THE INTERVENTIONALIST AS THE THOUGHT LEADER FOR RISK FACTOR MODIFICATION:IS POST INTERVENTION THE BEST TIME TO CONSIDER PCSK9 INHIBITION, CARDIAC REHAB, AND ADVANCED LIPID TESTING?

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Scripps Clinic and Research Foundation

Commercial Interest	Nature of Relevant Financial Relationship (Include all those that apply)			
	What was received	For what role	Self	Spouse/Partner
Amarin	Honorarium	Speaker	x	
Esperion	Honorarium	Speaker	x	
Amgen	Honorarium	Speaker	x	

RISK OF RECURRENT EVENTS

- Research to date has shown significant heterogeneity in the estimated 10-year risk in patients with previous cardiovascular disease ranging from less than 10% to over 50% risk of recurrent vascular events.
- A single one size fits all approach to secondary prevention is inappropriate. The identification of extreme high risk patients using risk stratification tools will prompt the initiation of more intensive treatments in order to reduce high residual risk.

Circulation:Nov 8, 2016;134(19):1441-1443

Multiple Prior Major ASCVD Events
MACE = 8.01%/yr

1 Major Prior ASCVD Event + Multiple High Risk Conditions
MACE = 4.02%/yr

Very High-Risk for Future ASCVD Events*

Table 4

Major ASCVD Events
Recent acute coronary syndrome (within the past 12 months)
History of myocardial infarction (other than recent acute coronary syndrome event listed above)
History of ischemic stroke
Symptomatic peripheral arterial disease (history of claudication with ankle brachial index <0.85, or previous revascularization or amputation)
High-Risk Conditions
Age ≥65 years
Heterozygous familial hypercholesterolemia
History of prior coronary artery bypass surgery or PCI outside of the major ASCVD event(s)
Diabetes Mellitus
Hypertension
Chronic kidney disease (eGFR 15-59 mL/min/1.73 m^2)
Current smoking
Persistently elevated LDL-C (LDL-C ≥100 mg/dL (≥2.6 mmol/L)) despite maximally tolerated statin therapy and ezetimibe
History of congestive heart failure

*Very High Risk includes a history of multiple major ASCVD events or one major ASCVD event and multiple high-risk conditions.

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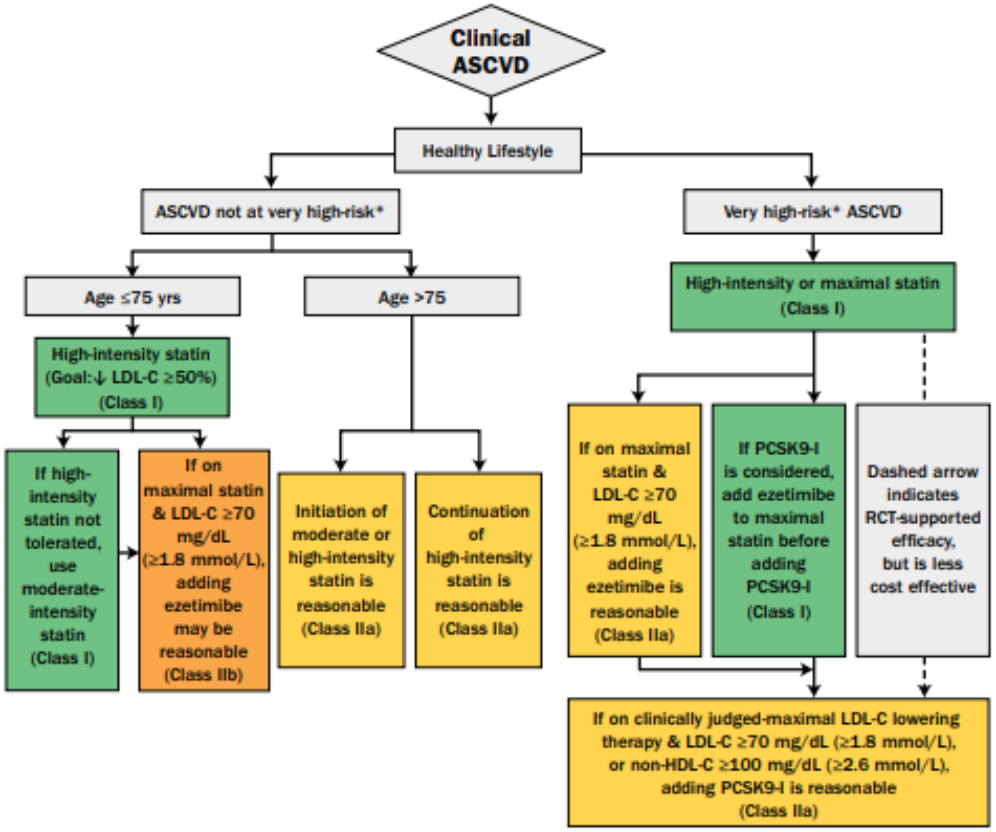
Figure 1:
Secondary Prevention in Patients with Clinical ASCVD



*Very high-risk includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions (Table 4 on following page).

Figure 1

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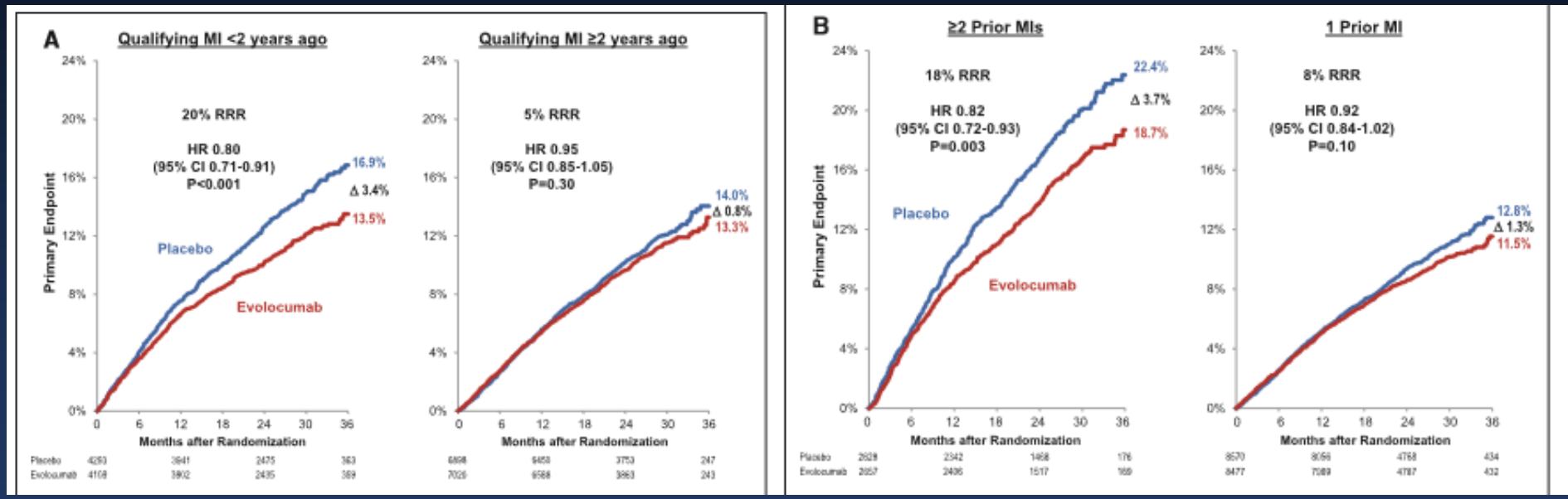
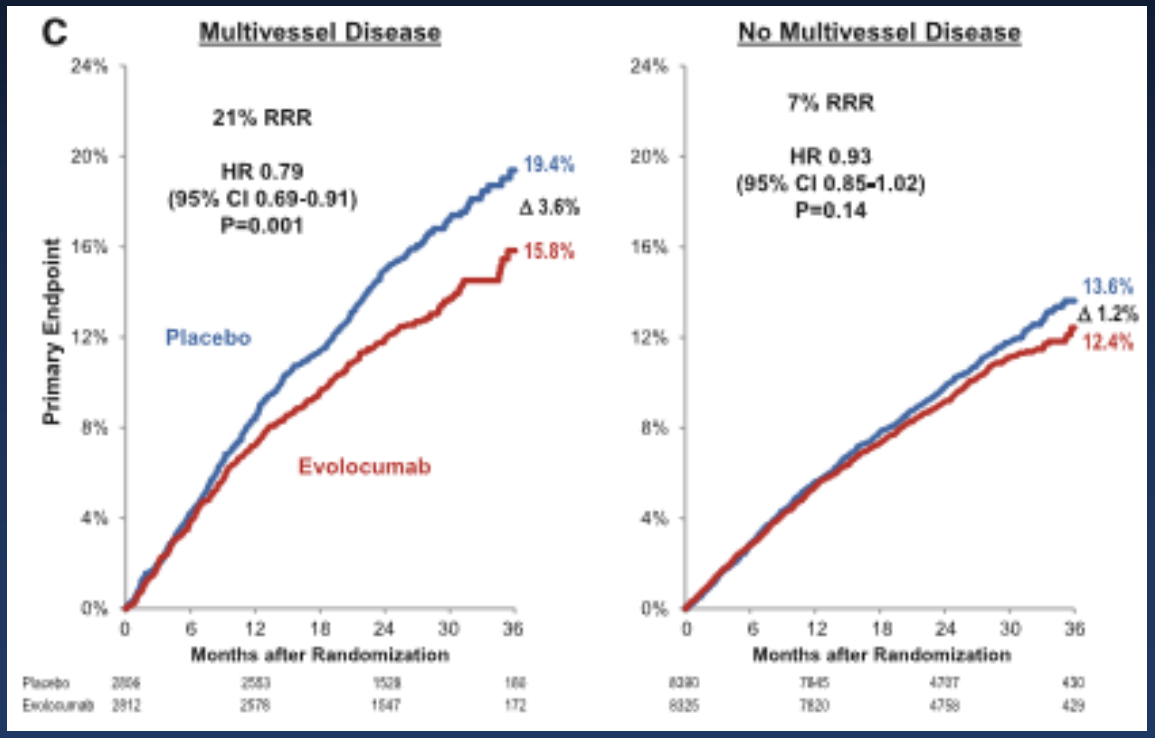
PCSK9 Inhibitors and Prior MI



Median time from MI =0.6 yrs vs 6 yrs

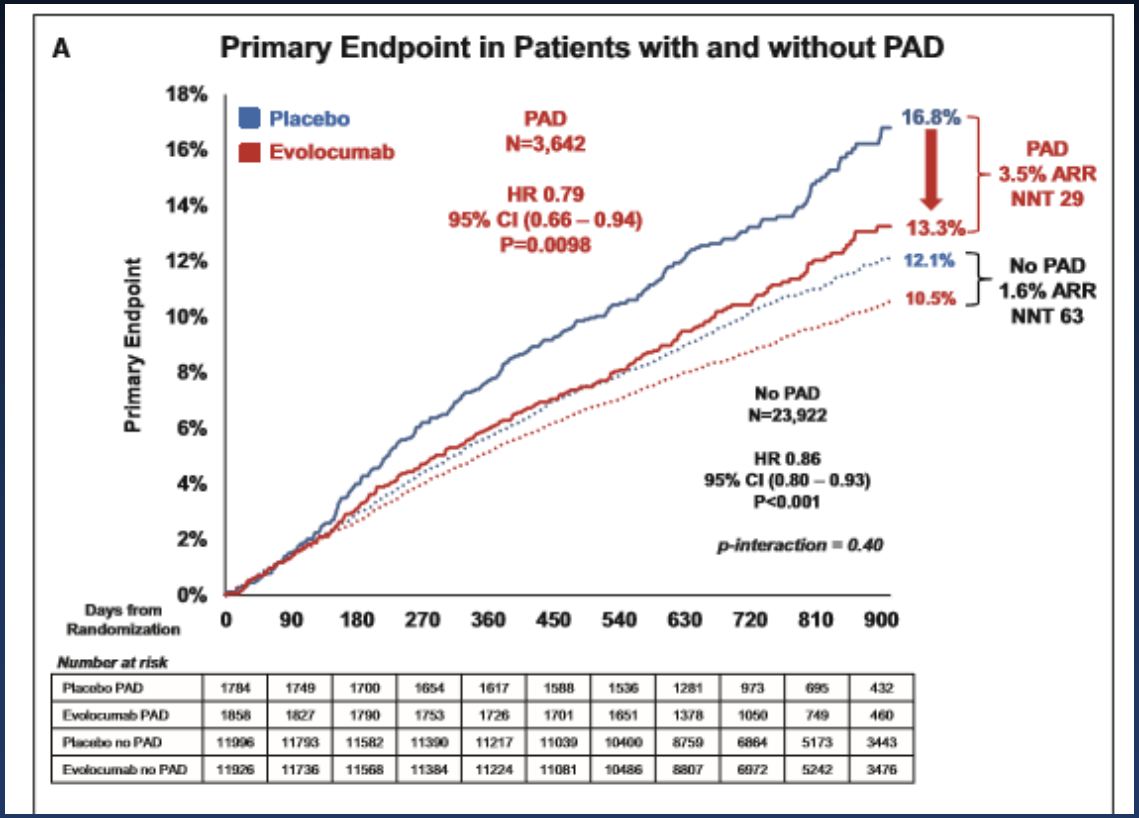
Circulation. 2018;138:756–766. DOI: 10.1161/CIRCULATIONAHA.118.034309

PCSK9 INHIBITORS AND MULTIVESSEL DISEASE



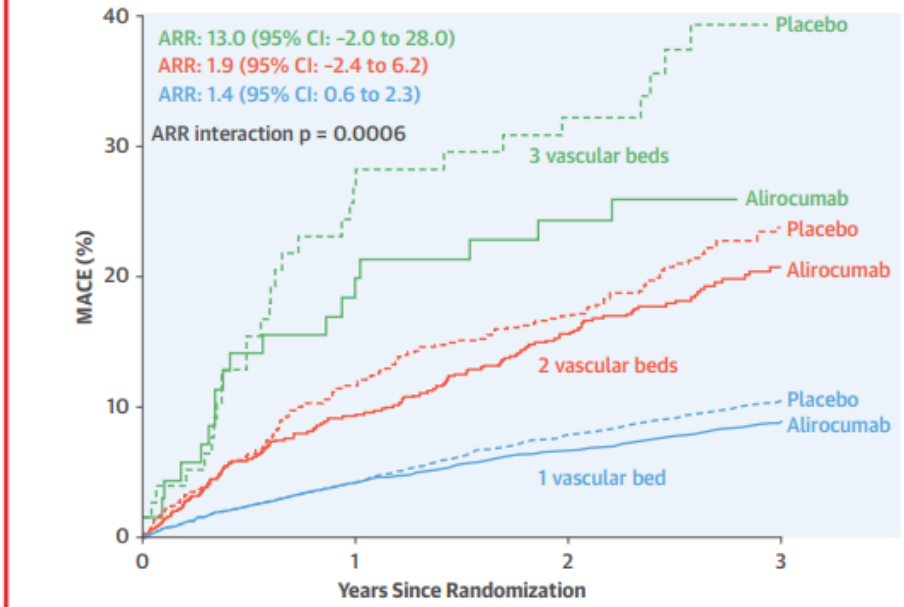
Circulation. 2018;138:756–766. DOI: 10.1161/CIRCULATIONAHA.118.034309

Fourier Trial and PAD

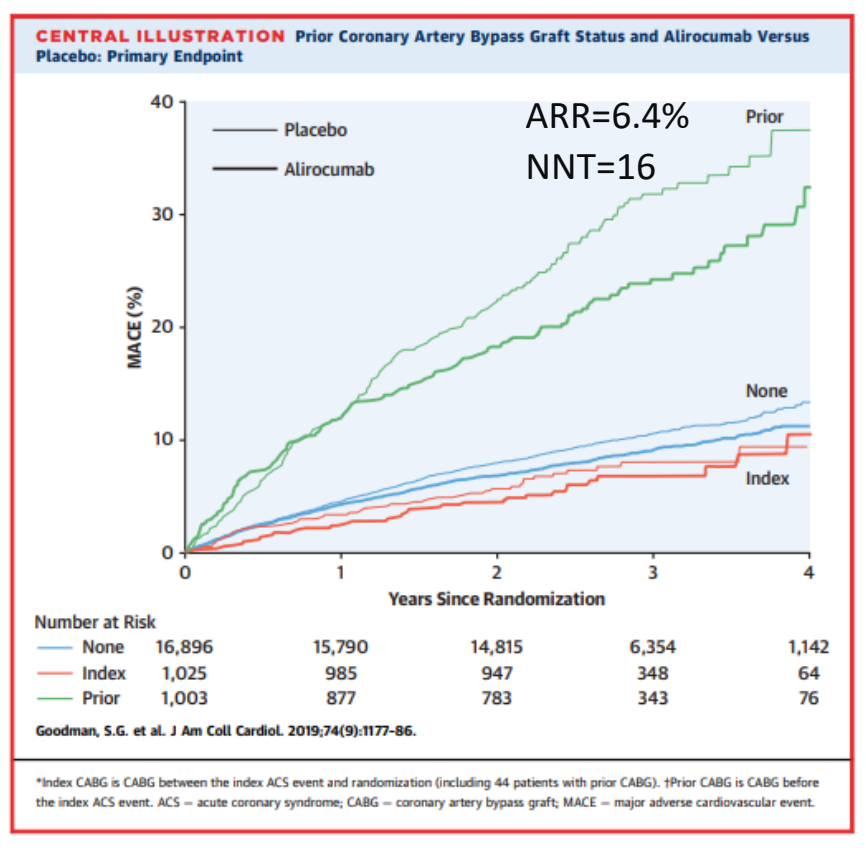


Circulation. 2018;137:338–350. DOI: 10.1161/CIRCULATIONAHA.117.032235

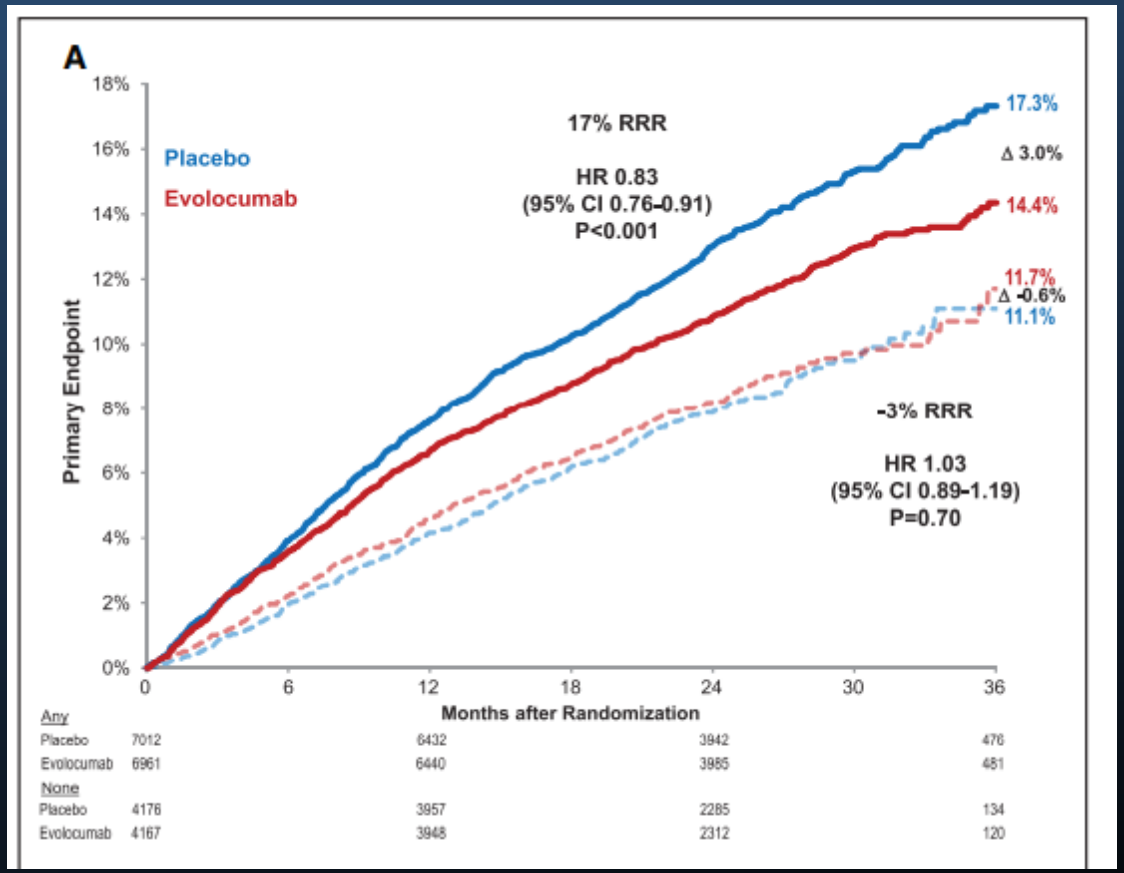
POLYVASCULAR DISEASE



ODYSSEY OUTCOME TRIAL AND PRIOR CABG



CLINICAL BENEFIT OF PCSK9 INHIBITORS BY SEVERITY AND EXTENT OF CAD



Circulation. 2018;138:756–766. DOI: 10.1161/CIRCULATIONAHA.118.034309

ADDITIONAL BENEFIT IN RISK STRATIFICATION WITH A BIOMARKER PANEL

- Hs-CRP
- Lp(a)
- Triglycerides
- Hs-Troponin
- NT-pro-BNP

INFLAMMATORY AND CHOLESTEROL RISK IN THE FOURIER TRIAL

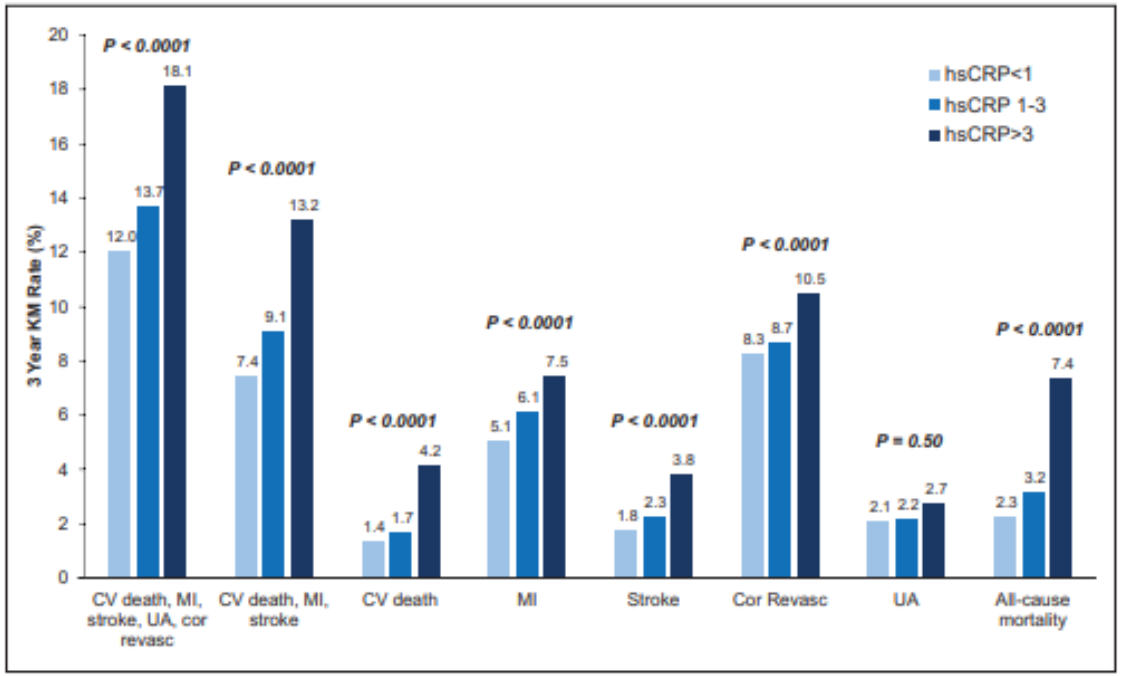
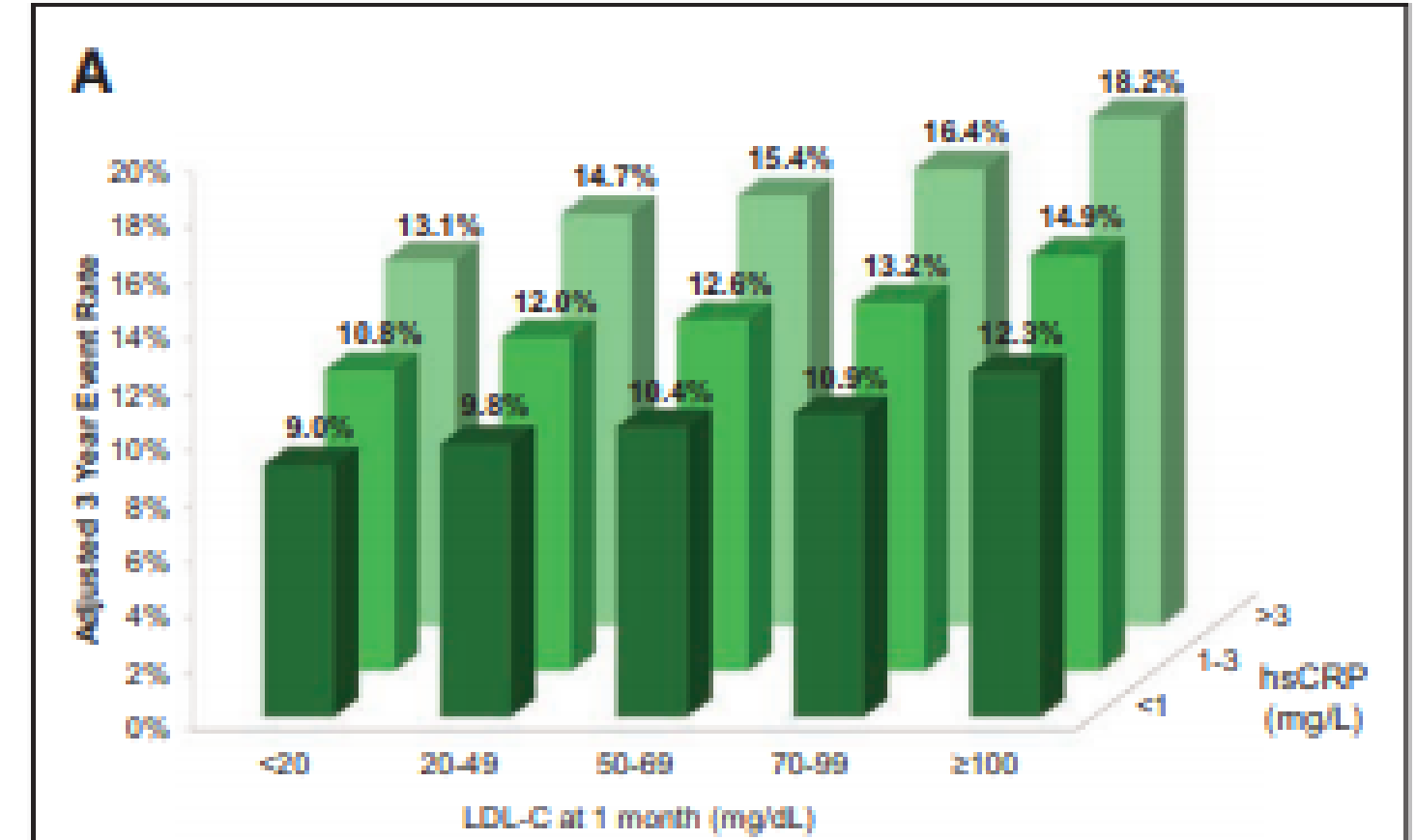


Figure 1. Gradient of cardiovascular risk by baseline hsCRP in the placebo arm.
Three-year Kaplan-Meier event rates stratified by low (<1 mg/L), intermediate (1–3 mg/L), and high (>3 mg/L) baseline hsCRP in subjects randomly assigned to placebo. The *P* value for trend across hsCRP subgroups is shown. Cor Revasc indicates coronary revascularization; CV, cardiovascular; hsCRP, high-sensitivity C-reactive protein; KM, Kaplan-Meier; MI, myocardial infarction; and UA, hospitalization for unstable angina.

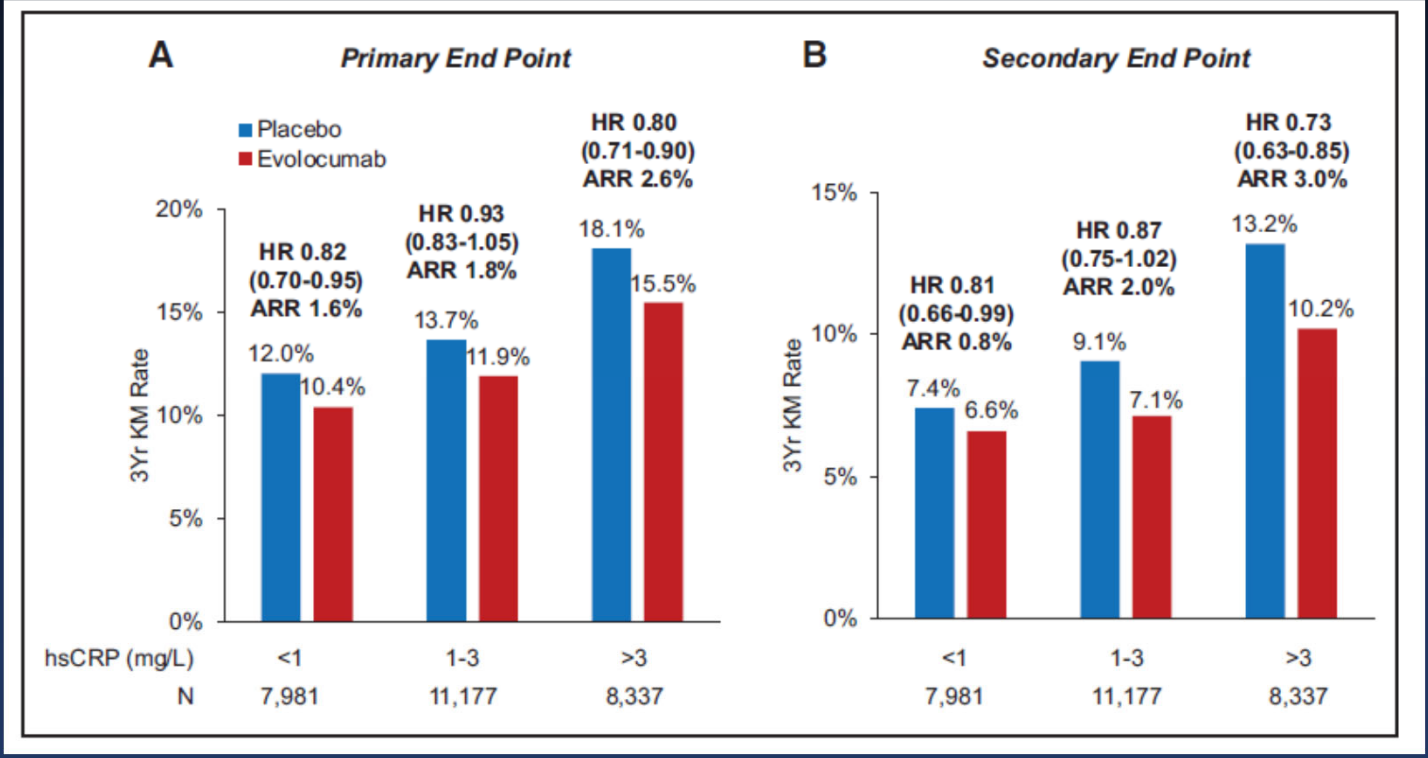
Circulation. 2018;137:00–00. DOI: 10.1161/CIRCULATIONAHA.118.034032

LDL RISK AND CRP RISK IN THE FOURIER TRIAL



Circulation. 2018;137:00–00. DOI: 10.1161/CIRCULATIONAHA.118.034032

Hs-CRP and CV Events in the Fourier Trial



Circulation. 2018;137:00–00. DOI: 10.1161/CIRCULATIONAHA.118.034032

COMPARISON OF DRUG EFFECTS ON CRP REDUCTION

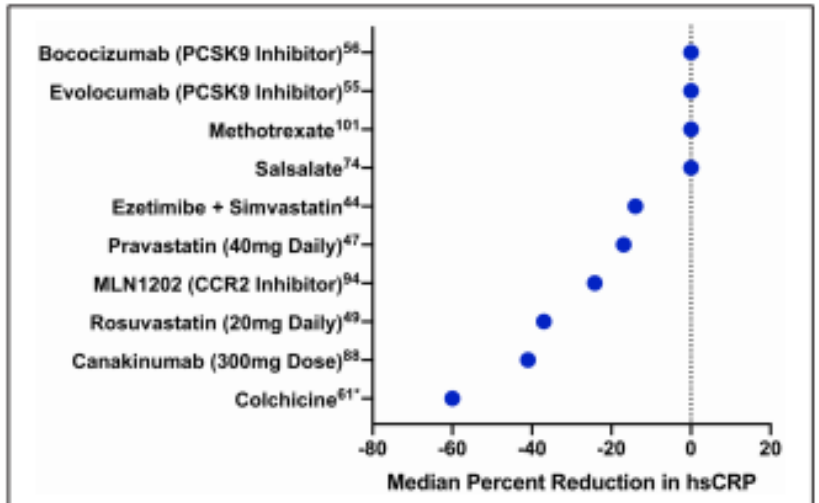
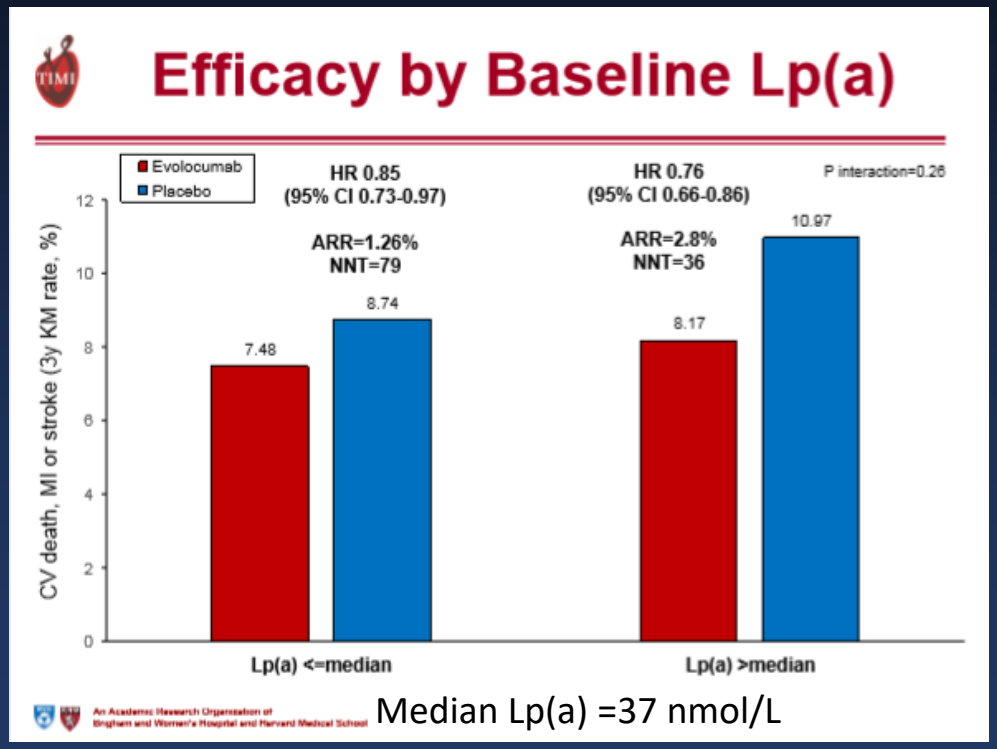


FIGURE 2 | Median percentage change in hsCRP with different cardiovascular drugs. Median percentage change in hsCRP is displayed for several drugs from trials of patients either with established cardiovascular disease or at high risk for cardiovascular events. Drugs are ordered by their impact on hsCRP. PCSK9 indicates proprotein convertase subtilisin-kexin type 9; CCR2, CC-chemokine ligand 2 receptor. *Mean, rather than median, percentage change.

Front. Cardiovasc. Med. 6:16. doi: 10.3389/fcvm.2019.00016

Lp(a) and the Fourier Trial



Median Lp(a) =37 nmol/L

Research

JAMA Cardiology | Original Investigation

Effect of C-Reactive Protein on Lipoprotein(a)-Associated Cardiovascular Risk in Optimally Treated Patients With High-Risk Vascular Disease

A Prespecified Secondary Analysis of the ACCELERATE Trial

Rishi Puri, MBBS, PhD; Steven E. Nissen, MD; Benoit J. Arsenault, PhD; Julie St John, MS; Jeffrey S. Riesmeyer, MD; Giacomo Ruotolo, MD, PhD; Ellen McErlean, MSN; Venu Menon, MD; Leslie Cho, MD; Kathy Wolski, MPH; A. Michael Lincoff, MD; Stephen J. Nicholls, MBBS, PhD

IMPORTANCE Although lipoprotein(a) (Lp[a]) is a causal genetic risk factor for atherosclerotic cardiovascular disease, it remains unclear which patients with established atherosclerotic cardiovascular disease stand to benefit the most from Lp(a) lowering. Whether inflammation can modulate Lp(a)-associated cardiovascular (CV) risk during secondary prevention is unknown.

OBJECTIVE To examine whether Lp(a)-associated CV risk is modulated by systemic inflammation in optimally treated patients at high risk of CV disease.

DESIGN, SETTING, AND PARTICIPANTS A prespecified secondary post hoc analysis of the double-blind, multicenter randomized clinical Assessment of Clinical Effects of Cholesteryl Ester Transfer Protein Inhibition With Evacetrapib in Patients at a High Risk for Vascular Outcomes (ACCELERATE) trial was conducted between October 1, 2012, and December 31, 2013; the study was terminated October 12, 2015. The study was conducted at 543 academic and community hospitals in 36 countries among 12 092 patients at high risk of CV disease (acute coronary syndrome, stroke, peripheral arterial disease, or type 2 diabetes with coronary artery disease) with measurable Lp(a) and high-sensitivity C-reactive protein (hsCRP) levels during treatment. Statistical analysis for this post hoc analysis was performed from September 26, 2018, to March 28, 2020.

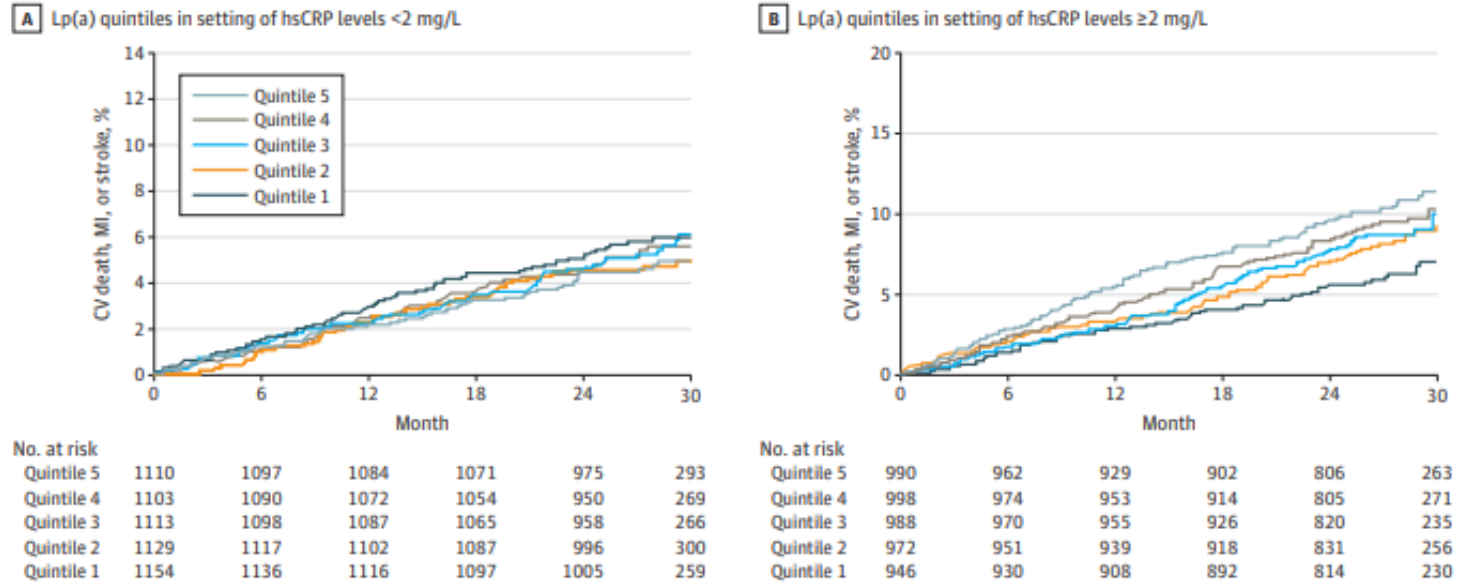
Supplemental content

28 month follow-up

JAMA Cardiol. doi:10.1001/jamacardio.2020.2413 Published online July 8, 2020.

INTERACTION BETWEEN hs-CRP AND Lp(a)

Figure 2. Kaplan-Meier Curves of Major Adverse Cardiovascular Events Stratified by Achieved Lipoprotein(a) (Lp[a]) Quintiles in the Setting of Achieved High-Sensitivity C-Reactive Protein (hsCRP) Levels of Less Than 2 vs 2 mg/L or More



No. at risk

Quintile 5	1110	1097	1084	1071	975	293
Quintile 4	1103	1090	1072	1054	950	269
Quintile 3	1113	1098	1087	1065	958	266
Quintile 2	1129	1117	1102	1087	996	300
Quintile 1	1154	1136	1116	1097	1005	259

No. at risk

Quintile 5	990	962	929	902	806	263
Quintile 4	998	974	953	914	805	271
Quintile 3	988	970	955	926	820	235
Quintile 2	972	951	939	918	831	256
Quintile 1	946	930	908	892	814	230

A, Test of trend across quintiles: $P = .44$. B, Test of trend across quintiles: $P < .001$. CV indicates cardiovascular; MI, myocardial infarction.

JAMA Cardiol. doi:10.1001/jamacardio.2020.2413 Published online July 8, 2020

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Lipids and CAD

Impact of Triglyceride Levels Beyond Low-Density Lipoprotein Cholesterol After Acute Coronary Syndrome in the PROVE IT-TIMI 22 Trial

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Baltimore, Maryland; Boston, Massachusetts; and Cambridge, United Kingdom

Objectives The purpose of this study was to assess the impact of on-treatment triglycerides (TG) on coronary heart disease (CHD) risk after an acute coronary syndrome (ACS).

Background The PROVE IT-TIMI (Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis In Myocardial Infarction) 22 trial demonstrated that low-density lipoprotein cholesterol (LDL-C) <70 mg/dl was associated with greater CHD event reduction than LDL-C <100 mg/dl after ACS. However, the impact of low on-treatment TG on CHD risk beyond LDL-C <70 mg/dl has not been explored.

Methods The PROVE IT-TIMI 22 trial evaluated 4,162 patients hospitalized for ACS and randomized to atorvastatin 80 mg or pravastatin 40 mg daily. The relationship between on-treatment levels of TG and LDL-C and the composite end point of death, myocardial infarction (MI), and recurrent ACS were assessed 30 days after initial presentation.

Results Low on-treatment TG (<150 mg/dl) was associated with reduced CHD risk compared with higher TG in univariate analysis (hazard ratio [HR] 0.73, 95% confidence interval [CI] 0.62 to 0.87; $p < 0.001$) and in adjusted analysis (HR 0.80, 95% CI 0.66 to 0.97; $p = 0.025$). For each 10-mg/dl decrement in on-treatment TG, the incidence of death, MI, and recurrent ACS was lower by 1.6% or 1.4% after adjustment for LDL-C or non–high-density lipoprotein cholesterol and other covariates ($p < 0.001$ and $p = 0.01$, respectively). Lower CHD risk was also observed with TG <150 mg/dl and LDL-C <70 mg/dl (HR 0.72, 95% CI 0.54 to 0.94; $p = 0.017$) or low on-treatment TG, LDL-C, and C-reactive protein (<2 mg/l) (HR 0.59, 95% CI 0.41 to 0.83; $p = 0.002$) compared with higher levels of each variable in adjusted analysis.

Conclusions On-treatment TG <150 mg/dl was independently associated with a lower risk of recurrent CHD events, lending support to the concept that achieving low TG may be an additional consideration beyond low LDL-C in patients after ACS. (The PROVE IT-TIMI 22 trial; NCT00382460) (J Am Coll Cardiol 2008;51:724–30) © 2008 by the American College of Cardiology Foundation

PROVE-IT TRIAL AND RESIDUAL RISK

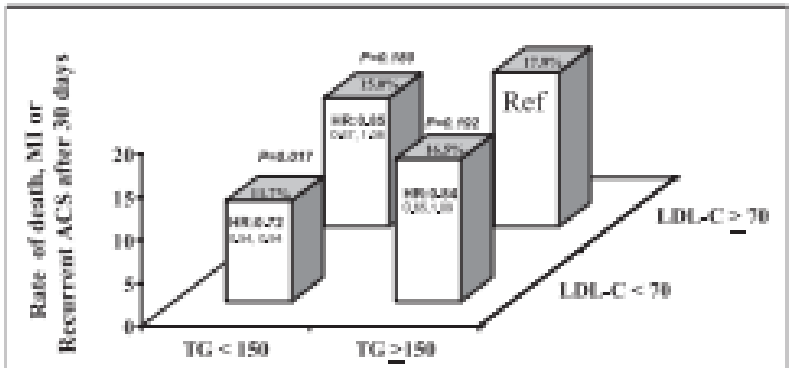
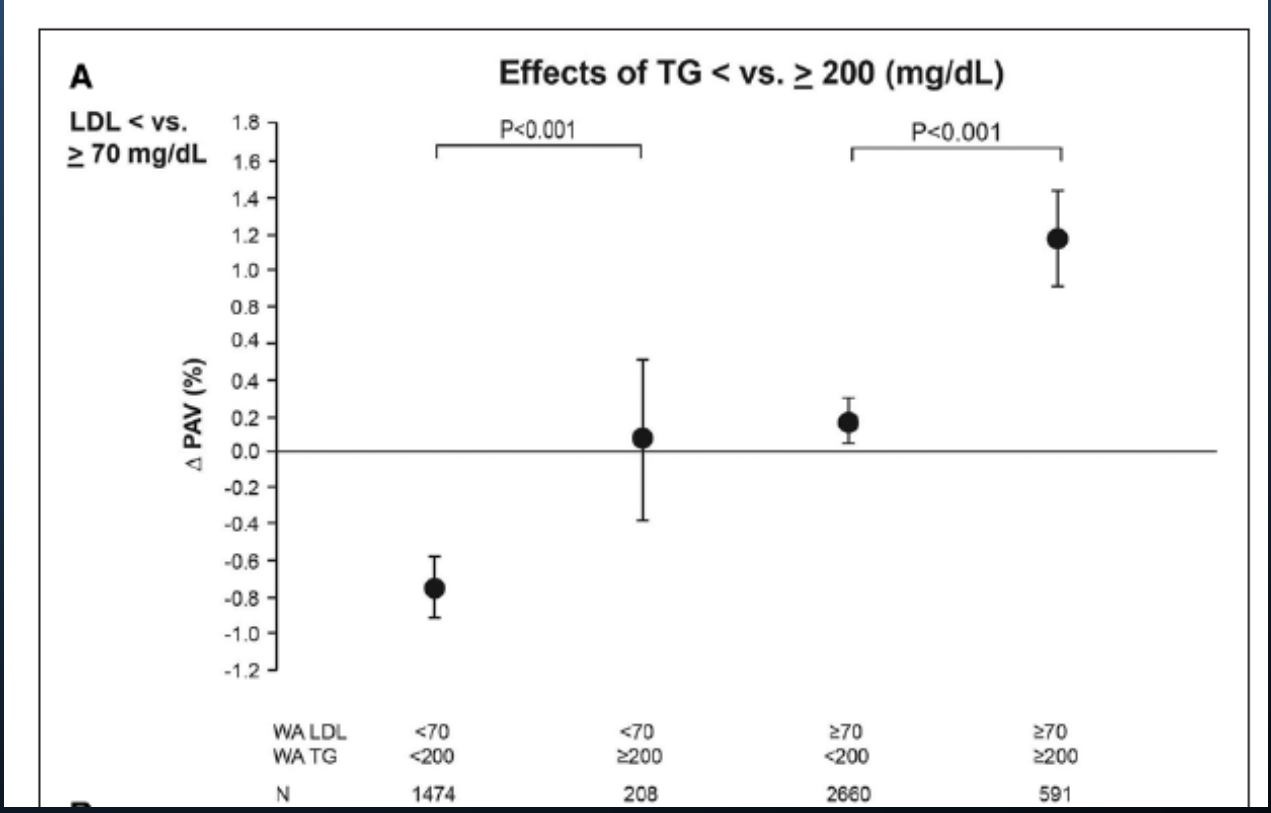


Figure 2 **Risk of Recurrent Events Using Selected Cut-Points of LDL-C and TG**

Event rate and adjusted hazard of death, myocardial infarction (MI), and recurrent acute coronary syndrome (ACS) between 30 days and 2 years of follow-up with achieved LDL-C and TG based on the designated cut-points of 70 mg/dl and 150 mg/dl, respectively. The referent (Ref) group is LDL-C ≥70 mg/dl and TG ≥150 mg/dl. This model is adjusted for age, gender, low HDL-C, smoking, hypertension, obesity, diabetes, prior statin therapy, prior ACS, peripheral vascular disease, and treatment effect. The 95% confidence intervals are located below the HRs. Abbreviations as in Figure 1.

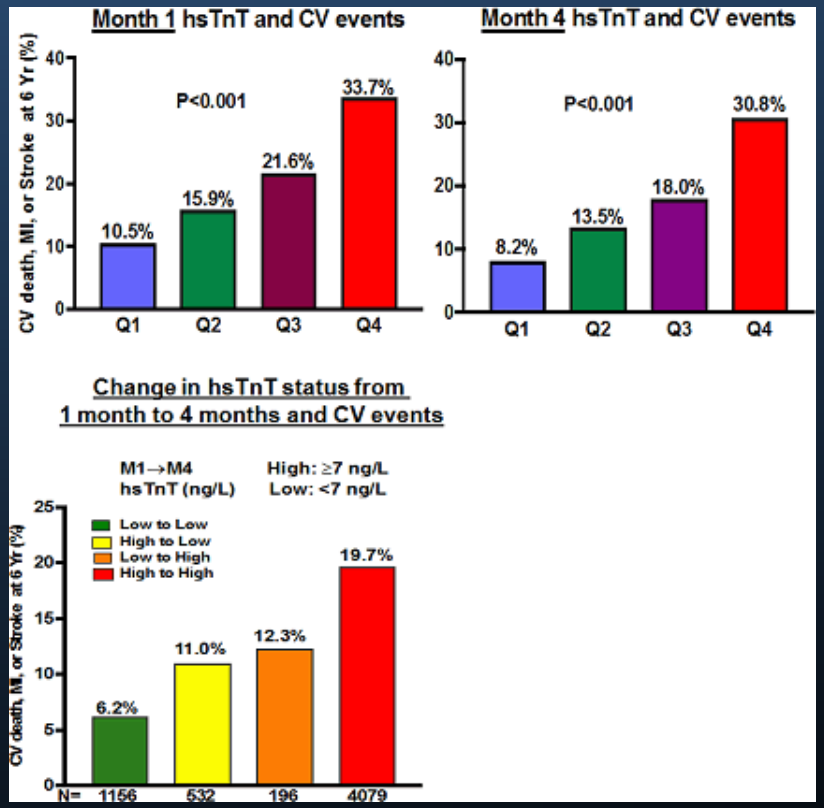
JACC Vol. 51, No. 7, 2008 Miller et al. 727 February 19, 2008:724–30

TRIGLYCERIDES AND CORONARY ATHEROMA PROGRESSION



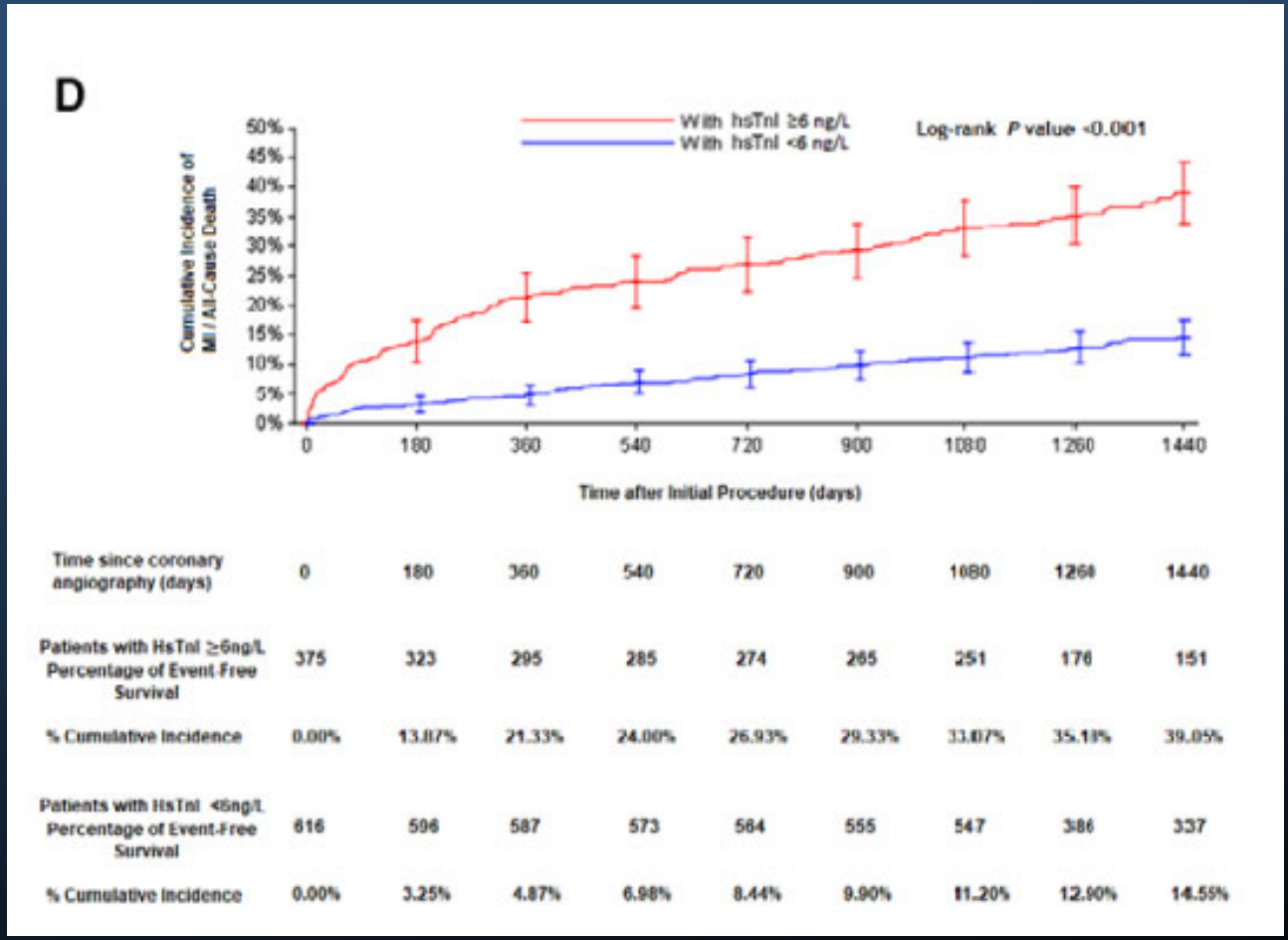
Arterioscler Thromb Vasc Biol. 2016;36:2220-2228. DOI: 10.1161/ATVBAHA.116.307601

SERIAL HIGH-SENSITIVITY TROPONIN AND CARDIOVASCULAR OUTCOMES IN THE IMPROVE-IT TRIAL



Circulation November 14, 2017 Vol 136, Issue suppl_1, abstract 16613

CASABLANCA STUDY



Time since coronary angiography (days)	0	180	360	540	720	900	1080	1260	1440
Patients with HsTnI ≥6ng/L Percentage of Event-Free Survival	375	323	295	285	274	265	251	176	151
% Cumulative Incidence	0.00%	13.87%	21.33%	24.00%	26.93%	29.33%	33.07%	35.18%	39.05%
Patients with HsTnI <6ng/L Percentage of Event-Free Survival	616	596	587	573	564	555	547	386	337
% Cumulative Incidence	0.00%	3.25%	4.87%	6.98%	8.44%	9.90%	11.20%	12.50%	14.55%

J Am Heart Assoc. 2018;7: e007975. DOI: 10.1161/JAHA.117.007975

Biomarkers and Clinical Cardiovascular Outcomes With Ezetimibe in the IMPROVE-IT Trial

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ABSTRACT

BACKGROUND Addition of ezetimibe to statin therapy reduces the risk of recurrent cardiovascular (CV) events in patients with prior acute coronary syndrome (ACS). The role of biomarkers in identifying subsets of patients who may derive greater clinical benefit with ezetimibe is unknown.

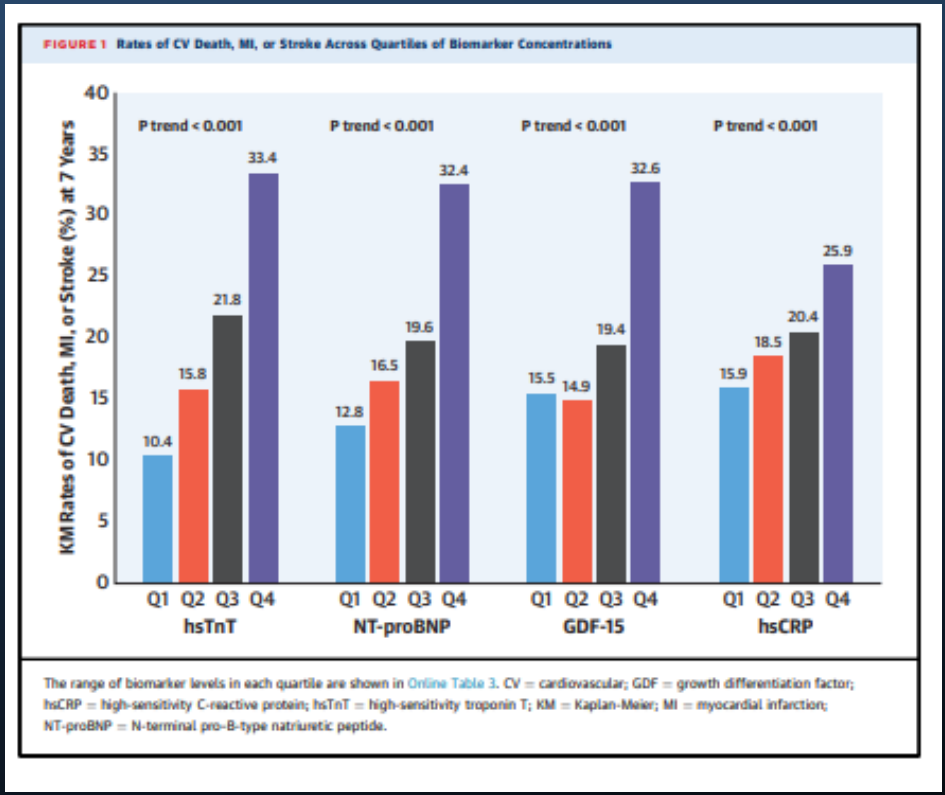
OBJECTIVES This study sought to evaluate the role of established CV biomarkers in assessing likely benefit with ezetimibe added to statin therapy in post-ACS patients.

METHODS In a pre-specified nested analysis within a randomized, double-blind trial of ezetimibe/simvastatin versus placebo/simvastatin (IMPROVE-IT [Improved Reduction of Outcomes: Vytorin Efficacy International Trial]), high-sensitivity troponin T, N-terminal pro-B-type natriuretic peptide, growth-differentiation factor-15, and high-sensitivity C-reactive protein was measured in 7,195 patients stabilized (1 month post-randomization) after ACS. A multimarker approach based on biomarker values was used to examine the risk of recurrent CV events and clinical benefit with ezetimibe.

RESULTS Elevated levels of each biomarker were independently associated with higher risks of CV death/myocardial infarction/stroke and CV death/heart failure ($p_{trend} < 0.001$ for each). There was a pattern of greater absolute risk reduction in CV death/myocardial infarction/stroke with the addition of ezetimibe to statin therapy in patients at higher risk on the basis of biomarker levels. High-risk patients (≥3 biomarkers "positive"; n = 1,437) had an absolute risk difference of −7.3% (95% confidence interval: −13.8% to −0.8%; p = 0.02) with ezetimibe, and intermediate-risk patients (1 to 2 biomarkers positive; n = 3,842) had an absolute risk difference of −4.4% (95% confidence interval: −9.7% to 0.8%), translating into numbers needed to treat at 7 years of 14 and 23, respectively. Low-risk patients (0 biomarkers positive; n = 1,916) did not appear to benefit from the addition of ezetimibe to statin therapy.

CONCLUSIONS A biomarker-based strategy identifies a gradient of risk among patients post-ACS, offering the potential to identify higher-risk patients with a correspondingly high absolute benefit from the addition of ezetimibe to statin therapy. (J Am Coll Cardiol 2019;74:1057-68)

IMPROVE-IT TRIAL AND BIOMARKERS



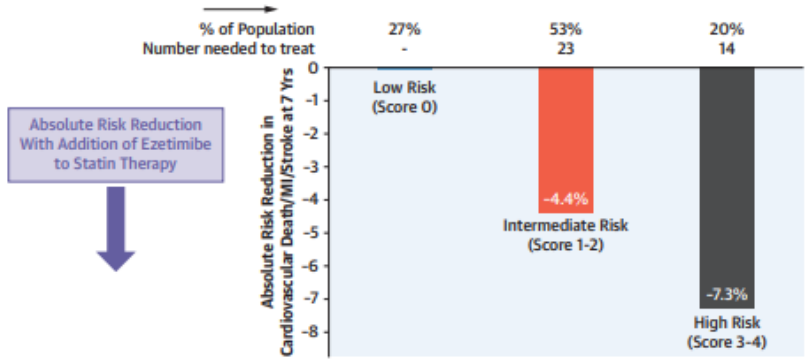
JACC VOL. 74, NO. 8, 2019 Qamar et al. AUGUST 27, 2019:1057 – 68

IMPROVE-IT AND BIOMARKERS

CENTRAL ILLUSTRATION **Absolute Risk Reduction and the Number Needed to Treat With the Addition of Ezetimibe to Statin Therapy Across Biomarker-Based Risk Categories**

Biomarker Score
Assign 1 point for each elevated biomarker

Biomarker	Points
High-sensitivity troponin T ≥14 ng/l	1
N-terminal pro-B-type natriuretic peptide ≥450 pg/ml	1
Growth differentiation factor-15 ≥1800 pg/ml	1
High-sensitivity C-reactive protein ≥2 mg/l	1
Maximum Possible Score	4

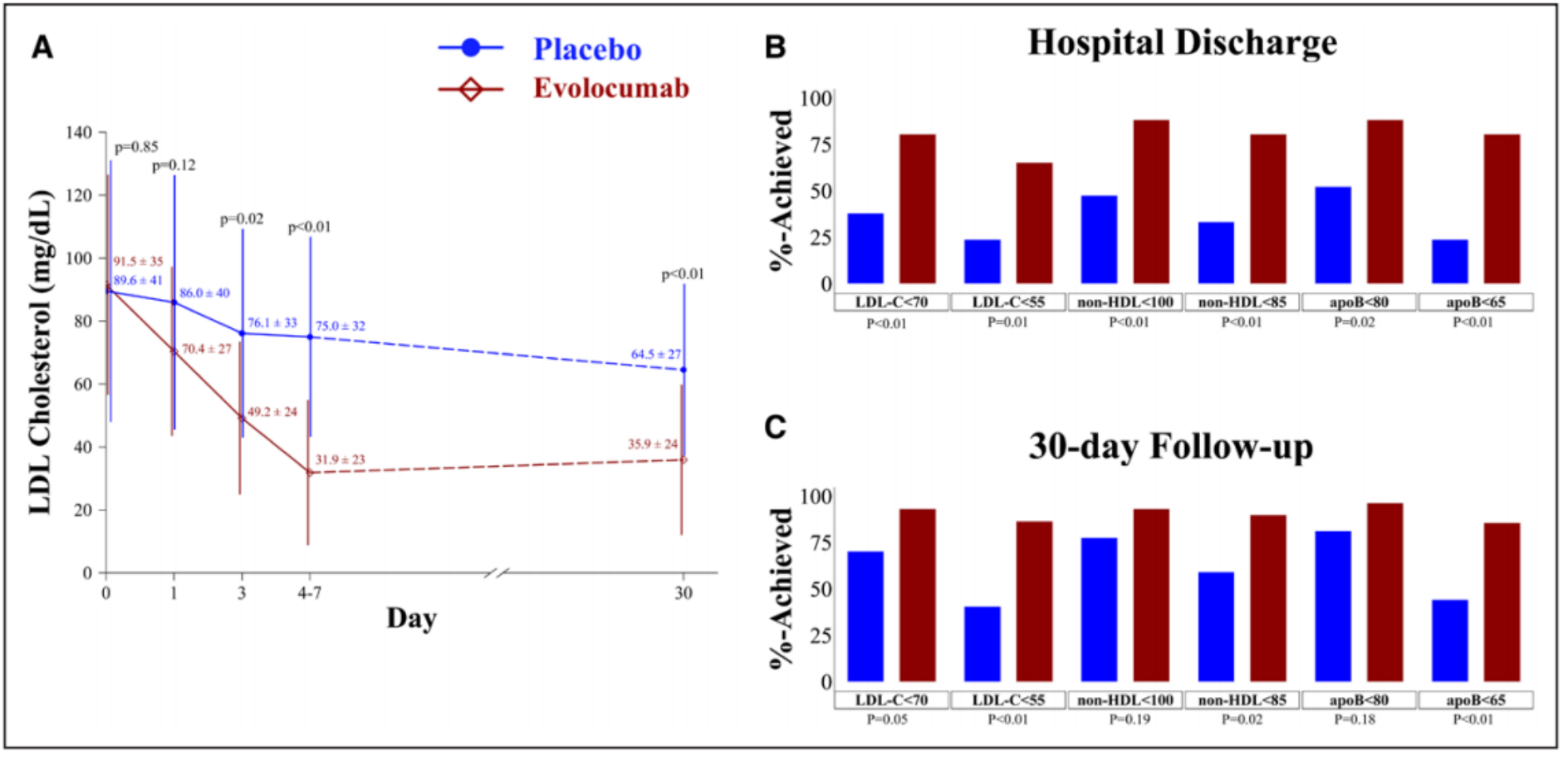


Qamar, A. et al. J Am Coll Cardiol. 2019;74(8):1057-68.

A multimarker approach using established cardiac biomarkers identified higher-risk patients who derived a correspondingly high benefit from the addition of ezetimibe to statin therapy. Therapeutic decision making with biomarkers offers the potential to personalize secondary preventive therapy in patients with stable ischemic heart disease. MI = myocardial infarction.

JACC VOL. 74, NO. 8, 2019 Qamar et al. AUGUST 27, 2019:1057 – 68

EARLY AGGRESSIVE PCSK9 INHIBITION



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Evolocumab for Early Reduction of LDL Cholesterol Levels in Patients With Acute Coronary Syndromes (EVOPACS)

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ABSTRACT

BACKGROUND Although guidelines recommend in-hospital initiation of high-intensity statin therapy in patients with acute coronary syndromes (ACS), low-density lipoprotein cholesterol (LDL-C) target levels are frequently not attained. Evolocumab, a rapidly acting, potent LDL-C-lowering drug, has not been studied in the acute phase of ACS.

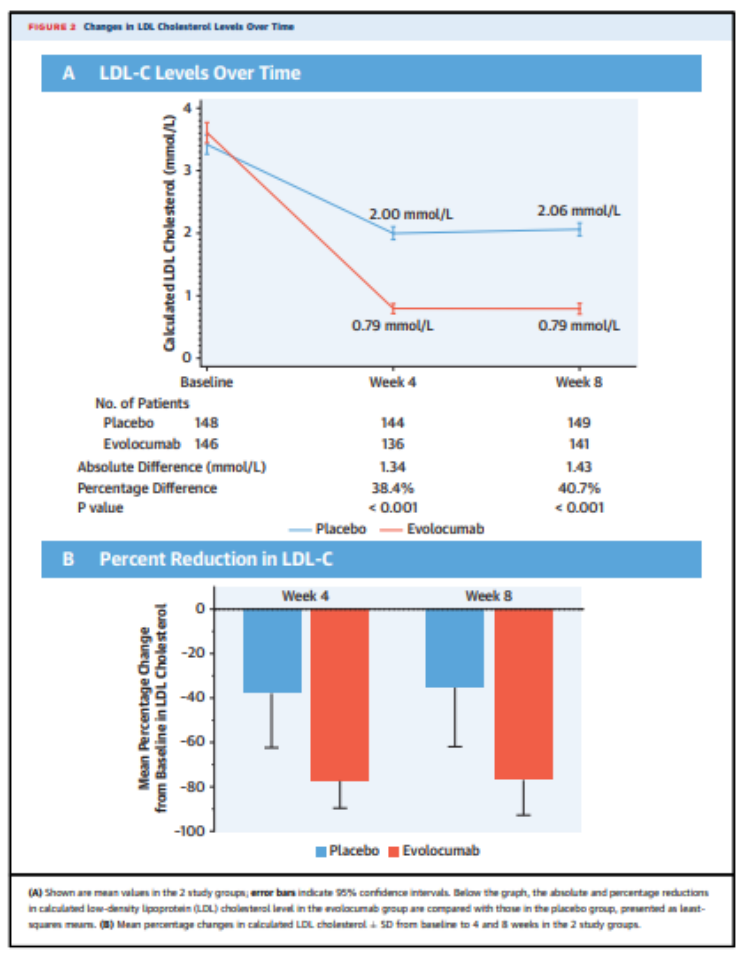
OBJECTIVES The purpose of this study was to assess the feasibility, safety, and LDL-C-lowering efficacy of evolocumab initiated during the in-hospital phase of ACS.

METHODS The authors conducted an investigator-initiated, randomized, double-blind, placebo-controlled trial involving 308 patients hospitalized for ACS with elevated LDL-C levels (≥1.8 mmol/l on high-intensity statin for at least 4 weeks; ≥2.3 mmol/l on low- or moderate-intensity statin; or ≥3.2 mmol/l on no stable dose of statin). Patients were randomly assigned 1:1 to receive subcutaneous evolocumab 420 mg or matching placebo, administered in-hospital and after 4 weeks, on top of atorvastatin 40 mg. The primary endpoint was percentage change in calculated LDL-C from baseline to 8 weeks.

RESULTS Most patients (78.2%) had not been on previous statin treatment. Mean LDL-C levels decreased from 3.61 to 0.79 mmol/l at week 8 in the evolocumab group, and from 3.42 to 2.06 mmol/l in the placebo group; the difference in mean percentage change from baseline was −40.7% (95% confidence interval: −45.2 to −36.2; $p < 0.001$). LDL-C levels <1.8 mmol/l were achieved at week 8 by 95.7% of patients in the evolocumab group versus 37.6% in the placebo group. Adverse events and centrally adjudicated cardiovascular events were similar in both groups.

CONCLUSIONS In this first randomized trial assessing a PCSK9 antibody in the very high-risk setting of ACS, evolocumab added to high-intensity statin therapy was well tolerated and resulted in substantial reduction in LDL-C levels, rendering >95% of patients within currently recommended target levels. (EVOlocumab for Early Reduction of LDL-cholesterol Levels in Patients With Acute Coronary Syndromes [EVOPACS]; NCT03287609)
(J Am Coll Cardiol 2019;74:2452-62) © 2019 by the American College of Cardiology Foundation.

EARLY AND AGGRESSIVE LDL-C REDUCTION AFTER ACS



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CARDIAC REHABILITATION

Exercise-Based Cardiac Rehabilitation for Coronary Heart Disease

Cochrane Systematic Review and Meta-Analysis

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ABSTRACT

BACKGROUND Although recommended in guidelines for the management of coronary heart disease (CHD), concerns have been raised about the applicability of evidence from existing meta-analyses of exercise-based cardiac rehabilitation (CR).

OBJECTIVES The goal of this study is to update the Cochrane systematic review and meta-analysis of exercise-based CR for CHD.

METHODS The Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, CINAHL, and Science Citation Index Expanded were searched to July 2014. Retrieved papers, systematic reviews, and trial registries were hand-searched. We included randomized controlled trials with at least 6 months of follow-up, comparing CR to no-exercise controls following myocardial infarction or revascularization, or with a diagnosis of angina pectoris or CHD defined by angiography. Two authors screened titles for inclusion, extracted data, and assessed risk of bias. Studies were pooled using random effects meta-analysis, and stratified analyses were undertaken to examine potential treatment effect modifiers.

RESULTS A total of 63 studies with 14,486 participants with median follow-up of 12 months were included. Overall, CR led to a reduction in cardiovascular mortality (relative risk: 0.74; 95% confidence interval: 0.64 to 0.86) and the risk of hospital admissions (relative risk: 0.82; 95% confidence interval: 0.70 to 0.96). There was no significant effect on total mortality, myocardial infarction, or revascularization. The majority of studies (14 of 20) showed higher levels of health-related quality of life in 1 or more domains following exercise-based CR compared with control subjects.

CONCLUSIONS This study confirms that exercise-based CR reduces cardiovascular mortality and provides important data showing reductions in hospital admissions and improvements in quality of life. These benefits appear to be consistent across patients and intervention types and were independent of study quality, setting, and publication date.
(J Am Coll Cardiol 2016;67:1-12)

CARDIAC REHABILITATION META-ANALYSIS

- 63 studies with 14,486 subjects with a median follow-up of 12 months.
- Cardiovascular mortality reduced 26% (ARR 2.8%,NNT 36)
- Cardiovascular hospitalizations reduced 18% (ARR 4.6%,NNT 22)
- Improved quality of life measures
- No significant difference in total mortality, MI or revascularizations.

J Am Coll Cardiol 2016;67:1–12

SUMMARY

- Demographics:
  - MI < 2 yrs
  - 2 or more MI
  - Residual multivessel disease (2 VD)
  - PAD
  - Polyvascular disease
  - Prior CABG
- Biomarkers:
- Hs-CRP > 3 mg/dl
- Lp(a) > 37 nmol/L
- TG > 150 mg/dl
- Hs-Troponin
- NT-ProBNP