou retentissement viscéral de l'HTA	Traitement pharmacologique **immédiat chez tous** les patients	Traitement pharmacologique **immédiat chez tous** les patients

Recommandations 2018 pour la prise en charge de l'hypertension artérielle de la Société européenne d'hypertension et de la Société européenne de cardiologie

Les cibles de pression artérielle, en mm Hg, selon la situation clinique et leur valeur de sécurité

Âge	Cibles de pression artérielle systolique au cabinet médical					Cible de pression artérielle diastolique
	HTA	Diabète	Insuffisance rénale	Maladie coronaire	Antécédent d'AVC ou AIT	
De 18 à 65 ans	**Cible à 130** (ou moins si bien tolérée) **Pas en dessous de 120**	**Cible à 130** (ou moins si bien tolérée) **Pas en dessous de 120**	**Entre 130 et 140** (si bien tolérée)	**Cible à 130** (ou moins si bien tolérée) **Pas en dessous de 120**	**Cible à 130** (ou moins si bien tolérée) **Pas en dessous de 120**	Entre 80 et 70
De 65 à 79 ans	**Entre 140 et 130** (si bien toléré)	Entre 140 et 130 (si bien toléré)	Entre 140 et 130 (si bien toléré)	Entre 140 et 130 (si bien toléré)	Entre 140 et 130 (si bien toléré)	Entre 80 et 70
≥ 80 ans	**Entre 140 et 130** (si bien toléré)	Entre 140 et 130 (si bien toléré)	Entre 140 et 130 (si bien toléré)	Entre 140 et 130 (si bien toléré)	Entre 140 et 130 (si bien toléré)	Entre 80 et 70
Cible de pression artérielle diastolique	Entre 80 et 70	Entre 80 et 70	Entre 80 et 70	Entre 80 et 70	Entre 80 et 70	

Patient à haut risque métabolique

- 74 ans
- 98 kilos, 1m73
- Diabète de type 2, sulfamide (car intolérance métformine)
- LDL : 0,82 g/l, HDL : 0,70 g/l,
- TG : 2,10 g/l
- PA : 105/70 sous IEC, Calcique, diurétique
- Aspirine

- Quelle espérance de vie?
- Sport et régime?
- Quelle cible d'HbA1c?
- Quelle cible de LDL? de HDL ? de TG ?
- Oméga 3 ou pas?
- Quelle PA cible?
- **Aspirine ou pas?**

Aspirine ou pas ?

JAMA | Original Investigation

Association of Aspirin Use for Primary Prevention With Cardiovascular Events and Bleeding Events
A Systematic Review and Meta-analysis

Sean L. Zheng, BM, BCh, MA, MRCP; Alistair J. Roddick, BSc

JAMA. 2019;321(3):277-287. doi:10.1001/jama.2018.20578

ESC European Society of Cardiology

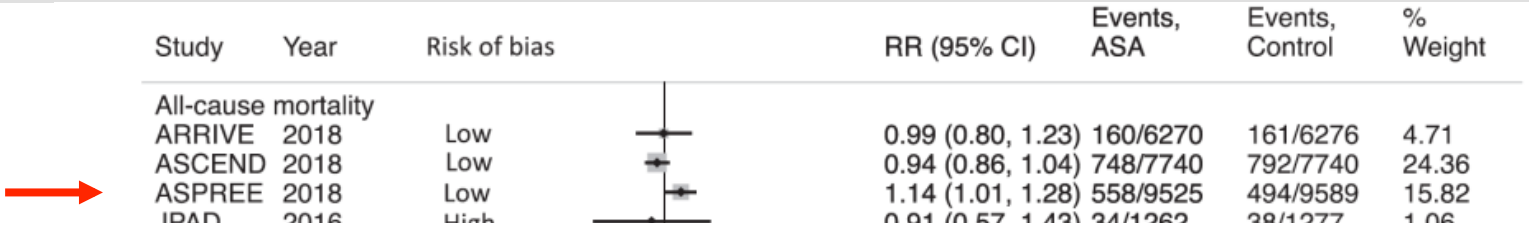
European Heart Journal (2019) **40**, 607–617
doi:10.1093/eurheartj/ehy813

FASTTRACK CLINICAL RESEARCH

Efficacy and safety of aspirin for primary prevention of cardiovascular events: a meta-analysis and trial sequential analysis of randomized controlled trials

Ahmed N. Mahmoud[1†], Mohamed M. Gad[2], Akram Y. Elgendy[1], Islam Y. Elgendy[1†], and Anthony A. Bavry[1,3*]

Effets de l'aspirine sur la mortalité et le risque d'hémorragies majeures



Study	Year	Risk of bias	RR (95% CI)	Events, ASA	Events, Control	% Weight
All-cause mortality						
ARRIVE	2018	Low	0.99 (0.80, 1.23)	160/6270	161/6276	4.71
ASCEND	2018	Low	0.94 (0.86, 1.04)	748/7740	792/7740	24.36
ASPREE	2018	Low	1.14 (1.01, 1.28)	558/9525	494/9589	15.82
IPAD	2016	High	0.91 (0.57, 1.43)	34/1262	38/1277	1.06

.2 1 5

ASA is associated with better outcome ASA is associated with worse outcome

4.6. Aspirin Use

Recommendations for Aspirin Use

Referenced studies that support recommendations are summarized in Online Data Supplements 17 and 18.

COR	LOE	Recommendations
IIb	A	1. Low-dose aspirin (75-100 mg orally daily) might be considered for the primary prevention of ASCVD among select adults 40 to 70 years of age who are at higher ASCVD risk but not at increased bleeding risk (S4.6-1–S4.6-8).
III: Harm	B-R	2. Low-dose aspirin (75-100 mg orally daily) should not be administered on a routine basis for the primary prevention of ASCVD among adults >70 years of age (S4.6-9).
III: Harm	C-LD	3. Low-dose aspirin (75-100 mg orally daily) should not be administered for the primary prevention of ASCVD among adults of any age who are at increased risk of bleeding (S4.6-10).

Mortalité

Hémorragies majeures

2019 ACC/AHA Guideline on the Primary Prevention of CV Disease doi.org/10.1016/j.jacc.2019.03.009

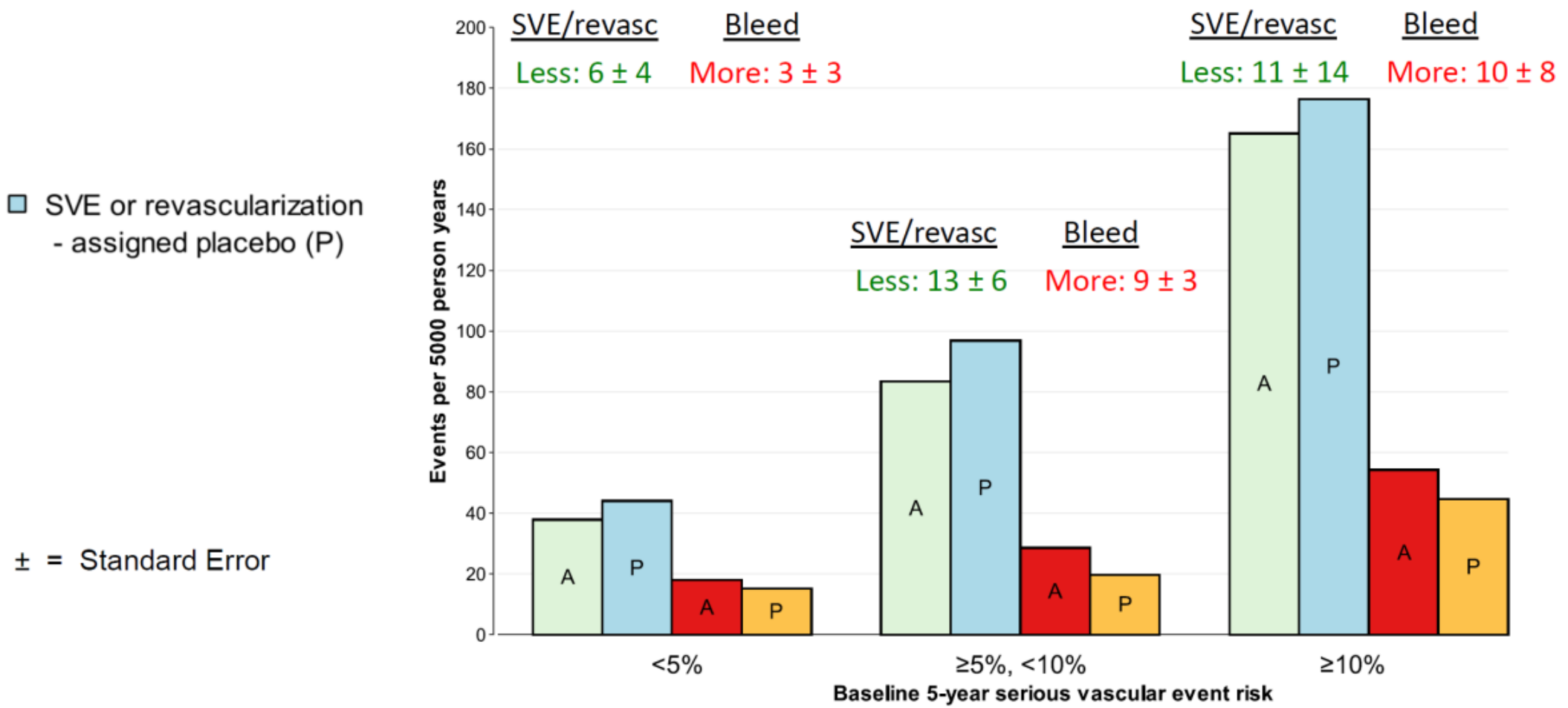
European Heart Journal (2019) 40, 607–617

Méta-analyse: 13 essais, 164 225 participants

RESULTS A total of 13 trials randomizing 164 225 participants with 1 050 511 participant-years of follow-up were included. The median age of trial participants was 62 years (range, 53-74), 77 501 (47%) were men, 30 361 (19%) had diabetes, and the median baseline risk of the primary cardiovascular outcome was 9.2% (range, 2.6%-15.9%). Aspirin use was associated with significant reductions in the composite cardiovascular outcome compared with no aspirin (57.1 per 10 000 participant-years with aspirin and 61.4 per 10 000 participant-years with no aspirin) (hazard ratio [HR], 0.89 [95% credible interval, 0.84-0.95]; absolute risk reduction, 0.38% [95% CI, 0.20%-0.55%]; number needed to treat, 265). Aspirin use was associated with an increased risk of major bleeding events compared with no aspirin (23.1 per 10 000 participant-years with aspirin and 16.4 per 10 000 participant-years with no aspirin) (HR, 1.43 [95% credible interval, 1.30-1.56]; absolute risk increase, 0.47% [95% CI, 0.34%-0.62%]; number needed to harm, 210).

JAMA. 2019;321(3):277-287. doi:10.1001/jama.2018.20578

Étude ASCEND : faut-il traiter les bas risques?



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)

Antiplatelet therapy is not recommended in individuals without CVD due to the increased risk of major bleeding.	III	B

Patient à haut risque métabolique

- 74 ans
- 98 kilos, 1m73
- Diabète de type 2, sulfamide (car intolérance métformine)
- LDL : 0,82 g/l, HDL : 0,70 g/l,
- TG : 2,10 g/l
- PA : 105/70 sous IEC, Calcique, diurétique
- Aspirine

- **EVALUER LE RISQUE : IA IA IA**
- **Sport et régime : oui : 1A**
- **Cible HbA1c: < 7 % : IA**
- **Cible LDL: < 0,7 ou 1g/l: IA**
- **Cible HDL : > 0,50 àu 0,60 g/l : IB**
- **Cible de TG: < 1,50 g/l : IB**
- **Oméga 3 : IIa**
- **PA cible: < 130 mm Hg : IA**
- **Aspirine : si haut risque: IIA**

Alors : qu'est-ce qui marche?

- **Le LDL le plus bas possible**: statines en première intention, dose maximale tolérée, puis ézétimibe, voire….
- **PA entre 130 et 140 mm Hg** utilisant un BSA et un calcique
- **HbA1c < 8** ou 9 **%,** glycémie inférieure à 3 g/l
- EPA 4 g/j… quand sera disponible

Jean Bart, Dunkerque

Merci de votre attention