



Evolocumab in patients with prior percutaneous coronary intervention and no prior MI: Results from the VESALIUS-CV trial

Brian A. Bergmark, Erin A. Bohula, Nicholas A. Marston, Jeong-Gun Park, Julia F. Kuder, Sabina A. Murphy, Gaetano De Ferrari, Lawrence A. Leiter, Jose C. Nicolau, Oleg Averkov, Min-Ji Charng, Christoph Ebenbichler, Andrejs Erglis, Ioanna Gouni-Berthold, Gilles Montalescot, Stephen J. Nicholls, Axel Sigurdsson, Peter R. Sinnaeve, Rimvydas Slapikas, Konstantinos Tsioufis, Subodh Verma, Margus Viigimaa, Ajay Bhatia, Lily Xin, Emileigh Walsh, E. Magnus Ohman, Robert P. Giugliano, Marc S. Sabatine





Potential Conflicts of Interest

Speaker's name: Brian Bergmark

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The VESALIUS-CV trial was sponsored by Amgen





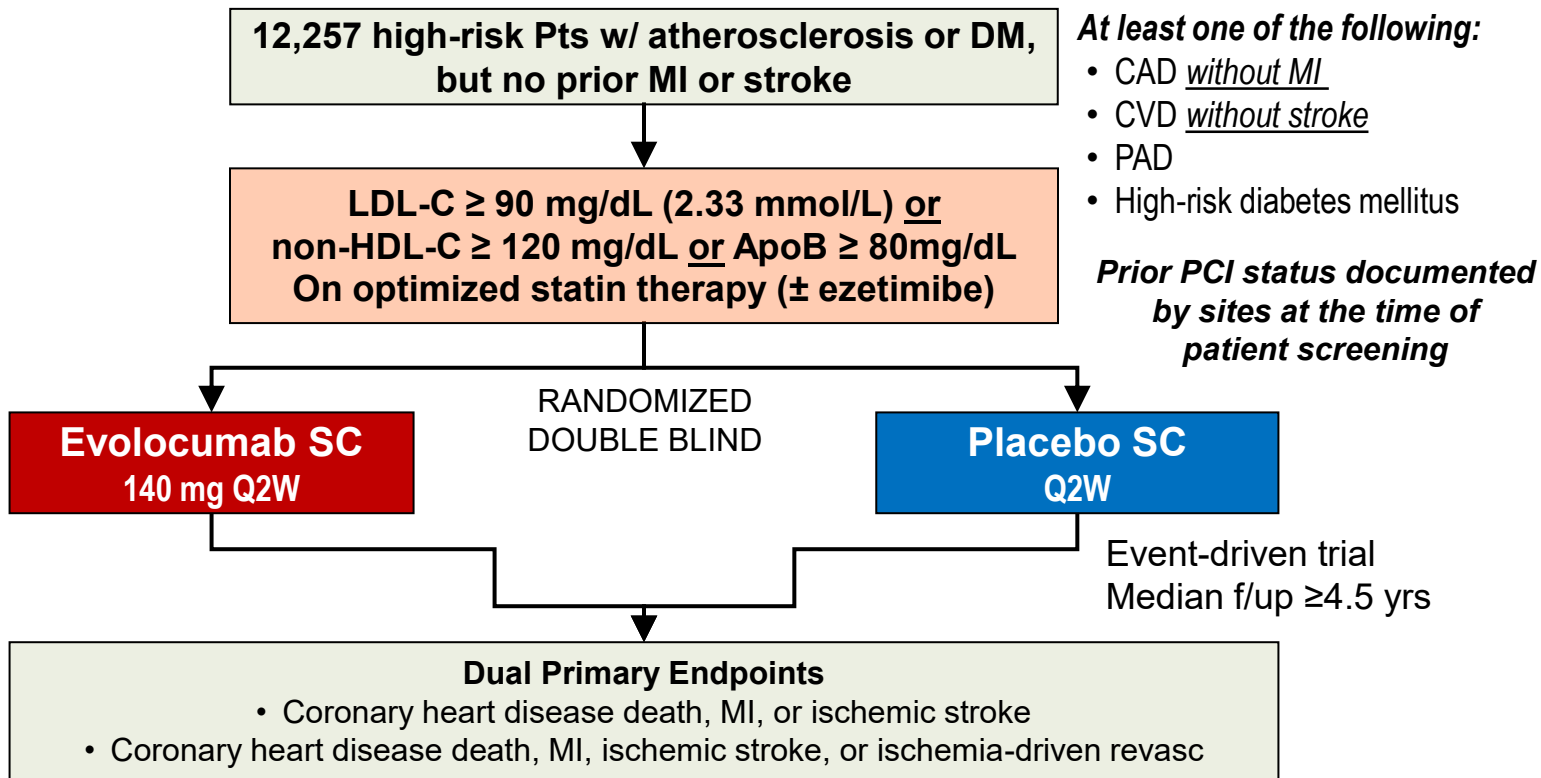
Background

- Patients with prior percutaneous coronary intervention (PCI) but without a prior myocardial infarction (MI) are commonly encountered and may be at heightened risk for CV events.
- In clinical practice, patients undergoing PCI outside the setting of an MI have low rates of LDL-C monitoring and optimization.
- The clinical benefit of intensive LDL-C-lowering with evolocumab in these patients is not established.





Vesalius-CV (TIMI 66)





Baseline Characteristics

Vesalius-cv
prior PCI subgroup 

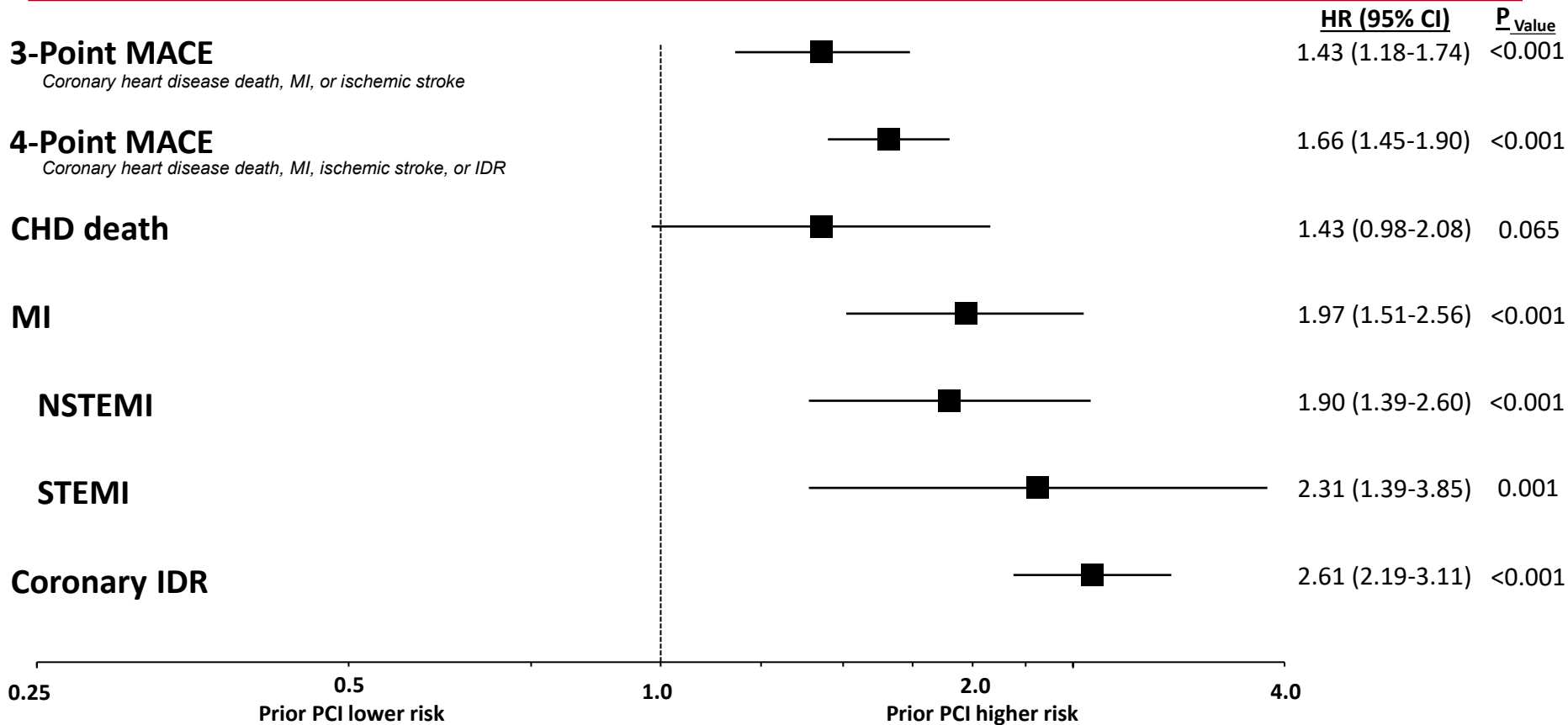
	Overall N=3627	Evolocumab N=1820	Placebo N=1807
Age (years)	66 (60-71)	66 (60-71)	66 (60-71)
Female	31	31	31
Caucasian	90	90	90
Diabetes mellitus	43	44	41
Current smoker	25	26	24
Any statin	89	89	89
High-intensity statin	71	71	72
Ezetimibe	26	25	26
Aspirin	80	80	81
Dual antiplatelet therapy	31	31	31
LDL-C (mmol/L)	3.0 (2.6-3.6)	3.0 (2.6-3.6)	3.0 (2.6-3.6)
Time from most recent PCI (yrs)	4 (1-8)	4 (1-8)	4 (1-8)

Numbers are % or median (IQR)
All P values <0.001 except for age (P=0.13)




Outcomes in pts with vs without prior PCI in the placebo arm

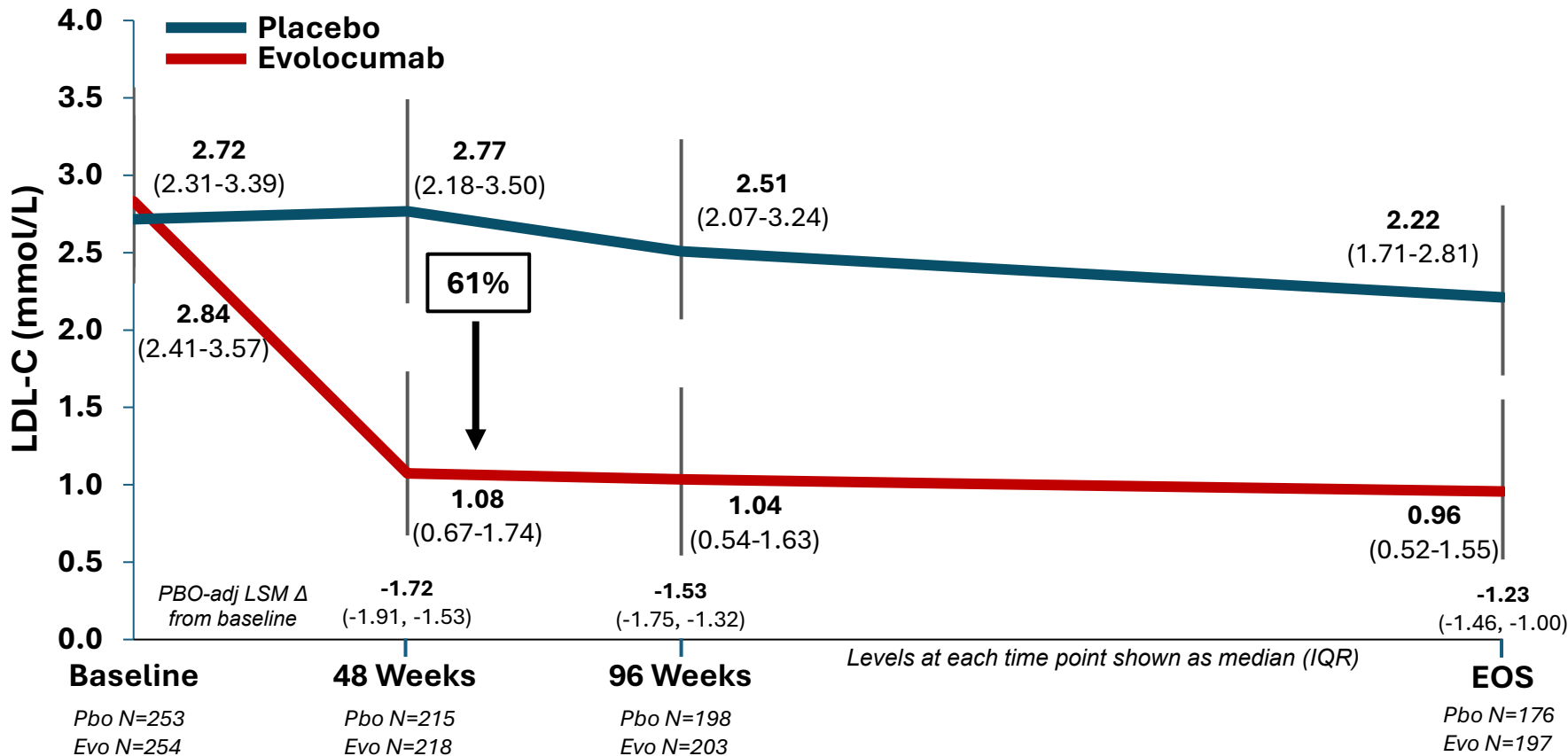
Vesalius-cv
prior PCI subgroup 





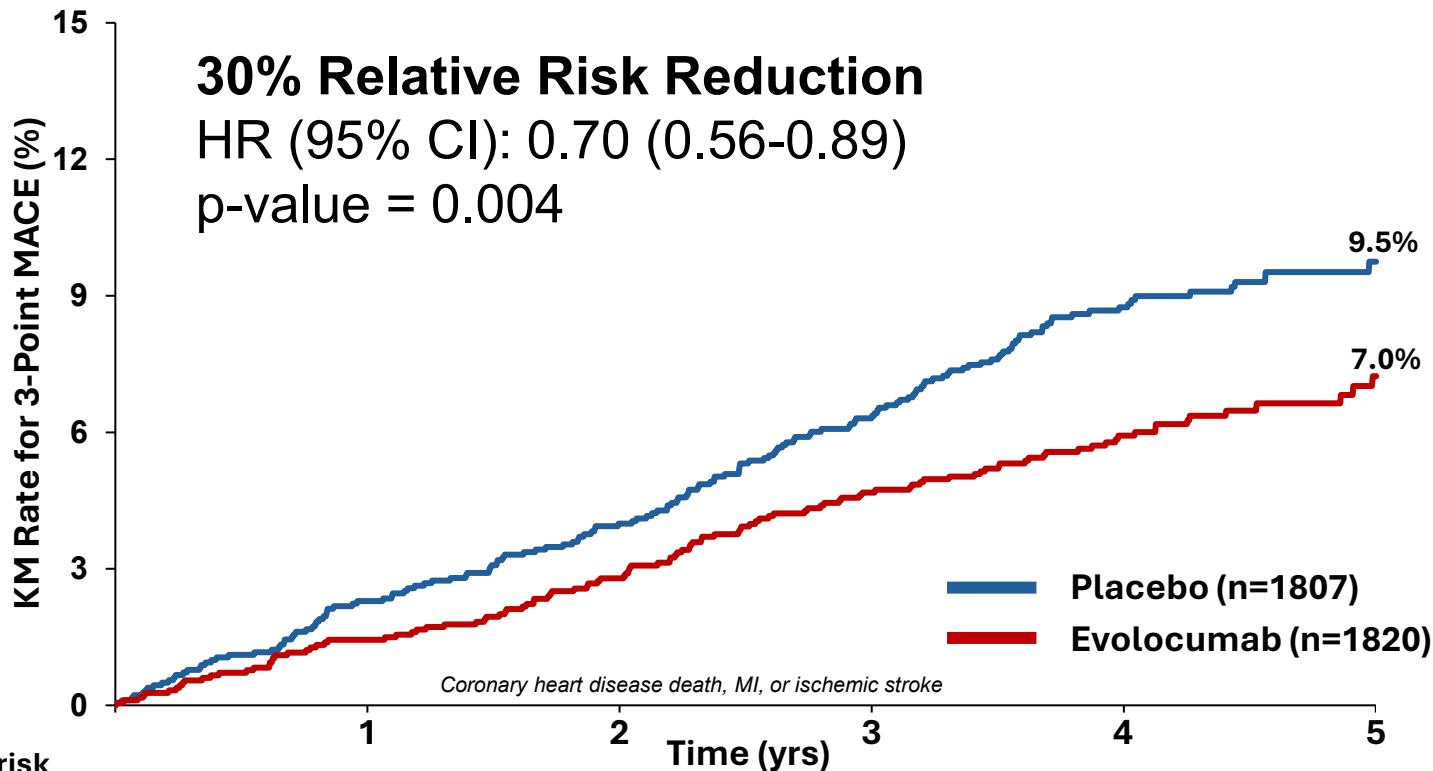
LDL-C in patients with prior PCI

Vesalius-cv
prior PCI subgroup 





3-Point MACE

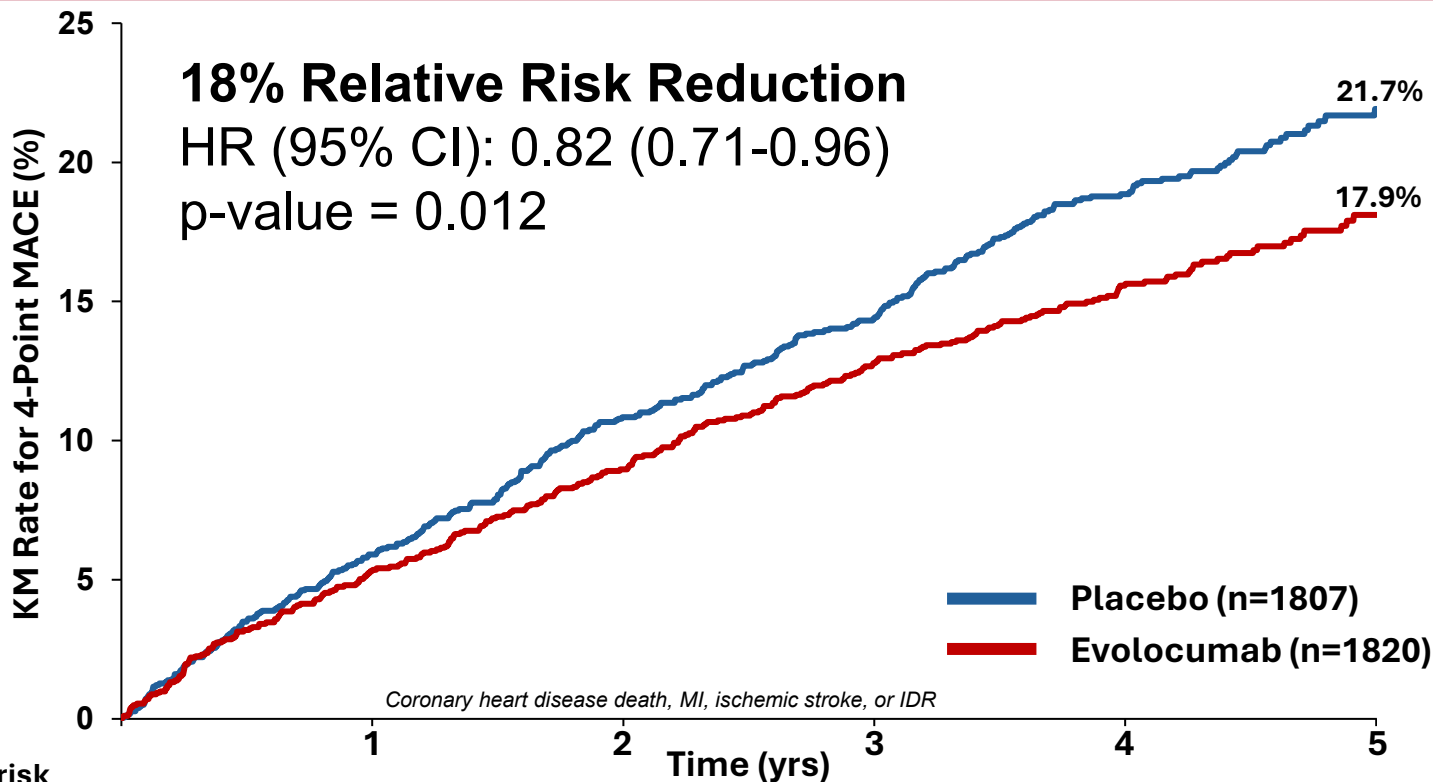


Number at risk

	0	1	2	3	4	5
Placebo	1807	1734	1679	1606	1204	416
Evolocumab	1820	1743	1715	1657	1278	453



4-Point MACE

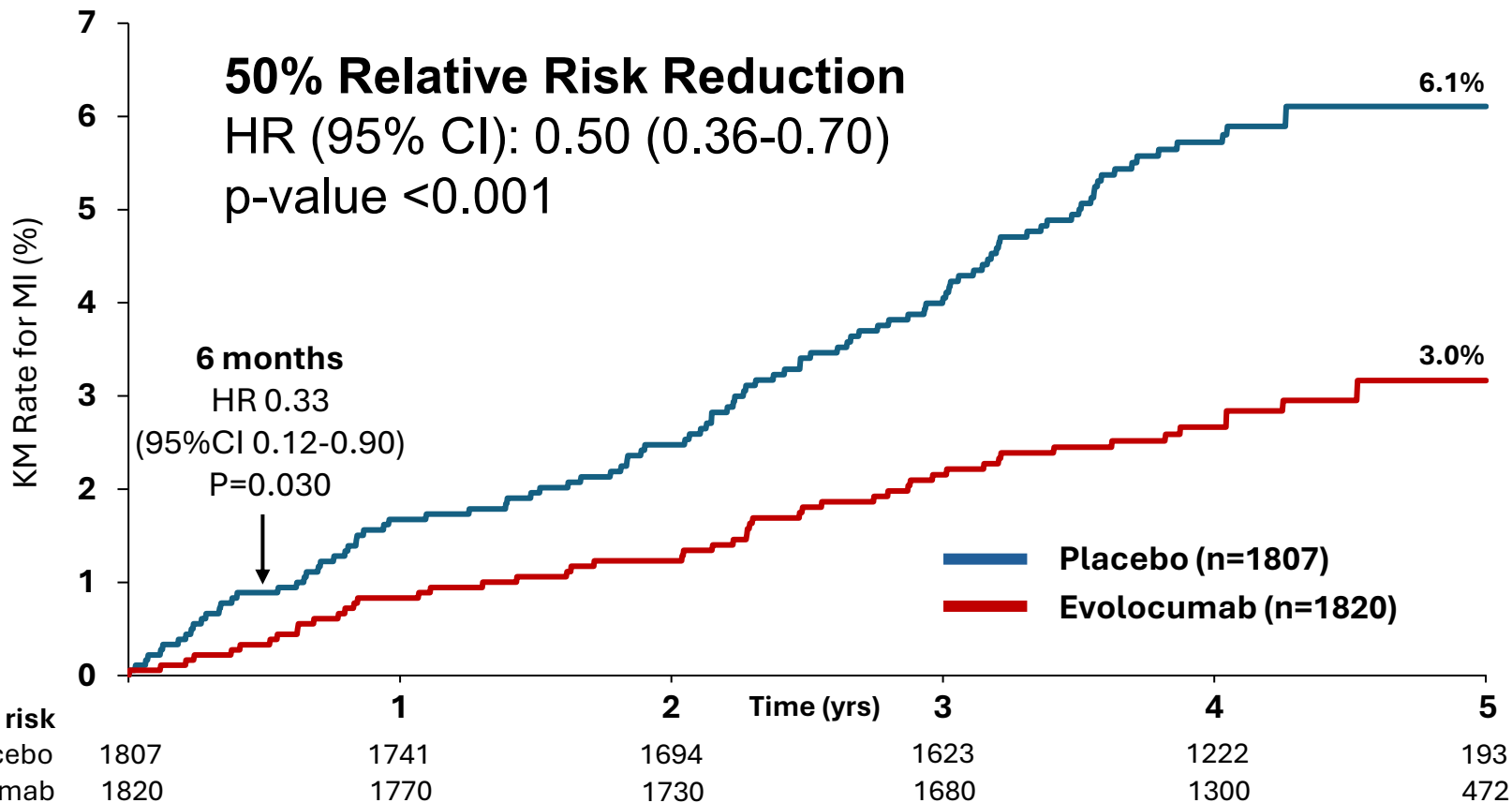


Number at risk

	0	1	2	3	4	5
Placebo	1807	1671	1560	1467	1073	362
Evolocumab	1820	1696	1608	1518	1140	402

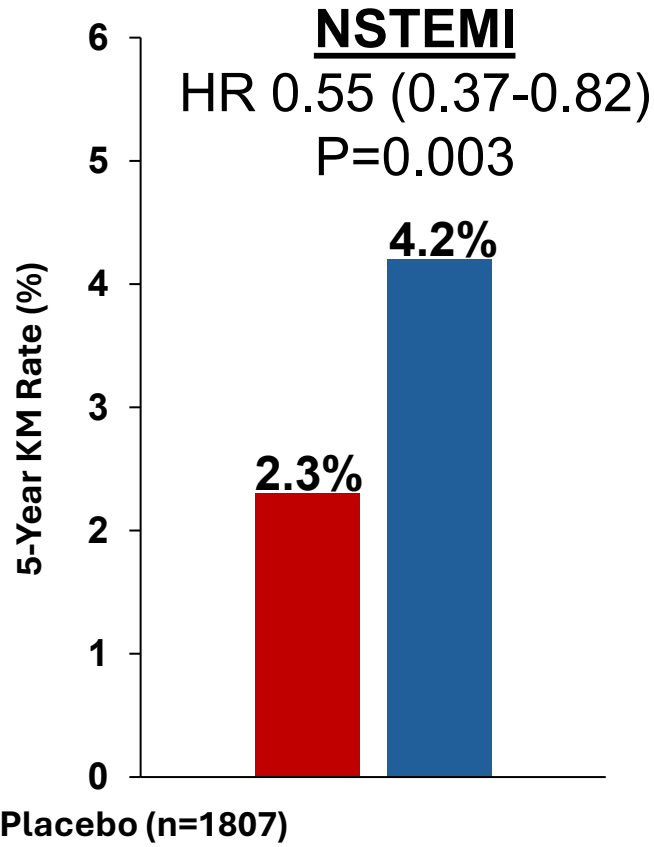
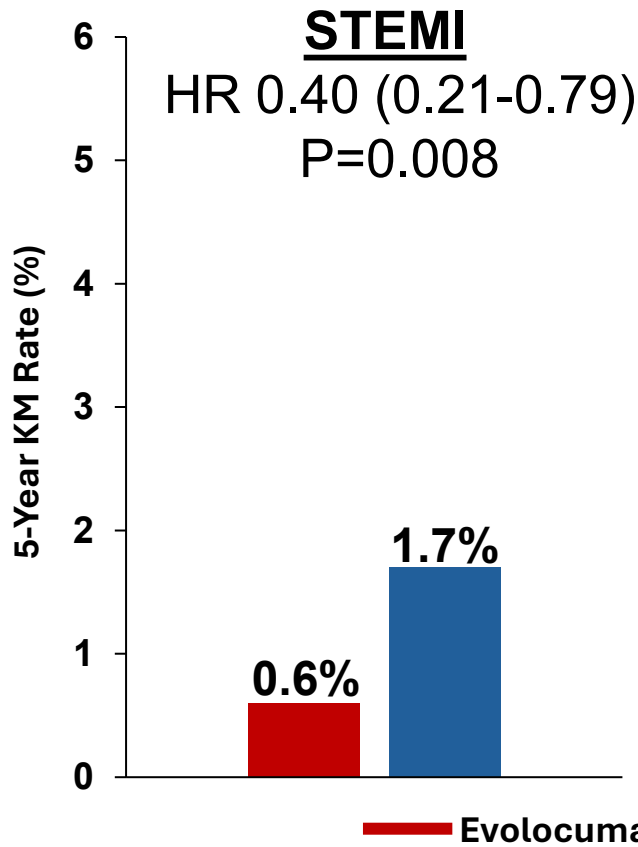


Myocardial Infarction





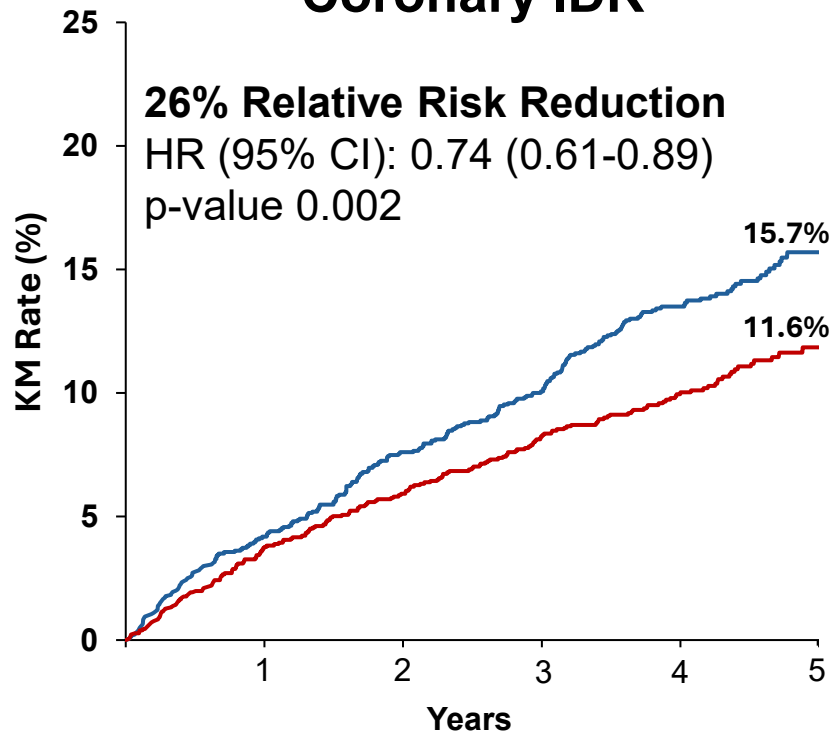
Myocardial Infarction



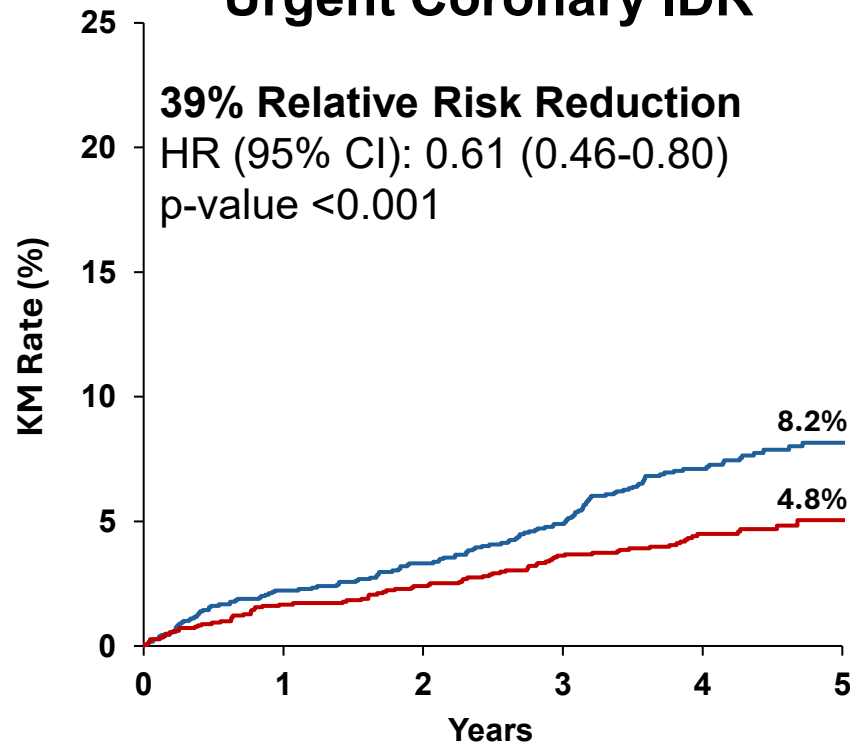


Coronary Revasc

Coronary IDR



Urgent Coronary IDR

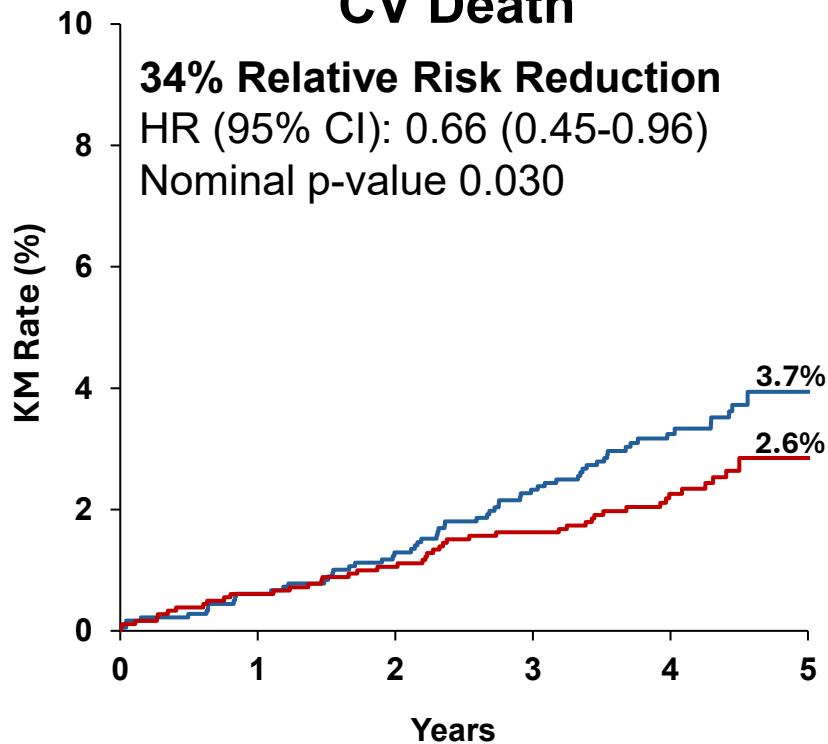


— Placebo (n=1807)
— Evolocumab (n=1820)

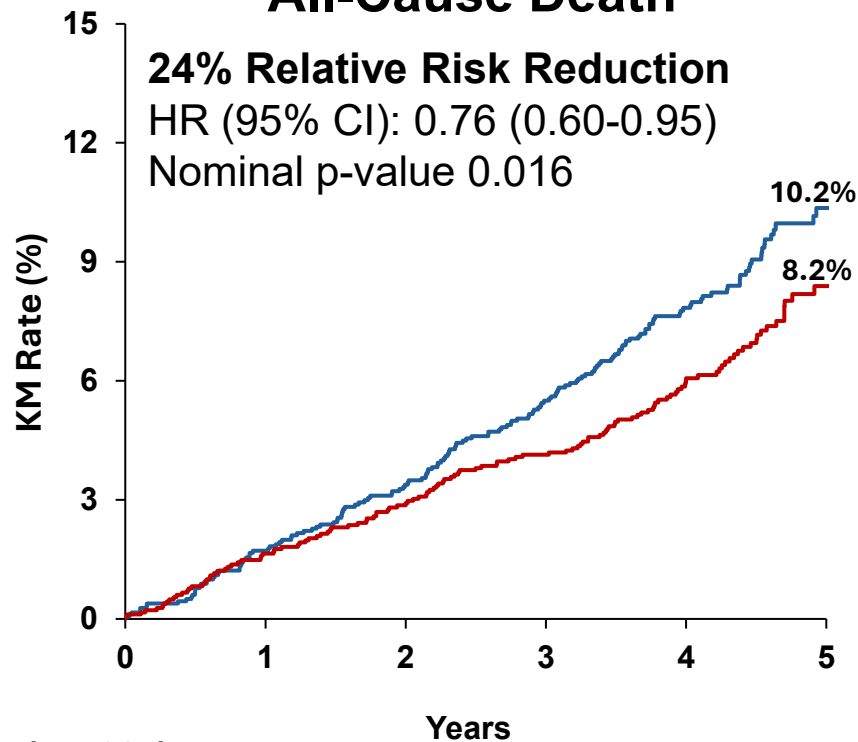


Mortality

CV Death



All-Cause Death



— Placebo (n=1807)
— Evolocumab (n=1820)



Effect on 3-Point MACE

HR (95% CI)

Age ≥ 65 years (N=2058)

Age < 65 years (N=1569)

Male (N=2512)

Female (N=1115)

Diabetes (N=1551)

No Diabetes (N=2076)

High-Intensity Statin (N=2588)

Low/Moderate-Intensity Statin (N=642)

No Statin (N=397)

Ezetimibe (N=931)

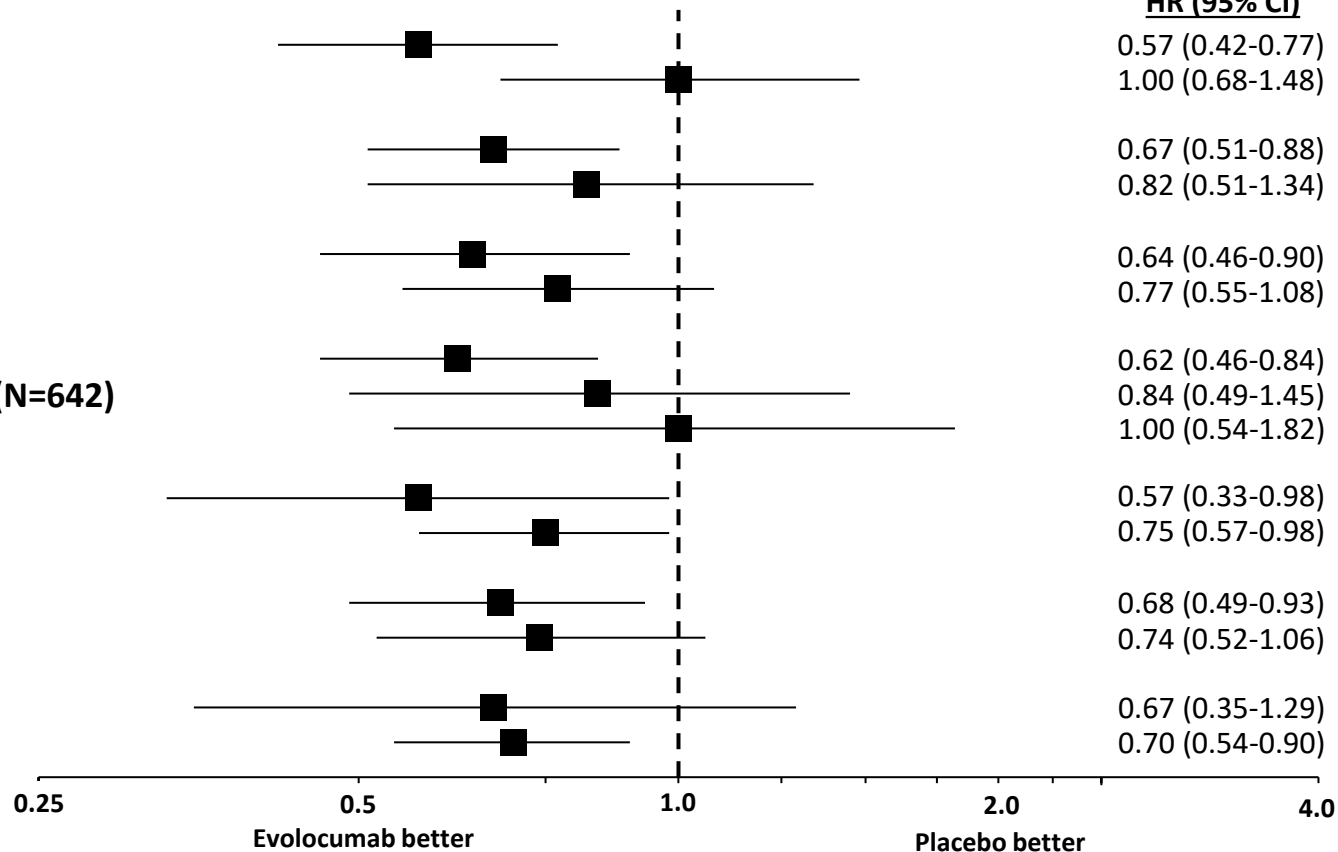
No Ezetimibe (N=2696)

LDL-C ≥ Median (N=1812)

LDL-C < Median (N=1815)

Prior PCI within 1 Year (N=592)

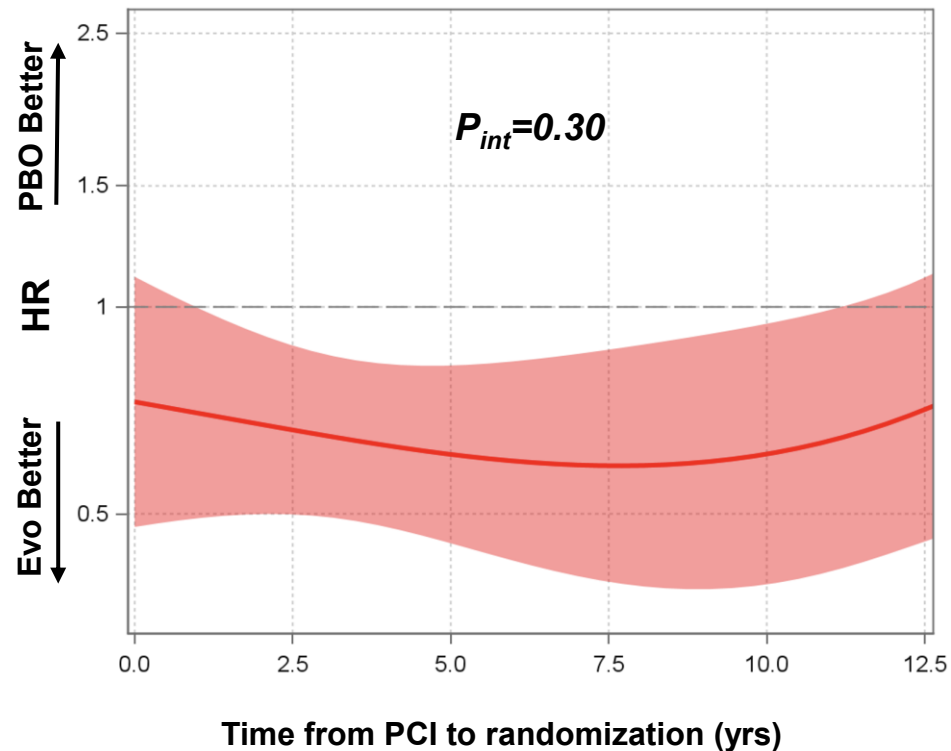
Prior PCI ≥ 1 Year (N=3033)



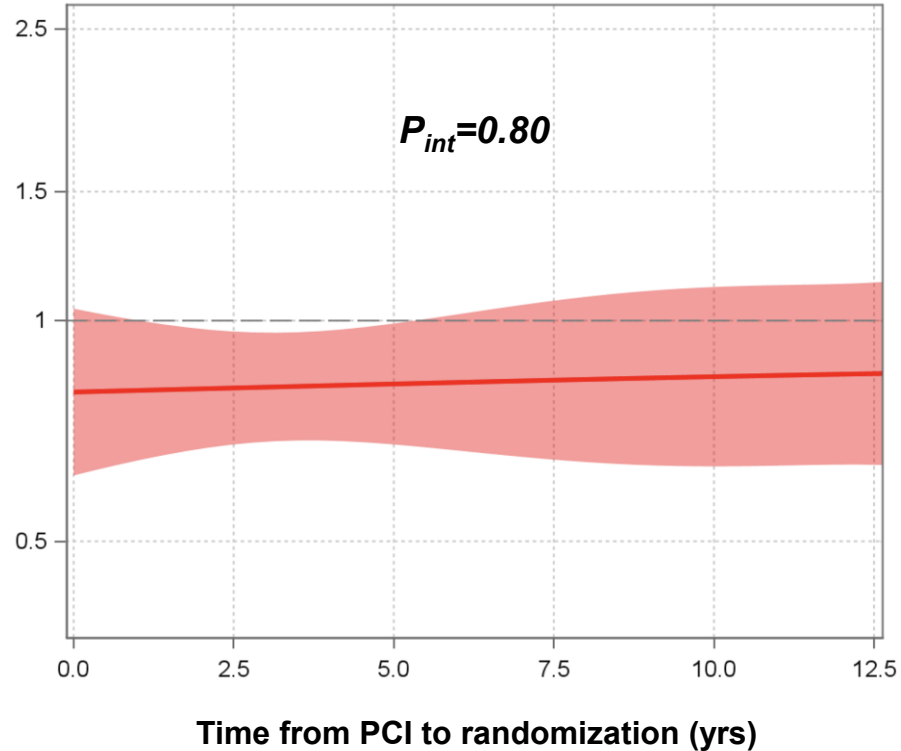


Time from PCI

3-Point MACE



4-Point MACE





Safety

Adverse Event	Evolocumab N=1820	Placebo N=1804	P value
Any adverse event	696 (38)	690 (38)	0.99
Serious adverse event	599 (33)	596 (33)	0.94
AE leading to study medication discontinuation	56 (3)	66 (4)	0.33

Numbers are n (%)



Limitations

- Coronary and procedural details of prior interventions were not collected.
- Similarly, for incident events during the trial, specific data regarding the target lesion and vessel were not available.
- Recent guidelines have begun to support more intensive LDL-C-lowering in patients with established ASCVD but without a prior acute event.
 - Enrolled patients were considered optimized by their treating team
 - Benefit consistent regardless of baseline LDL-C
 - As such, the large differences in LDL-C levels achieved with evolocumab in VESALIUS-CV likely reflect the potential benefit in clinical practice





Conclusion

Evolocumab significantly reduced the risk of major CV events in stable patients with prior PCI but no MI or stroke.

These findings support intensive LDL-C-lowering to ~1 mmol/L in patients who have undergone PCI even in the absence of prior MI.



Circulation

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